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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

GARY NORTHRUP,)	Case No. EDCV 20-00355 DDP (SPx)
)	
Plaintiff,)	
)	ORDER GRANTING DEFENDANT'S MOTION
v.)	TO EXCLUDE EXPERT OPINIONS AND
)	MOTION FOR SUMMARY JUDGMENT
COVIDIEN, LP,)	
)	[Dkt. 76, 77]
Defendants.)	
)	

Presently before the court is Defendants Covidien, LP and Medtronic Inc. (collectively, "Covidien")'s Motion to Exclude Opinions of David Grischkan (Dkt. 76), as well as Covidien's Motion for Summary Judgment (Dkt. 77). Having considered the submissions of the parties and heard oral argument, the court grants the motions and adopts the following Order.

I. Background

Plaintiff Gary Northrup underwent abdominal surgery in 2008. He subsequently developed bowel obstructions in 2009 and 2011. Plaintiff underwent a second abdominal surgery in September 2011, during which the surgeon observed that it "looked like a bomb went off" in Plaintiff's abdomen. The surgeon repaired four or five small hernias.

1 In December 2012, Plaintiff was diagnosed with another hernia.
2 Dr. Lawrence Kong recommended surgical repair with mesh. Due to
3 the complexity of the repair as a result of Plaintiff's prior
4 abdominal surgeries, Dr. Kong referred Plaintiff to Dr. Deron
5 Tessier. Dr. Tessier performed the hernia repair surgery in
6 September 2013. Dr. Tessier observed "extensive adhesions" of
7 Plaintiff's bowel to the abdominal wall. Dr. Tessier repaired
8 Plaintiff's hernia with a "PCOx" mesh, manufactured by Covidien's
9 subsidiary. PCOx, short for Parietex Optimized Composite Mesh, is
10 made of polyester, with a resorbable collagen coating on one side.

11 In March 2016, Plaintiff presented with abdominal pain and
12 gastrointestinal symptoms. (Declaration of Jessica Wilson ISO MSJ,
13 Ex. 28.) A doctor recommended that Plaintiff stop taking
14 testosterone and steroids. (Id.) In June 2017, another doctor
15 surmised that continuing gastrointestinal symptoms and chronic
16 abdominal pain may have been related to Plaintiff's continued use
17 of narcotic painkillers. (Wilson Decl., Ex. 27.) Later that year,
18 Dr. Tessier offered Plaintiff nerve block injections, which only
19 relieved Plaintiff's abdominal pain temporarily.

20 In January 2018, Dr. Tessier performed another abdominal
21 surgery, this time to remove tacks and sutures used during the 2013
22 hernia repair surgery. Plaintiff's abdominal pain persisted,
23 however. Accordingly, on March 24, 2018, Dr. Tessier performed a
24 third abdominal surgery to remove the PCOx mesh and all visible
25 tacks and sutures remaining from the 2013 hernia repair surgery.
26 The surgical notes indicate that Plaintiff had "dense, fibrotic,
27 chronically inflamed and scarred down adhesions." (Wilson Dec.,
28 Ex. 36.) Surgeons divided the mesh in two, cleared overlying

1 fascia and tissue off one half of the mesh, and "sharply excised"
2 the mesh. (Id.) Tacks in the mesh and abdominal wall "were
3 excised entirely as well." (Id.) The "meticulous dissection and
4 excision of the mesh was repeated for the [other] half of the mesh
5 . . . in a similar fashion." (Id.) Dr. Tessier later testified
6 that he removed all of the mesh, and that he did not see any
7 problems with the mesh itself. (Wilson Decl., Ex. 21 at 43:21-
8 144:5.)

9 Plaintiff's abdominal pain persisted. Plaintiff sought
10 medical care seven times in 2019, and filed the instant action in
11 2020. (Wilson Dec., Exs. 40-46.) Plaintiff's Complaint alleges a
12 strict liability claim against Covidien on a failure to warn
13 theory, as well as a negligence claims based on failure to warn and
14 alleged defective manufacturing and design of the PCOx mesh. Now,
15 following the exchange of expert witness reports, Covidien seeks to
16 exclude the opinions of Plaintiff's expert, Dr. David Grischkan.
17 Covidien also seeks summary judgment on all claims.

