UNDER SEAL

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

MEMORANDUM OPINION AND ORDER ON MOTION FOR CLASS CERTIFICATION [ECF No. 229]

Before the Court is the motion of Plaintiff Painters and Allied Trades District Council 82 Health Care Fund ("Painters") and Plaintiff Annie M. Snyder (jointly, "Plaintiffs") for the following relief:

- to certify two classes—a National Third-Party Payer ("TPP") Class and a California Consumer Class;
- to appoint Painters and Snyder as representatives of those two classes, respectively;
- to appoint attorneys R. Brent Wisner, Michael L. Baum, and Christopher L. Coffin as Class Counsel; and
- to direct Class Counsel to propose a comprehensive notice plan for each class.[1]

Defendant Takeda Pharmaceuticals USA, Inc. and its parent company Defendant Takeda Pharmaceutical Company Limited (jointly, "Takeda") oppose Plaintiffs' Motion to Certify.[2] Defendant Eli Lilly & Company ("Lilly") filed a joinder to Takeda's Opposition.[3] After conducting a hearing and considering the voluminous papers filed in support and in opposition,[4] the Court orders that the Motion is **GRANTED** with respect

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[1] Mot. for Class Certification (the "Motion to Certify") [ECF No. 229]; *see also* Unredacted Mot. for Class Certification (the "Sealed Motion to Certify") [ECF No. 234].

[2] Takeda's Opp'n to Pls.' Motion (the "Opposition") [ECF No. 247]; Takeda's Unredacted Opp'n to Pls.' Motion (the "Sealed Opposition") [ECF No. 248].

[3] Lilly's Joinder in the Opposition (the "Joinder") [ECF No. 239]; Lilly's Unredacted Joinder in the Opposition (the "Sealed Joinder") [ECF No. 251].

[4] The Court considered the documents of record in this case, including the following (as well as their attachments):

- Second Am. Compl. (the "Amended Complaint") [ECF No. 127];
- Motion to Certify;
- Sealed Motion to Certify;
- Opposition;
- Sealed Opposition;
- Joinder;
- Sealed Joinder;
- Pls.' Reply in Supp. of the Motion (the "Reply") [ECF No. 257];
- Pls.' Unredacted Reply in Supp. of the Motion (the "Sealed Reply") [ECF No. 260-1];
- Pls.' Reply to the Joinder (the "Reply to Joinder") [ECF No. 261-1];
- Pls.' Unredacted Reply to the Joinder (the "Sealed Reply to Joinder") [ECF No. 271-1];
- Pls.' Suppl. Brief Regarding *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC* ("Plaintiffs' Supplemental Brief") [ECF No. 310];
- Defs.' Suppl. Brief in Opp'n to Class Certification ("Defendants' Supplemental Brief") [ECF No. 311];
- Pls.' Not. of Suppl. Authority ("Plaintiffs' Notice") [ECF No. 315];
- Defs.' Response to Plaintiffs' Notice ("Defendants' Response") [ECF No. 316];
- Pls.' [Second] Not. of Suppl. Authority ("Plaintiffs' Second Notice") [ECF No. 317];
- Defs.' Response to Plaintiffs' Second Notice ("Defendants' Second Response") [ECF No. 318];

to the National TPP Class and **DENIED** with respect to the California Consumer Class, for the reasons set forth herein.

I. BACKGROUND

A. Procedural History

This putative class action was originally filed as part of a multi-district litigation pending in the Western District of Louisiana, MDL No. 6:11-md-2299 (the "MDL Court"). The MDL Court consolidated various claims asserted across the country related to the drug Actos.[5] This case differs from the MDL cases because Plaintiffs here do not assert personal injury or product liability claims. Rather, they allege that Takeda and Lilly conspired to market Actos fraudulently by concealing the association between its use and its users' subsequent development of bladder cancer.[6] In September 2017, the MDL Court ordered this case transferred to this district.[7] Three months later, Plaintiffs filed the presently operative pleading—the Amended Complaint—in which they assert claims for relief under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961–1968 ("RICO"), and state consumer fraud laws.[8]

