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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

<p>QUIDEL CORPORATION,</p> <p style="text-align: right;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>SIEMENS MEDICAL SOLUTIONS USA, INC., <i>et al.</i>,</p> <p style="text-align: right;">Defendants.</p>	<p>Case No. 16-cv-3059-BAS-AGS</p> <p>ORDER DENYING PLAINTIFF’S MOTION TO EXCLUDE REBUTTAL OPINIONS AND TESTIMONY OF ARTHUR L. CAPLAN</p> <p>[ECF No. 151]</p>
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Plaintiff Quidel Corporation and Defendants Siemens Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics Inc. have filed motions seeking to exclude the opinions of the other party’s expert. The Court first turns to Plaintiff’s motion to exclude the rebuttal opinions and testimony of Defendants’ expert Dr. Arthur L. Caplan. (“Caplan Mot.,” ECF No. 151.) For the foregoing reasons, the Court denies the Motion.

I. Relevant Background¹

On January 11, 2019, the deadline for expert designation disclosure, Quidel

¹ A more extensive background and summary of allegations is available in prior orders. Therefore, the Court only includes background information here that is relevant to the present Motion.

1 designated Dr. George J. Kahaly as a scientific expert, and submitted his opening
2 expert report. (“Roosevelt Decl.,” ECF No. 151-2, at ¶ 2.) Dr. Kahaly opined
3 generally that Defendants’ assay IMMULITE is “not specific for the detection of
4 TSI.” (“Kahaly Report,” Exhibit 32 to ECF 156-1, at 23.) He relied, *inter alia*, on
5 two publications authored by him and other scholars:

- 6 • T. Diana, C. Wuster, M. Kanitz, G. Kahaly, *Highly variable sensitivity*
7 *of five binding and two bio-assays*, *Journal of Endocrinological*
8 *Investigation* (April 2016); and
- 9 • T. Diana, C. Wuster, P. Olivo, A. Unterrainer, J. Konig, M. Kanitz, A.
10 Bossowski, B. Decallonne, G. Kahaly, *Performance and Specificity of*
11 *Immunoassays for TSH Receptor Antibodies: A Multicenter Study*,
12 *European Thyroid Journal* (August 2017).

13 (*Id.* at 27.) The Court will refer to the two studies as “Diana 2016” and “Diana 2017”
14 respectively. Diana is listed as the lead author for both studies, but Kahaly also
15 participated in the studies and is listed as an author for both.

16 On March 29, 2019, the deadline for rebuttal expert disclosures, Defendants
17 served the Expert Rebuttal Report of Dr. Arthur L. Caplan. (Roosevelt Decl. ¶ 3.)
18 Caplan’s report was submitted “to respond to and rebut the opinions offered by
19 Kahaly in this case.” (“Caplan Report,” Exhibit A to ECF No. 153, at 2.) In his
20 report, Caplan provides that he was advised that Kahaly’s opinions largely depend
21 on Diana 2016 and Diana 2017. Caplan wrote the report to address the adequacy of
22 the authors’ disclosures made in the two publications and how this affected the
23 publications’ scientific integrity. (*Id.*) Caplan was provided information regarding
24 Quidel’s relationship with Kahaly and the other authors. (*Id.* at 6–10.) Caplan
25 believes that the relationships were not sufficiently disclosed to the publisher before
26 the studies were published. Specifically, in the journals’ “conflict of interest”
27 sections for both studies, Diana and Kanitz stated they had “nothing to disclose” and
28

