UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, a third-party healthcare payor fund, ANNIE M. SNYDER, a California consumer, RICKEY D. ROSE, a Missouri consumer, JOHN CARDARELLI, a New Jersey consumer, MARLYON K. BUCKNER, a Florida consumer, and SYLVIE BIGORD, a Massachusetts consumer, on behalf of themselves and ALL others similarly situated,

Plaintiffs,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese corporation; TAKEDA PHARMACEUTICALS USA, Inc., an Illinois corporation (fka TAKEDA PHARMACEUTICALS NORTH AMERICA, Inc.); and ELI LILLY & COMPANY, an Indiana corporation,

Defendants.

Case No. 2:17-cv-07223-JWH-AS

ORDER ON DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT WITNESS WILLIAM S. COMANOR [ECF Nos. 249 & 250]

UNDER SEAL

I. INTRODUCTION

Before this Court is the motion[1] of Defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals USA Inc. (jointly, "Takeda") to exclude the testimony of expert witness Dr. William S. Comanor.[2] Plaintiff Painters and Allied Trades District Council 82 Health Care Fund ("Painters") and Plaintiff Annie M. Snyder (jointly, "Plaintiffs") oppose.[3]

The underlying lawsuit concerns the anti-diabetes medication Actos. Plaintiffs contend that Takeda and co-Defendant Eli Lilly & Company ("Lilly") misled the FDA regarding the risk of bladder cancer from the use of Actos by generating false studies, manipulating study results, and controlling the messaging about Actos to conceal aspects of the drug's mechanism that could have raised concerns.[4] Plaintiffs also allege that Takeda and Lilly misled prescribing physicians, consumers, and third-party payors into believing that Actos did not create an increased risk of bladder cancer.[5] According to Plaintiffs, Takeda and Lilly had reason to know about the increased bladder cancer risk, but they chose not to disclose it to increase their profits from the sale of Actos.[6]

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[1] Defs.' Mot. to Exclude William S. Comanor (the "Motion") [ECF No. 249]; *see also* Defs.' Unredacted Mot. to Exclude William S. Comanor (the "Sealed Motion") [ECF No. 250].

[2] Expert Report of William S. Comanor (the "Comanor Report") [ECF No. 234-6].

[3] Pls.' Unredacted Opp'n to the Motion (the "Opposition") [ECF No. 264]; *see also* Pls.' Unredacted Opp'n to the Motion (the "Sealed Opposition") [ECF No. 276].

[4] *See, e.g.*, Second Am. Complaint [ECF No. 127] ¶¶ 31-35, 48-50, 59-63, 70-87, & 95.

[5] *See, e.g.*, *id.* at ¶¶ 1, 44, 45, 60-62, 67, 79, 85-87, 100, 134, & 135.

[6] *See, e.g.*, *id.* at ¶¶ 25-28 & 36.

Plaintiffs seek to certify two classes: a National Third-Party Payer ("TPP") class and a California Consumer class.[7] Comanor's analysis features prominently in Plaintiffs' pending Motion to Certify those two classes. Accordingly, the Court decides this Motion first.

The Court conducted a hearing in March 2022 concerning both the Motion to Certify and the instant Motion to exclude the Comanor Report. After considering the papers filed in support and in opposition,[8] as well as the arguments of counsel, the Court orders that the Motion is **DENIED**.

II. LEGAL STANDARD

Takeda argues that the applicable legal standard for the admission or exclusion of the Comanor Report is set out in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), as that case applies to Rule 702 of the Federal Rules of Evidence.[9] Takeda insists that *Daubert* should not be "watered down" even during class certification,[10] pointing to several district court cases that applied *Daubert* to expert testimony at this stage of the litigation.[11] However, the Ninth Circuit has cautioned district courts against applying the "formal strictures of

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[7] *See generally* Mot. for Class Certification (the "Motion to Certify") [ECF No. 229]; *see also* Sealed Motion 1:2-6.

[8] In connection with its adjudication of this Motion, the Court considered the documents of record in this action, including the following papers: (1) Motion; (2) Opposition; (3) Defs.' Reply in Supp. of the Motion (the "Reply") [ECF No. 279]; and (4) Defs.' Unredacted Reply in Supp. of the Motion (the "Sealed Reply") [ECF No. 288].

[9] Sealed Motion 5:24-6:21.

[10] Sealed Reply 1:24-25.