In February 2018, the Court dismissed the case, finding that Plaintiffs had not adequately pleaded causation.[9] That decision was reversed by the Ninth Circuit in *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 943 F.3d 1243 (9th Cir. 2019), *cert. denied*, 141 S. Ct. 86 (2020) ("*Painters & Allied Trades*"). The Ninth Circuit held that Plaintiffs adequately alleged proximate causation to support their civil RICO claim, and it remanded the case to this Court for further proceedings. *Id.* at 1260.

- Pls.' [Third] Not. of Suppl. Authorities ("Plaintiffs' Third Notice") [ECF No. 321];
- Defs.' Response to Plaintiffs' Third Notice ("Defendants' Third Response") [ECF No. 322];
- Defs.' Not. of Suppl. Authority ("Defendants' Notice") [ECF No. 323]; and
- Pls.' Response to Defendants' Notice ("Plaintiffs' Response")[ECF No. 324].

5 ACTOS is a registered trademark of Takeda Pharmaceutical Company Limited, Reg. No. 2307686.

6 *See generally* Amended Complaint.

7 Order on Mot. to Transfer Case [ECF No. 55].

8 *See* Amended Complaint ¶¶ 55-74.

9 *See* Order Partially Granting Mot. to Dismiss [ECF No. 140].

In August 2020, Takeda again moved to dismiss.[10] Lilly filed a joinder[11] in which it adopted the contentions in Takeda's Motion to Dismiss and raised additional arguments specific to Lilly. In February 2021, this Court denied both motions.[12]

In July 2021, Plaintiffs moved to certify the National TPP Class and the California Consumer Class.[13] Takeda opposed two months later, and Lilly joined.[14] Plaintiffs replied in support of the Motion to Certify in November 2021 and submitted a corrected response to Lilly's joinder shortly thereafter.[15] After several stipulated continuances, the Court conducted a lengthy hearing on the Motion to Certify in March 2022.

About a month after that hearing, the Ninth Circuit issued an *en banc* decision in *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651 (9th Cir. 2022) ("*Olean*"). Because the parties' initial briefing relied on the previously vacated decision in *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 993 F.3d 774 (9th Cir. 2022),[16] the Court ordered supplemental briefing,[17] which the parties filed in April 2022.[18] Four months later the parties *sua sponte* filed supplemental briefs regarding a decision issued by a court in the Northern District of California, *In re Juul Labs, Inc., Marketing Sales Practices and Products Liability Litigation*, 2022 WL 2343268 (N.D. Cal. June 28, 2022).[19] Plaintiffs contend that *Juul Labs* supports their position in support of certification of the California Consumer Class, and Takeda and Lilly disagree. In November 2022, Plaintiffs alerted the Court that the Supreme Court denied a petition for *certiorari* in *Olean*, and Takeda and Lilly responded a few days later by again arguing that *Olean* is substantively different from the instant case.[20] In February 2023, Plaintiffs

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10 Takeda's Mot. to Dismiss Under Rules 12(b)(6) and 9(b) and/or Mot. to Strike Class Allegations Under Rule 12(f) (the "Motion to Dismiss") [ECF No. 173].

11 Lilly's Joinder in the Motion to Dismiss (the "Joinder to the Motion to Dismiss") [ECF No. 174].

12 Order on the Motion to Dismiss and Joinder to the Motion to Dismiss [ECF No. 206].

13 *See generally* Motion to Certify.

14 *See generally* Opposition & Joinder. Initially Takeda filed its Opposition as ECF No. 238 on the docket but refiled on September 29 as ECF No. 247. The Court refers to only the latest filing.

15 *See generally* Reply; Reply to Joinder.

16 *See, e.g.,* Sealed Motion to Certify 5:3-7, 28:21, & 31:9-11; Sealed Opposition 7:25-28 & 11:27-28.