18 **II. Legal Standard**

19 Where "scientific, technical, or other specialized knowledge
20 will assist the trier of fact" to understand evidentiary or factual
21 issues, an expert witness who is qualified by "knowledge, skill,
22 experience, training, or education" may "testify thereto in the
23 form of an opinion or otherwise." Fed. R. Evid. 702. An expert's
24 experience alone can provide a sufficient foundation for expert
25 testimony, so long as the witness explains "how that experience
26 leads to the conclusion reached, why that experience is a
27 sufficient basis for the opinion, and how that experience is
28 reliably applied to the facts." Fed. R. Evid. 702 Advisory

1 Committee Note to 2000 Amdt. Trial courts, however, have a
2 gatekeeping function regarding expert testimony. Daubert v.
3 Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 n.7 (1993).
4 The two touchstones of admissibility are relevance and reliability.
5 Id. Courts employ a flexible inquiry tied to the facts of the
6 particular case to make determinations regarding the reliability of
7 expert testimony. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S.
8 137, 152 (1999). The focus should be “solely on principles and
9 methodology, not on the conclusions they generate.” Daubert, 509
10 U.S. at 595; see also Fed. R. Evid. 702 Adv. Comm. Note to 2000
11 Amdt. Factors relevant to reliability include, but are not limited
12 to, “whether the theory or technique employed by the expert is
13 generally accepted in the scientific community; whether it's been
14 subjected to peer review and publication; whether it can be and has
15 been tested; and whether the known or potential rate of error is
16 acceptable.” Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227, 1232
17 (9th Cir. 2017) (internal quotation marks and citation omitted).
18 The proponent of the expert testimony has the burden of
19 establishing that the relevant admissibility requirements are met
20 by a “preponderance of the evidence.” Daubert, 509 U.S. at 592
21 n.10 (citing Bourjaily v. United States, 483 U.S. 171, 175 (1987)).

22 Summary judgment is appropriate where the pleadings,
23 depositions, answers to interrogatories, and admissions on file,
24 together with the affidavits, if any, show “that there is no
25 genuine dispute as to any material fact and the movant is entitled
26 to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A party
27 seeking summary judgment bears the initial burden of informing the
28 court of the basis for its motion and of identifying those portions

1 of the pleadings and discovery responses that demonstrate the
2 absence of a genuine issue of material fact. See Celotex Corp. v.
3 Catrett, 477 U.S. 317, 323 (1986). All reasonable inferences from
4 the evidence must be drawn in favor of the nonmoving party. See
5 Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 242 (1986). If the
6 moving party does not bear the burden of proof at trial, it is
7 entitled to summary judgment if it can demonstrate that "there is
8 an absence of evidence to support the nonmoving party's case."
9 Celotex, 477 U.S. at 323.

10 Once the moving party meets its burden, the burden shifts to
11 the nonmoving party opposing the motion, who must "set forth
12 specific facts showing that there is a genuine issue for trial."
13 Anderson, 477 U.S. at 256. Summary judgment is warranted if a
14 party "fails to make a showing sufficient to establish the
15 existence of an element essential to that party's case, and on
16 which that party will bear the burden of proof at trial." Celotex,
17 477 U.S. at 322. A genuine issue exists if "the evidence is such
18 that a reasonable jury could return a verdict for the nonmoving
19 party," and material facts are those "that might affect the outcome
20 of the suit under the governing law." Anderson, 477 U.S. at 248.
21 There is no genuine issue of fact "[w]here the record taken as a
22 whole could not lead a rational trier of fact to find for the
23 nonmoving party." Matsushita Elec. Indus. Co. v. Zenith Radio
24 Corp., 475 U.S. 574, 587 (1986).