1 Kahaly said he “consults for Quidel.” (*Id.* at 12, 14.)² Caplan opined that the conflict
2 of interest disclosures “are inconsistent with widely accepted ethical disclosure
3 standards, the represented disclosure standards of the two publishing journals, and
4 [the Johannes Gutenberg University Medical Center]’s disclosure standards as stated
5 by Kahaly.” (*Id.* at 15.) According to Caplan and the information he was provided,
6 Quidel “funded both studies and paid for Diana [and Kanitz] to work full time on
7 Quidel-funded studies since 2011” and this should have been disclosed. (*Id.* at 15,
8 16.) The studies were “initialed by Quidel, supervised by Quidel, and resulted in
9 findings that directly benefited Quidel and its commercial interests.” (*Id.* at 16.) This
10 adversely affects the scientific integrity of the studies. (*Id.*) In sum, “Kahaly’s expert
11 opinions have limited (if any) probative value, particularly to the extent his opinions
12 rely on the *Diana 2016* and *Diana 2017* publications.” (*Id.* at 22.)

13 **II. Analysis**

14 Quidel seeks to exclude the opinions and testimony of Dr. Caplan. Quidel’s
15 argument is three-fold: first, Dr. Caplan’s rebuttal opinions are not actually made in
16 rebuttal, second, Dr. Caplan’s opinions do not meet the *Daubert* standard of
17 reliability and relevance, and third, Dr. Caplan’s opinions are likely to mislead and
18 confuse the jury and will encroach on the jury’s function to make credibility
19 determinations.

20 **A. Whether Caplan’s Report is Appropriately a Rebuttal Report**

21 **1. Legal Standard for Rebuttal Reports**

22 Expert rebuttal reports must be “intended solely to contradict or rebut evidence
23 on the same subject matter identified by another party” in that other party’s expert
24

25 ² Defendants provide an in-depth background section laying out the details of Kahaly and Quidel’s
26 relationship, along with over a dozen exhibits providing evidence of the relationship. (“Caplan
27 Opp’n,” ECF No. 154, at 3–9; ECF No. 154-1.) The details of the relationship are irrelevant. What
28 is relevant is that Kahaly had a relationship with Quidel before he conducted the studies, he
disclosed to the publishing journal that he was a “consultant,” and Caplan opined the disclosure
was insufficient.

1 disclosures. Fed. R. Civ. P. 26(a)(2)(D)(ii). The phrase “same subject matter” should
2 be read narrowly because a broad reading that “encompass[es] any possible topic that
3 relates to the subject matter at issue[] will blur the distinction between ‘affirmative
4 expert’ and ‘rebuttal expert.’” *Vu v. McNeil–PPC, Inc.*, No. CV 09–1656, 2010 WL
5 2179882, at *3 (C.D. Cal. May 7, 2010). “Accordingly, a careful analysis of each of
6 the Plaintiff’s expert[’]s proposed testimony and the corresponding [Defendant’s]
7 expert[’]s rebuttal testimony is required to determine if the rebuttal testimony is
8 proper.” *Hellman–Blumberg v. Univ. of Pac.*, No. 12–cv–00286, 2013 WL 3422699,
9 at *2 (E.D. Cal. July 8, 2013).

10 If a disclosed rebuttal expert is not proper, “Rule 37 ‘gives teeth’ to Rule 26’s
11 disclosure requirements by forbidding the use at trial of any information that is not
12 properly disclosed.” *Goodman v. Staples the Office Superstore, LLC*, 644 F.3d 817,
13 827 (9th Cir. 2011) (citing *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d
14 1101, 1106 (9th Cir.2001)). Rule 37(c)(1)’s exclusion sanction is mandatory unless
15 failure to disclosure is substantially justified or harmless. Fed. R. Civ. Pro. 37(c)(1).

16 2. Analysis

17 Quidel argues Caplan is not a rebuttal expert to Kahlay because the report is
18 not a response to Kahaly’s. Specifically, Caplan opines on conflict of interest
19 disclosures, but Kahaly has not been designated and is not providing expert opinions
20 on conflict of interest disclosures. (Caplan Mot. at 6.)