[11] *See id.* at 2:6-26 (citing *Shiferaw v. Sunrise Senior Living Management, Inc.*, 2014 WL 12585796, at *25 n.17 (C.D. Cal. June 11, 2014), *Grodzitsky v. Am. Honda Motor Co.*, 957 F.3d 979, 987 (9th Cir. 2020) (affirming lower court decision in *Grodzitsky v. Am. Honda Motor Co.*, 2017 WL 8943159 (C.D. Cal. Oct. 30, 2017)), *Cholakyan v. Mercedes-Benz USA, LLC*, 281 F.R.D. 534, 541-42 (C.D. Cal. 2012), *In re NJOY, Inc. Consumer Class Action Litig.*, 2016 WL 787415, at *3-*6 (C.D. Cal. Feb. 2, 2016), and *Pedroza v. PetSmart, Inc.*, 2013 WL 1490667, at *4-*5 (C.D. Cal. Jan. 28, 2013)). Each of those district court decisions predates the Ninth Circuit's decision in *Sali v. Corona Reg'l Med. Ctr.*, 909 F.3d 996 (9th Cir. 2018).

trial" during the class certification stage. *Sali v. Corona Reg'l Med. Ctr.*, 909 F.3d 996, 1004 (9th Cir. 2018). "Limiting class-certification-stage proof to admissible evidence risks terminating actions before a putative class may gather crucial admissible evidence. And transforming a preliminary stage into an evidentiary shooting match inhibits an early determination of the best manner to conduct the action." *Id.* Accordingly, the Ninth Circuit has instructed that:

> The court may consider whether the plaintiff's proof is, or will likely lead to, admissible evidence. Indeed, in evaluating challenged expert testimony in support of class certification, a district court should evaluate admissibility under the standard set forth in *Daubert*. But admissibility must not be dispositive. Instead, an inquiry into the evidence's ultimate admissibility should go to the weight that evidence is given at the class certification stage. This approach accords with our prior guidance that a district court should analyze the persuasiveness of the evidence presented at the Rule 23 stage.

Id. at 1006 (internal quotations and citations omitted). Since then, courts in this district and sister districts have used *Daubert* as a guide to determine the weight that evidence receives at the certification stage. *See, e.g.*, *Heredia v. Sunrise Senior Living, LLC*, 2021 WL 6104188, at *5 (C.D. Cal. Nov. 16, 2021); *Aberin v. Am. Honda Motor Co., Inc.*, 2021 WL 1320773, at *4 (N.D. Cal. Mar. 23, 2021) (denying motion to strike and using both parties' arguments regarding the reliability of the proffered expert testimony to assist the court in evaluating the weight of the evidence as it related to class certification); *Bally v. State Farm Life Ins. Co.*, 335 F.R.D. 288, 297 (N.D. Cal. 2020) (denying motion to strike expert testimony because *Sali* "explicitly instruct[s] that a *Daubert* analysis alone, while relevant, should not prevent a court from considering expert testimony at the class certification stage"); *Coates v. United Parcel Serv., Inc.*, 2019 WL 8884492, at *8 (C.D. Cal. July 2, 2019) (holding that a court could not "simply

exclude" an expert declaration for not meeting Rule 702). This Court follows their lead.

III. DISCUSSION

"[A]ll models are wrong, but some are useful." George E.P. Box & Norman R. Draper, *Empirical Model Building and Response Surfaces* 424 (1987). Notwithstanding Takeda's criticisms, Comanor's work falls in the latter category—it is useful. The flaws that Takeda identifies do not overwhelm the utility of Comanor's model; at most, they are methodological imperfections and shortcomings that could be improved at the margins, but not so much as to render his analysis unhelpful or unreliable. *See* Fed. R. Evid. 702(d). Takeda's critiques do not insinuate that regression, as an analytical method, is improper or that it cannot be used to establish causation, generally speaking.[12] In fact, Takeda concedes as much.[13] Moreover, Takeda does not impugn Comanor's credentials as a foremost expert in his field.[14] Thus, the Court concludes that, on balance, the Comanor Report is reliable and that it would pass muster under *Daubert* as admissible evidence as it relates to the National TPP Class, even though that hurdle is higher than the one that Plaintiffs must meet here. *Sali*, 909 F.3d at 1006.

Takeda criticizes the Comanor Report on five grounds. The first four concern his report as it relates to the National TPP Class; only the fifth relates to the California Class. The Court reviews each in turn and concludes that none is so persuasive as to limit the Court's consideration of Comanor's testimony, let alone exclude it outright.

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[12] Sealed Opposition 5:17-7:15.

[13] Sealed Reply 4:17-22.

[14] Sealed Opposition 4:5-5:3; *see generally* Sealed Reply (making no argument).

A. Reliance on Dr. Riddle

First, Takeda argues that Comanor's reliance on his colleague, Dr. Jon Riddle, should disqualify the Comanor Report because Riddle was not designated as an expert.[15] However, because Plaintiffs have proffered a rebuttal report from Riddle and this Court ruled that that report survived Takeda's motion to strike,[16] this criticism is no longer of any consequence.