25 It is not the court's task "to scour the record in search of a
26 genuine issue of triable fact." Keenan v. Allan, 91 F.3d 1275,
27 1278 (9th Cir. 1996). Counsel have an obligation to lay out their
28 support clearly. Carmen v. San Francisco Sch. Dist., 237 F.3d

1 1026, 1031 (9th Cir. 2001). The court "need not examine the entire
2 file for evidence establishing a genuine issue of fact, where the
3 evidence is not set forth in the opposition papers with adequate
4 references so that it could conveniently be found." Id.

5 **III. Discussion**

6 A. Dr. Grischkan's Causation Opinion

7 Plaintiff's expert, Dr. David Grischkan, opined that "the
8 post-operative and current abdominal pain experienced by Mr.
9 Northrup was and is to this day directly caused by the Parietex
10 Optimized Composite mesh." (Declaration of Jessica Wilson ISO MTE,
11 Ex. 1.) Covidien contends that this conclusion was not the product
12 of any scientific methodology, and that Dr. Grischkan's opinion as
13 to causation is inadmissible.

14 Dr. Grischkan did not identify any methodology in his expert
15 report. At his deposition, however, Dr. Grishckan testified that
16 he performed a "differential diagnosis." (Wilson Dec. ISO MTE, Ex.
17 2.) As an initial matter, Defendants do not appear to dispute
18 Plaintiff's contention that Dr. Grischkan was not required to
19 conduct a differential diagnosis. The fact remains, however, that
20 Dr. Grischkan claimed to have done so, and Plaintiff does not
21 identify any alternative process that Dr. Grischkan employed or
22 claimed to have employed.

23 Differential diagnosis has long been recognized in this
24 circuit as a reliable methodology, so long as it is "properly
25 conducted." Clausen v. M/V NEW CARISSA, 339 F.3d 1049, 1057, 1058
26 (9th Cir. 2003) (citing Kennedy v. Collagen Corp., 161 F.3d 1226
27 (9th Cir.1998)); see also Messick v. Novartis Pharms. Corp., 747
28 F.3d 1193, 1199 (9th Cir. 2014). The Ninth Circuit laid out the

1 differential diagnosis process in Clausen. First, an expert should
2 "compile a comprehensive list of hypotheses that might explain the
3 set of salient clinical findings." Clausen, 339 F.3d at 1057.
4 Failure to consider even a rare potentially explanatory hypothesis
5 may be indicative of unreliability. Id. at 1058. Next, the expert
6 must eliminate hypotheses until a conclusion is reached as to the
7 most likely cause of the findings at issue. Id. "The expert must
8 provide reasons for rejecting alternative hypotheses using
9 scientific methods and procedures[,] and the elimination of those
10 hypotheses must be founded on more than subjective beliefs or
11 unsupported speculation." Id. (internal quotation marks and
12 citation omitted).

13 At his deposition, Dr. Grischkan was asked to explain how he
14 conducted his differential diagnosis in this case. (Declaration of
15 Kristy M. Arevalo IOT MTE, Ex. A at 9.) Dr. Grischkan responded,
16 "By considering various aspects of this case, both in terms of
17 visits to the emergency rooms, the surgical treatments -- all three
18 surgical procedures that he had, indications and so on, all of
19 those were based on differential diagnosis considerations." (Id.)
20 When asked to lay out his process "step by step," Dr. Grischkan
21 testified, "I used a thought process -- for example issues related
22 to pain or any other factors and then arrived at a conclusion . . .
23 ." (Wilson Dec. ISO MTE, Ex. 2 at 16:35-17:4.) When asked to
24 describe the thought process, Dr. Grischkan replied, "It's called
25 the brain." "(Id. at 17:9.) When specifically asked whether he
26 made a list of possible causes of Plaintiff's abdominal pain, Dr.
27 Grischkan testified that he did not make any such list. (Id. at
28 20:25.) Dr. Grischkan later stated that he "ruled in all the

1 potential causes that [he] felt were appropriate," but that a "list
2 would be endless." (Id. at 21.) He later testified, however, that
3 he did rule in "every factor I could think of," including prior
4 abdominal surgeries, prior opioid use, prior history of bowel
5 obstructions, and psychosocial issues. (Id. at 24, 26.)