21 The Court disagrees. Caplan is responding to a portion of Kahaly’s report.
22 Kahaly relies on and cites Diana 2016 and Diana 2017 in his report. (Kahaly Report
23 at 27.) Caplan opines that the studies are flawed, and therefore, the report is flawed
24 to the extent it relies on the studies. The Court finds that this is sufficiently a rebuttal
25 report. Indeed, there is no requirement that “a rebuttal expert read[] the opening
26 expert report cover to cover, and then write[] a rebuttal report outlining each and
27 every criticism of the opening expert’s opinions.” *Pinterest, Inc. v. Pintrips, Inc.*,
28 No. 13-cv-4608, 2015 WL 2268498, at *2 (N.D. Cal. May 14, 2015). Caplan

1 responds to what Defendants deem to be a “fundamental flaw” in Kahaly’s report.
2 *Id.* “That [Caplan’s] work was targeted at a specific topic identified by counsel—as
3 opposed to addressing all purported defects in the [Kahaly report]—makes
4 [Caplan’s] testimony no less proper as rebuttal evidence.” *Id.* Rebuttal testimony is
5 permitted to “question the assumptions and methods” of an opposing expert.”
6 *LaFlamme v. Safeway, Inc.*, No. 09-cv-514-ECR-VPC, 2010 WL 3522378, at *8 (D.
7 Nev. Sept 2, 2010). Caplan’s report does so, questioning a partial basis of Kahaly’s
8 report. Caplan’s report is appropriately deemed a rebuttal report and the Court
9 declines to strike the report for this reason.

10 **B. Whether Dr. Caplan’s Opinions Are Reliable, Relevant, and**
11 **Appropriate**

12 **1. Legal Standard**

13 Rule 702 of the Federal Rules of Evidence governs the admissibility of expert
14 testimony. *Ollier v. Sweetwater Union High Sch. Dist.*, 768 F.3d 843, 859 (9th Cir.
15 2014). Rule 702 provides that a witness “qualified as an expert by knowledge, skill,
16 experience, training, or education may testify in the form of an opinion or otherwise
17 if”:

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

24 Fed. R. Evid. 702. Under Rule 702, expert testimony must be both relevant and
25 reliable. *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 462 (9th Cir. 2014).
26 Relevancy simply requires that “[t]he evidence . . . logically advance a material aspect
27 of the party’s case.” *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007). Reliability
28 requires that an expert’s testimony “have a reliable basis in the knowledge and

1 experience of his discipline.” *Estate of Barabin*, 740 F.3d at 462 (quoting *Kumho*
2 *Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 148 (1999)).

3 Courts are not concerned with the “correctness of the expert’s conclusions but
4 the soundness of his [or her] methodology.” *Primiano v. Cook*, 598 F.3d 558, 564
5 (9th Cir. 2010) (quoting *Daubert v. Merrell Dow Pharms.*, 43 F. 3d 1311, 1318).
6 “For scientific opinion, the court must assess the reasoning or methodology, using as
7 appropriate such criteria as testability, publication in peer reviewed literature, and
8 general acceptance, but the inquiry is a flexible one.” *Id.* at 564. “Shaky but
9 admissible evidence is to be attacked by cross examination, contrary evidence, and
10 attention to the burden of proof, not exclusion.” *Id.*; *see also Daubert*, 509 U.S. at
11 595–96.

12 The duty falls upon the district court to act “in a gatekeeping role, to assess
13 whether the reasoning or methodology underlying the testimony is valid and whether
14 that reasoning or methodology properly can be applied to the facts in issue.” *Ollier*,
15 768 F.3d at 860 (quoting *Daubert*, 509 U.S. at 592–93) (internal quotation marks
16 omitted). The party seeking to offer the testimony bears the burden of establishing
17 its admissibility. *In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 549 (C.D. Cal. 2014).