B. Flaws with Causation

Next, Takeda raises five technical critiques of Comanor's methodology as it relates to issues of causation for the putative National TPP Class. After careful review, the Court concludes that none of these flaws merits excluding the Comanor Report, especially at this stage of the litigation.

First, the Court finds it reasonable for Comanor to have used post-damages-period data because it helped Comanor estimate the dispensation of Actos prescriptions "before and after."[17] That step is essential to a determination of causation; it is not irrelevant, as Takeda contends.[18]

Second, Takeda takes issue with Comanor's use of December 2013 as a benchmark month.[19] But the Court finds that this month is a reasonable estimate, in view of the empirical evidence showing the numbers of Actos prescriptions reaching a new stable state equilibrium—*i.e.*, flatlining.[20] The data also contradicts Takeda's assertion that a 2007 cardiovascular risk warning could have reduced the sales earlier,[21] because it shows that pioglitazone use

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15 Sealed Motion 6:22-9:22.

16 *See generally* Order on Defs.' Mot. to Strike Untimely Expert [ECF No. 303].

17 Comanor Report 43.

18 Sealed Motion 10:11-14.

19 *Id.* at 12:11-13:18.

20 Sealed Opposition 18:15-24

21 Sealed Motion 13:27-14:18.

remained flat, if not marginally increasing, in the months after the cardiovascular risks became publicly known.[22]

Third, Takeda argues that Comanor's causation analysis is flawed because Comanor assumes that "all TPPs in the class are the same and all would be equally impacted on a proportionate basis by his overall calculations."[23] In fact, according to Takeda's expert, Dr. James Hughes, the IQVIA data on which Comanor relies explicitly shows that some TPPs reimbursed ***more*** Actos prescriptions in the three months following the 2010 FDA warning than before.[24] Plaintiffs attack that finding as unreliable, because Hughes did not address the issue of whether plan growth could impact his findings.[25] Plaintiffs then offer reasons and data to suggest that plans ***did*** grow from the introduction of the Affordable Care Act around the times that Hughes measured.[26] Takeda does not grapple with the response directly, but instead he says that this critique only highlights the need for an individualized, tailored analysis, rather than a class action.[27] That latter point is not directly pertinent to the issue here—the reliability of Comanor's methods. As such, the Court concludes that Comanor's use of assumptions is not unreasonable, at least for the purposes of his model.

Fourth, Takeda contends that Comanor's regression is unreliable and methodologically flawed because it omits the impact of legal advertisements.[28] The Court is not persuaded that lawyer ads make Comanor's analysis

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22 *See* Sealed Opposition 19:3-20.

23 Sealed Motion 14:26-28.

24 *Id.* at 15:9-21.

25 Sealed Opposition 20:4-11.

26 Pls.' Unredacted Mot. to Limit Consideration of Hughes (the "Sealed Motion for Limiting Consideration") [ECF No. 276-1] 9:8-25.

27 Defs.' Unredacted Response to Pls.' Mot. to Limit Consideration (the "Sealed Opposition to Limiting Consideration") [ECF No. 289] 7:2-25.

28 Sealed Motion 16:8-16.

unsound.[29] Introducing a collinear variable like lawyer ads, for one thing, would not add any more explanatory power to the model, so its omission is not unsound.[30] For another, the means of communication—whether through the radio, on TV, or word of mouth—is less important than the message itself. If anything, the presence of advertisements lends credence to the idea that the December 2013 benchmark is a reasonable one for the fully informed world, since those advertisements would have aided awareness.

Fifth, Takeda contests the manner in which Comanor deals with generic drugs—*i.e.*, Comanor treats the entry of a new generic drug in the same way as the entry of a brand-new drug. But the Court finds that this approach is reasonable. Common sense suggests that generic drugs compete with existing drugs in the marketplace. Apparently, statistical evidence does too, as Comanor conducted the same analysis "using the Defendants' preferred variable for rival drugs, and the results were no different."[31] Takeda makes no response to that point in its Reply.[32]

C. Methodology for Identifying Injured Members

Takeda takes issue with the probability analysis that Comanor used to identify injured TPPs.[33] This analysis is central to Plaintiffs' class definition. Comanor determined that, if a TPP paid for five independent prescriptions, then there was a 98.5% probability that at least one prescription was induced by fraud.[34] Takeda maintains that this probability analysis is flawed because (1) Comanor unwarrantedly assumes that TPPs are similarly situated and that

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29 *Id.* at 16:19-18:1.

30 Sealed Opposition 20:13-21:7.

31 *Id.* at 21:19-21.

32 *See generally* Sealed Reply.