6 When asked how he eliminated other possible causes of
7 Plaintiff's abdominal pain, Dr. Grischkan responded, "This isn't an
8 elimination game." (Id. at 24:23.) Instead, Grischkan agreed that
9 his methodology consisted of reviewing records "and then relying on
10 [] training, experience, knowledge of hernia surgery, and
11 literature."¹ (Id. at 25:6-9.) And, when asked whether he ruled
12 out Plaintiff's prior surgeries as the cause of Plaintiff's current
13 pain, Dr. Grischkan testified, "I did not rule out anything." (Id.
14 at 26:4.) He further testified that he "cannot give you any
15 specific details in regards to how I came to those conclusions
16 [listed in the report] or what the conclusions entailed in terms of
17 the factors." (Id. at 2:12-15.)

20 ¹ A differential diagnosis "grounded in significant clinical
21 experience and examination of medical records and literature" may
22 be admissible. Messick, 747 F.3d at 1199. This does not mean,
23 however, that a particular diagnosis is necessarily "properly
24 conducted" simply by dint of having been undertaken by an
25 experienced clinician who examines medical records and literature.
26 An expert must consider multiple hypotheses and provide a reasoned
27 basis for rejecting alternative hypotheses before arriving at a
28 conclusion. Clausen, 339 F.3d at 1057-58. Nor does Plaintiff
appear to dispute that Dr. Grischkan did not review all of
Plaintiff's medical records prior to rendering his opinion as to
causation. Dr. Grischkan testified, however, that additional
records, which he reviewed prior to his deposition, were not
necessary and "would not have made any difference." (Wilson Dec.
ISO MTE, Ex. 2 at 13:7.) As discussed above, however, Dr.
Grischkan provides no reasoning that would explain why the
additional records would have had little effect on his conclusions.

1 Dr. Grischkan's testimony is not sufficient to establish by a
2 preponderance of the evidence that he conducted a proper
3 differential diagnosis. Even assuming that Dr. Grischkan,
4 notwithstanding his failure to compile a "comprehensive list," did
5 consider all possible causes of Plaintiff's abdominal pain, there
6 is no evidence of any reasoned basis for the elimination of any
7 potential cause other than the PCOx mesh. Indeed, it is difficult
8 to discern how Dr. Grischkan arrived at his conclusion, given his
9 testimony that he did not rule out other potential causes and his
10 inability to provide "any specific details in regards to how I came
11 to those conclusions."

12 Absent any indication that Dr. Grischkan's causation opinion
13 was the product of a properly conducted differential diagnosis, or
14 any other reliable methodology, his opinion is not admissible.

15 B. Design Defect Opinion

16 Dr. Grischkan criticized the design of the PCOx mesh for not
17 having a permanent collagen barrier and for being made of
18 polyester. (Wilson Dec. ISO MTE, Ex. 2 at 61:6-8, 24-25.) With
19 respect to his causation opinion, Defendants challenge Dr.
20 Grischkan's methodology rather than his qualifications, as
21 discussed above. With respect to design defects, however,
22 Defendants argue that Dr. Grischkan is not qualified to render an
23 opinion on whether the design of Covidien's PCOx mesh is defective.

24 It is axiomatic that "[a]n expert in one field . . . cannot
25 express an opinion relying on data that requires expertise in
26 another" United States v. Santini, 656 F.3d 1075, 1078
27 (9th Cir. 2011). Dr. Grischkan acknowledged that he is not a
28 materials scientist or an expert in biomaterials or in the

1 manufacturing of mesh. (Id. at 59:18, 21; 60:9.) Dr. Grishckan
2 stated, however, that "as an end user, having done just about
3 25,000 hernia repairs, I think it qualifies me to be quite
4 knowledgeable in the arena of materials." (Id. at 59:22-24.)
5 Although he has never implanted a polyester mesh, he has removed
6 polyester mesh approximately six times. (Id. at 55:18-24.) Dr.
7 Grischkan also "worked . . . to develop a prosthesis . . . based on
8 a non-polypropylene formulation," a study of which was released in
9 1999. (Wilson Dec. ISO MTE, Ex. 1 at 2.)