18 2. Analysis

19 Quidel argues Caplan’s opinions are “speculative and unhelpful.” (Caplan
20 Mot. at 7.) In making this argument, Quidel focuses on the substance of the Kahaly
21 report, arguing that Caplan does not discuss “whether the science in the two journal
22 articles or in Dr. Kahaly’s report is valid or invalid.” (*Id.*) But this is irrelevant.
23 Caplan specifically stated he is “not offering any opinions in this case on the science
24 relating to Grave’s [sic] disease testing.” (“Caplan Depo.,” Exhibit B to ECF No.
25 153, at 17:8–12.) Therefore, his report did not, and actually should not, focus on the
26 underlying science, but instead focused on one specific aspect: conflict of interest
27 disclosures. This does not mean his report is “unhelpful.” It is also not relevant that
28 Caplan may be unaware “to what extent” Kahaly relied on the Diana articles.

1 (Caplan Mot. at 7.) Caplan opined that to the extent Kahaly’s report is based on the
2 two articles, the opinions have little if any probative value. The value of Kahaly’s
3 report as it depends on the two publications is relevant and therefore not speculative.
4 The Court declines to strike the report for this reason.

5 Quidel next argues Caplan’s opinions are unreliable because he is not qualified
6 to testify on the adequacy of disclosures in scientific journal articles. (Caplan Mot.
7 at 8.) Quidel provides almost no detail behind this argument besides stating that
8 Caplan has not previously been retained as an expert on the subject. But an expert
9 can be qualified “by knowledge, skill, experience, training, or education.” Fed. R.
10 Evid. 702. And Quidel admits Caplan has written “8 or 9 articles on the topic of
11 adequacy of disclosures in journal articles.” (*Id.* at 3.)³ Caplan analyzed what
12 conflicts the two journals require authors to disclose, and what other relevant
13 authorities require. Based on this, he opines the authors’ disclosures for both Diana
14 studies were insufficient. Caplan is therefore qualified based on his knowledge,
15 experience, and studies. A criticism that Caplan did not consider enough material in
16 forming his opinion is not a proper objection. *Kennedy v. Collagen Corp.*, 161 F.3d
17 1226, 1231 (9th Cir. 1998) (“Disputes as to the strength of [an expert’s] credentials,
18 faults in his use of [a particular] methodology, or lack of textual authority for his
19 opinion, go to the weight, not the admissibility, of his testimony.” (internal quotation
20 marks omitted)).

21 Quidel’s further argues that the Diana studies were “accepted for publication”
22 and therefore the peer review process before publication shows the studies were
23 “good science” and should not be questioned here. (Caplan Mot. at 11.) This
24 argument has no merit. Simply because an article is deemed sufficient for publication
25

26 ³ Quidel strangely focuses on the fact that Caplan has written approximately 800 articles in his
27 career, and Quidel points out that “only” 8 or 9 of this large number of articles were written on the
28 topic of disclosures. (Caplan Mot. at 3.) Caplan’s breadth of knowledge is completely irrelevant.
Simply because someone is widely published on a variety of topics does not mean that he cannot
be qualified to provide an opinion on one of those topics.

1 does not mean that the publisher looked for any possible conflict of interest. Instead,
2 there is no evidence that the publisher did not simply accept the authors' submissions
3 that there was no relevant conflict of interest. A "peer review" showing that the study
4 was "good science" has nothing to do with whether the authors operated under a
5 conflict of interest.

6 Quidel's last argument is that Caplan is improperly trying to evaluate Kahaly's
7 credibility, which is a jury function. (Caplan Mot. at 9.) This is not true. Caplan
8 opines on the soundness of Kahaly's expert report based on the evidence he cited;
9 this has nothing to do with whether Kahaly is a credible witness. Caplan's report
10 should not be struck for this reason.


11 The Court finds Caplan's report to be sufficiently reliable and relevant, and
12 that it does not invade the province of the jury.

13 **III. Conclusion**

14 For the foregoing reasons, the Court **DENIES** Plaintiff's Motion to Strike,
15 (ECF No. 151).

16 **IT IS SO ORDERED.**

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18 **DATED: September 27, 2019**

19 
20 **Hon. Cynthia Bashant**
21 **United States District Judge**

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