17 *See* Order Regarding Suppl. Briefing [ECF No. 309].

18 *See generally* Plaintiffs' Supplemental Brief & Defendants' Supplemental Brief.

19 *See* Plaintiffs' Notice; Defendants' Response.

20 *See* Plaintiffs' Second Notice; Defendants' Second Response.

provided the Court with notice of two recent orders in which district courts addressed motions for class certification—*Turrey v. Vervent, Inc.*, 2023 WL 163200 (S.D. Cal. Jan. 11, 2023), and *In re National Football League's Sunday Ticket Antitrust Litig.*, 2023 WL 1813530 (C.D. Cal. Feb. 7, 2023)—and Takeda and Lilly provided their response a week later.[21] Finally, in March 2023, Takeda and Lilly invited the Court's attention to *Van v. LLR, Inc.*, 61 F.4th 1053 (9th Cir. 2023), in which the Ninth Circuit vacated and remanded a district court's order granting class certification.[22] Plaintiffs responded that *Van* actually supports their instant Motion to Certify.[23]

B. Factual Summary

Takeda and Lilly developed and marketed a diabetes drug called Actos. *Painters & Allied Trades*, 943 F.3d at 1246. Takeda obtained Food and Drug Administration ("FDA") approval for Actos in 1999. *Id.* Plaintiffs "allege that despite learning through multiple studies over the next several years that Actos increased a patient's risk of developing bladder cancer, Defendants refused to change Actos's warning label or otherwise inform the public of such risk." *Id.*

Plaintiffs contend that Takeda and Lilly misled the FDA regarding the risk of bladder cancer 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.[24] 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.[25] According to Plaintiffs, Takeda and Lilly had reason to know about the increased bladder cancer risk, but they chose not to disclose that risk in order to increase their profits from the sale of Actos.[26]

After the bladder cancer risk became known, a group of patients who developed bladder cancer—along with their families—sued Takeda and Lilly, asserting personal injury and wrongful death claims. Those claims were consolidated before the MDL Court in the Western District of Louisiana. *See Painters & Allied Trades*, 943 F.3d at 1246.[27] The MDL Court conducted a 37-day bellwether trial in 2014, and the jury returned a

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21 *See* Plaintiffs' Third Notice; Defendants' Third Response.

22 *See* Defendants' Notice.

23 *See* Plaintiffs' Response.

24 *See, e.g.*, Amended Complaint ¶¶ 29-35, 48-50, 59-63, 70-87, & 95.

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

26 *See, e.g.*, *id.* at ¶¶ 25-28, 36, & 95.

27 *See also id.* at ¶¶ 121-26.

verdict in favor of those patients and their families.[28] The MDL Court concluded, among other things, that "the Plaintiffs presented evidence that the Defendants were aware of the risk of death by way of bladder cancer associated with Actos® use and that they chose to conceal and obfuscate those risks in order to sell more product and to increase their profit."[29] *In re Actos (Pioglitazone) Prod. Liab. Litig.*, 2014 WL 12776173, at *36 (W.D. La. Sept. 5, 2014).

The instant action was filed by Painters, a third-party payor, and five individual patients.[30] The individual patients allege that neither they nor their physicians knew that Actos use increased the risk of bladder cancer, and they aver that they would not have purchased Actos if they had known of its risks.[31] As a result of the "fraudulent concealment of the bladder cancer risk," Painters says that it "reimbursed a significant number of claims at potentially elevated prices for Actos" that would not have been reimbursed "but for the fraud."[32]