10 Plaintiff argues that Dr. Grischkan's experience qualifies him
11 to render an opinion as to the design of PCOx mesh, notwithstanding
12 his lack of expertise in biomaterials or mesh production. Rule 702
13 "contemplates a broad conception of expert qualifications." Thomas
14 v. Newton Int'l Enterprises, 42 F.3d 1266, 1269 (9th Cir. 1994).
15 Indeed, "the text of Rule 702 expressly contemplates that an expert
16 may be qualified on the basis of experience." Fed. R. Evid. 702,
17 2000 Adv. Comm. Note. Here, however, Dr. Grischkan's experience is
18 not sufficient to render him an expert in polyester mesh product
19 design. First, Dr. Grischkan could not state whether, of the six
20 polyester meshes he removed over the course of several decades, any
21 were PCOx meshes, and there is no indication whether any of those
22 meshes included a collagen barrier of any sort. (Wilson Dec. ISO
23 MTE, Ex. 2 at 56:3,7.) Second, although Dr. Grischkan had some
24 (somewhat vague) prior experience with the design of a mesh
25 product, that experience was over two decades old, and involved a
26 non-polypropylene (and presumably non-polyester) mesh. Third,
27 despite claiming to be "quite knowledgeable in the arena of
28 materials," and notwithstanding his opinion that a non-defective

1 PCOx design would have included a permanent collagen barrier, Dr.
2 Grischkan was not aware of any mesh that included such a barrier,
3 either in 2013 when Plaintiff's mesh was installed or in August
4 2021, when Dr. Grischkan was deposed. (Id. at 61.) Indeed, Dr.
5 Grischkan did not know whether "it's even possible, [] from a
6 material standpoint, to develop a collagen or glycerol barrier that
7 can permanently exist without absorbing into the body." (Id. at
8 143.) Further, Dr. Grischkan's opinion as to "the nature of
9 polypropylene" and its propensity to cause inflammation appears to
10 have been based largely on his experience of having removed
11 polyester meshes.² (Id. at 62.) As discussed above, however, that
12 experience spanned only six instances, the most recent of which was
13 at least five to ten years prior to his deposition, and may have
14 been as many as thirty years in the past. (Id. at 63.) This
15 limited experience is insufficient to qualify Dr. Grischkan as an
16 expert in polyester mesh product design.

17 C. Instructions for Use Opinion

18 Dr. Grischkan also opined that the instructions for use
19 ("IFU") accompanying the PCOx mesh "fail[] to adequately warn
20 surgeons of the potential for severe chronic pain that would
21 mandate surgical removal of the device." (Wilson Dec. ISO MTE, Ex.
22

23
24 ² Dr. Grischkan's opinion that COVx is defectively designed,
25 insofar as it is made of polyester and lacks a permanent barrier,
26 is difficult to square with his testimony that a reasonable surgeon
27 might choose to use PCOx even today, and that polyester meshes
28 should not be pulled off the market, even though he is not aware of
any product that uses a permanent barrier and does not know
whether, as a question of materials science, such a barrier is
feasible. (Wilson Decl. ISO MTE, Ex. 2 at 132, 135.) In other
words, Dr. Grischkan appears to opine that it is reasonable to use
a product that he believes is defectively designed.

1 1 at 7.) Covidien argues that Dr. Grischkan lacks the
2 qualifications to render an expert opinion on IFUs.

3 During a deposition in other litigation earlier this year, Dr.
4 Grischkan was asked whether a certain warning should be included in
5 an IFU for another product. (Wilson Dec. ISO MTE, Ex. 9 at 105.)
6 Dr. Grischkan responded that he could not comment on what should or
7 should not be included, as that is "the manufacturer's
8 responsibility." (Id. at 106:1-3.) In this matter, Dr. Grischkan
9 testified that he has not looked at any IFU in fifteen to twenty
10 years. (Id., Ex. 2 at 34:6-7.)