33 Sealed Motion 19:8-20:14.

34 *See* Unredacted Mot. for Class Certification [ECF No. 234] 31:17-32:1.

each would have the same probability; and (2) Comanor averages the probability for the 12-year class period even though he recognizes that the probability varies over time.[35] At the margins, those probabilities vary quite substantially. For example, there was a roughly 11% chance that a prescription written in 2000 was fraudulently induced, compared to a roughly 64% chance in 2008.[36]

But when the evidence was presented during the hearing, the Court observed that the probabilities appear to follow a normal distribution, so it is not unsurprising that Takeda could identify outliers. For the purpose of the model describing large populations, the use of averages is acceptable and reliable. *See, e.g.*, *In re Aftermarket Auto. Lighting Prod. Antitrust Litig.*, 276 F.R.D. 364, 373 (C.D. Cal. 2011). Whether it satisfies the question of predominance, as discussed at the hearing, is a separate question altogether—but it is not a reason to exclude expert testimony, at least in this instance.

D. Unreliable Damages Methodology

Takeda also critiques Comanor's methodology for calculating damages. Takeda claims that Comanor's decision to rely on simple averages means that he ignores individual differences among TPPs, which could lead to inequitable losses or surpluses to the TPP class members.[37] However, Takeda misstates Comanor's approach to damages. Comanor's analysis looks at the overall class, for which the use of averages is sensible. As for calculating individual damages (assuming that the class is certified and the case proceeds to trial), Plaintiffs explained at the hearing that they would take the sum of each TPP's volume of prescriptions multiplied by the probability that any given prescription was induced by fraud, using probabilities pegged to that particular month. Such an

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[35] Sealed Motion 19:14-20:14.

[36] Sealed Reply 7:13-14; *see also* Comanor Report 64 (listing probabilities by year).

[37] Sealed Motion 20:16-21:7.

approach does not ignore individual differences, as Takeda alleges; it explicitly incorporates them.

Similarly, Takeda says that Comanor improperly relies on averages when assessing what alternative drug would have been prescribed in lieu of Actos and how much the price of that alternative drug would offset damages. Here, Comanor exclusively relied on average prices for the drug Metformin as a proxy to calculate that offset.[38] Takeda disparages Comanor's use of averages, asserting that his model "drifts further and further away from reality to the point where his damages calculation is completely untethered to Plaintiffs' liability theory."[39]

The Court is not convinced. The question is whether the averages and proxies that Comanor used are reasonable. Metformin is a reasonable substitute because it is similar to Actos and it was the most expensive oral antidiabetic drug on the market for most of the class period.[40] Tellingly, Takeda never makes an affirmative argument why Metformin is ***not*** a reasonable or reliable proxy for an offset; Takeda merely quibbles with the use of averages, such as the average price of Metformin, the average rebates for Metformin, and so on.[41] Thus, the Court finds that Comanor's damages methodology is sufficiently reliable.

E. Comanor's Speculation Regarding the California Class

Lastly, Takeda takes issue with the Comanor Report as it relates to the California Class—or, more precisely, how it does not. Plaintiffs admit that Comanor has not yet "run the numbers" for the methodology that he proposes to use for that class.[42] Plaintiffs argue that merely identifying Comanor's

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38 *Id.* at 23:11-24:7.

39 Sealed Reply 9:14-17.

40 Plaintiffs presented evidence of this fact during the hearing in the context of establishing injury under RICO.

41 Sealed Reply 9:11-17.

42 Sealed Opposition 12:9.

proposed methodology is sufficient under *Comcast Corp. v. Behrend*, 569 U.S. 27 (2013).[43] Not so, says Takeda. Not only is Comanor's opinion here incomplete—in violation of Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure—but it also lacks the explication needed to be admissible under *Daubert*.[44] *See, e.g.*, *Bruton v. Gerber Prod. Co.*, 2018 WL 1009257, at *12 (N.D. Cal. Feb. 13, 2018) (holding that the regression model did not satisfy *Comcast*).

The Court need not enter the fray here. Because Takeda is moving to exclude testimony that has not even been submitted, the Motion is premature. Takeda refrains from arguing that the methodology discussed in *Krueger* is unreliable or flawed, so the Court need not opine on it here. If Plaintiffs seek to offer further Comanor testimony regarding the California Class, the Court will hear any pertinent motions, including *Daubert* motions, at the appropriate time.

IV. DISPOSITION

For the foregoing reasons, the Court hereby **ORDERS** that Takeda's instant Motion to exclude Comanor's expert testimony is **DENIED**.

IT IS SO ORDERED.

Dated: May 22, 2023

John W. Holcomb
UNITED STATES DISTRICT JUDGE

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[43] *Id.* at 12:25-28 (citing the methodology applied in *Krueger v. Wyeth, Inc.*, 396 F. Supp. 3d 931, 947–54 (S.D. Cal. 2019)).

[44] Sealed Motion 24:8-25:16.