That theory of causation is known as the "quantity effect theory." *Painters & Allied Trades*, 943 F.3d at 1247. In support of their theory, Plaintiffs offer evidence of emails, testimony, and internal marketing studies, some dating back to 1999, that suggest that Takeda and Lilly were aware that language linking Actos to bladder cancer would reduce sales of Actos.[33] If true, that foresight was prescient, because sales of Actos began to decline in 2010 when the FDA announced that it would investigate Actos for bladder cancer risk. Sales dropped even more precipitously after a bladder cancer warning was added to the Actos label in August 2011.[34] Plaintiffs provide evidence of reports studying the causal relationship between the use of Actos and bladder cancer taken from internal Takeda researchers and external academic researchers.[35] Lastly, Plaintiffs introduce an econometric regression model from their expert, Dr. William S. Comanor.[36] His analysis found—with an R^2 value of 99%—that, had a bladder cancer warning been issued from the

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28 *Id.* at ¶ 124. The parties later "agreed to a global settlement program for all eligible personal injury claimants who used Actos before December 1, 2011 and had been diagnosed with bladder cancer." *Painters & Allied Trades*, 943 F.3d at 1246 (citing *In re Actos (Pioglitazone) Prods. Liab. Litig.*, 274 F. Supp. 3d 485, 503 (W.D. La. 2017)).

29 Amended Complaint ¶ 126.

30 Amended Complaint ¶¶ 2-7.

31 *Id.* at ¶¶ 139-205.

32 *Id.* at ¶ 138.

33 Sealed Motion to Certify 19:2-22:19.

34 *Id.* at 22:22-23:23.

35 *Id.* at 23:24-27:10.

36 *Id.* at 28:9-17.

beginning, TPPs would have paid for 56% fewer Actos prescriptions during the class period.[37]

II. LEGAL STANDARD

The class action is "an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (internal quotations omitted). To certify a class, "plaintiffs must prove the facts necessary to carry the burden of establishing that the prerequisites of Rule 23 are satisfied by a preponderance of the evidence." *Olean*, 31 F.4th at 665.

Rule 23(a) imposes the following requirements for the certification of a class: (1) the class is so numerous that a joinder of all members is impracticable (numerosity); (2) there are questions of law or fact common to the class (commonality); (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class (typicality); and (4) the representative parties will fairly and adequately protect the interests of the class (adequacy). *See* Fed. R. Civ. P. 23(a). "A plaintiff seeking class certification bears the burden of affirmatively demonstrating through evidentiary proof that the class meets the prerequisites of Rule 23(a)." *Sali v. Corona Reg'l Med. Ctr.*, 909 F.3d 996, 1003–04 (9th Cir. 2018) (internal quotations omitted).

In addition, at least one element of Rule 23(b) must be satisfied for a court to certify a class. *See* Fed. R. Civ. P. 23(b). Here, Plaintiffs focus on the third element—*i.e.*, predominance and superiority[38]—which would allow this Court to certify a class where:

> the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. The matters pertinent to these findings include:
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> > (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
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> > (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

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37 *Id.* at 29:8-30:7.

38 *See generally id.*

> (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
>
> (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3). With respect to the predominance element, what matters is not merely "the raising of common questions," but, rather, "the capacity of a class-wide proceeding to generate common answers apt to drive the resolution of the litigation." *Dukes*, 564 U.S. at 350 (internal quotations omitted).

Lastly, the Court observes that its decision on this Motion to Certify is preliminary in nature, because an "order that grants or denies class certification may be altered or amended before final judgment." Fed. R. Civ. P. 23(c)(1)(C).

III. THE AMENDED NATIONAL TPP CLASS

Plaintiffs seek to certify a nationwide class of TPPs for Plaintiffs' civil RICO claims against Takeda and Lilly.[39] In view of issues raised in Takeda's briefs, Plaintiffs amended their definition of the putative National TPP Class from what appears in the Amended Complaint.[40] Plaintiffs now define that class as:

> All third-party payers ("TPPs") in the United States and its territories, that purchased, paid for, and/or reimbursed all or any portion of the price for Actos, ActosPlus MET, ActosPlus MET XR, Duetact, and/or Oseni, for 5 or more independent prescriptions, between July 1, 1999 and September 17, 2010, for purposes other than resale. Excluded from this class are any TPPs that have released claims covered by this lawsuit.[41]

As discussed below, Plaintiffs' proposed National TPP Class easily satisfies the four mandatory requirements under Rule 23(a). Plaintiffs also succeed in showing that the class action form is superior, thereby satisfying one of two prongs of Rule 23(b)(3). The heart of the dispute over the certification of the National TPP Class is the final prong

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[39] Amended Complaint ¶¶ 127 & 239-51 (alleging that (1) Takeda and Lilly conducted an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c) and, additionally and in the alternative, (2) Takeda and Lilly conspired to conduct or participate in the conduct of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d)).