11 Plaintiff argues that Dr. Grischkan's admission in another
12 case that he is not qualified to offer an opinion on what should
13 have been included in an IFU does not disqualify him as an expert
14 here because he "is not opining on what warning should have been
15 given to Plaintiff, only that the warnings contained in the PCOx
16 IFU were inadequate." (Opp. to MTE at 19:27-20:1.) This argument
17 has no merit. Dr. Grischkan opined that the IFU here was
18 inadequate because it did not adequately warn of the risk of severe
19 chronic pain. In other words, Dr. Grischkan opined that the PCOx
20 IFU should have included a warning regarding the possibility of
21 severe chronic pain. Although Plaintiff argues, as he does with
22 respect to product design, that Dr. Grischkan's "over 30 years of
23 experience" qualifies him to render an expert opinion on IFUs, that
24 experience is limited. As discussed above, Dr. Grischkan has never
25 implanted a PCOx mesh. He has only removed approximately six
26 polyester meshes, and there is no indication that he reviewed any
27 of the IFUs for those products. Indeed, the evidence suggests that
28 he has not, as Dr. Grischkan himself acknowledged that he has not

1 reviewed an IFU for fifteen or twenty years. This testimony also
2 undercuts Plaintiff's argument that Dr. Grischkan has experience
3 with IFUs pertaining to "a host of uncoated and coated
4 polypropylene meshes, ePTFE (Gore-Tex), compressed PTFE, polyester,
5 and absorbable meshes" (Id. at 19:18-21.) To the
6 contrary, Dr. Grischkan testified that he has not reviewed an IFU
7 in fifteen to twenty years because he has used the same product for
8 that entire period of time. ((Wilson Dec. ISO MTE, Ex. 2 at 34:6-
9 7.) The record does not, therefore, establish that Dr. Grischkan
10 has sufficient experience with IFUs related to a "a host" of mesh
11 products to qualify him as an IFU expert. His IFU opinion is,
12 therefore, inadmissible under Rule 702.

13 D. Summary Judgment

14 "A product liability case must be based on substantial
15 evidence establishing both the defect and causation [W]here
16 . . . the complexity of the causation issue is beyond common
17 experience, expert testimony is required to establish causation."
18 Stephen v. Ford Motor Co., 134 Cal. App. 4th 1363, 1373 (2005); see
19 also Reed v. Stryker Howmedica Osteonics, No. CV1210745MWFSHX, 2014
20 WL 12558120, at *4 (C.D. Cal. Apr. 22, 2014) ("District courts . .
21 . grant summary judgment for defendants[] where the plaintiff has
22 failed to introduce competent expert testimony"). With
23 respect to negligence claims, courts have also concluded that
24 plaintiffs cannot meet their burden to show a violation of the
25 standard of care, let alone causation, without expert proof. See,
26 e.g., Kamerik v. Depuy Orthopaedics, Inc., No. CV110692OMMMANX,
27 2013 WL 12322041, at *6 (C.D. Cal. Jan. 28, 2013); Sanchez v.

28

1 Stryker Corp., No. 2:10-CV-08832-ODW, 2012 WL 1570569, at *6 (C.D.
2 Cal. May 2, 2012).

3 Here, for the reasons discussed above, the opinions of Dr.
4 Grischkan must be excluded. Plaintiff has not put forward any
5 other expert evidence. Because there is no admissible evidence to
6 support Plaintiff's strict liability or negligence claims, Covidien
7 is entitled to summary judgment on all claims.

8 **IV. Conclusion**

9 Dr. Grischkan is not qualified to render an opinion as to the
10 PCOx product design or IFU. Although his qualifications are not at
11 issue with respect to causation, Dr. Grischkan's opinion is not the
12 product of a properly conducted differential diagnosis, or any
13 other discernible methodology. For these reasons, and for the
14 reasons stated above, Covidien's Motion to Exclude is GRANTED. In
15 the absence of any admissible expert evidence supporting
16 Plaintiff's claims, Covidien's Motion for Summary Judgment is
17 GRANTED.

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20 IT IS SO ORDERED.

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23 Dated: November 24, 2021

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DEAN D. PREGERSON
United States District Judge