[40] Sealed Reply 1:26-28.

[41] *Id.* at 2:1-3; *see also* Amended Complaint ¶ 222.

of Rule 23(b)(3): do common questions of law and fact predominate over Plaintiffs' RICO claims? The Court answers that question in the affirmative.

A. Rule 23(a) Requirements

"Rule 23(a) ensures that the named plaintiffs are appropriate representatives of the class whose claims they wish to litigate." *Dukes*, 564 U.S. at 349.

1. Numerosity

Takeda's documents reveal that there are hundreds, if not thousands, of TPPs in the United States that reimbursed Actos prescriptions.[42] That finding alone would satisfy the numerosity requirement. *See, e.g.*, *Ochinero v. Ladera Lending, Inc.*, 2021 WL 2295519, at *9 (C.D. Cal. Feb. 26, 2021) ("Typically, courts have found that the numerosity requirement is satisfied when the proposed class includes at least forty members."). Neither Takeda nor Lilly disputes that finding or raises challenges to numerosity,[43] so the Court concludes that numerosity is satisfied.

2. Commonality

"[C]ommonality requires that the class members' claims 'depend upon a common contention' such that 'determination of its truth or falsity will resolve an issue that is central to the validity of each claim in one stroke.'" *Abdullah v. U.S. Sec. Assocs., Inc.*, 731 F.3d 952, 957 (9th Cir. 2013) (quoting *Dukes*, 564 U.S. at 350). Here, Takeda and Lilly stipulated to the notion that the existence of an alleged RICO enterprise between Takeda and Lilly would qualify as a common question for all class members at any given point in time.[44] Because the Court agrees with that proposition, and neither Takeda nor Lilly raises any other issues concerning commonality,[45] the Court concludes that Rule 23(a)(2) is satisfied.

3. Typicality

"To demonstrate typicality, Plaintiffs must show that the named parties' claims are typical of the class." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 984 (9th Cir. 2011) (citing Fed. R. Civ. P. 23(a)(3)). "The test of typicality 'is whether other members have

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42 *See* Motion to Certify, Ex. 6 [ECF No. 229-7].

43 *See generally* Sealed Opposition; Sealed Joinder.

44 Sealed Motion to Certify 7:7-11; *see generally* Sealed Opposition (making no objection); *see also* Sealed Joinder 4:9-25 (acknowledging the stipulation but qualifying its reach with respect to liability).

45 Sealed Reply 2:7.

the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct.'" *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992) (quoting *Schwartz v. Harp*, 108 F.R.D. 279, 282 (C.D. Cal. 1985)). The Rule 23(a) standard is "permissive," and it requires only that the representative's claims are "reasonably co-extensive with those of absent class members." *Rodriguez v. Hayes*, 591 F.3d 1105, 1124 (9th Cir. 2010) (citation omitted).

Plaintiffs argue that Painters is typical of the National TPP Class for two reasons. First, Painters' injuries—*i.e.*, payments for excess prescriptions—are based upon the same legal theories as those of the absent TPPs.[46] And second, the manner in which Painters administers its benefits—*i.e.*, via a pharmacy benefit manager—mirrors the approach of TPPs across the country.[47] According to Plaintiffs' expert Dr. Peter Penna, the relationship between Painters and its pharmacy benefit manager—Prime Therapeutics—"is typical of such relationships in the United States," and it includes "usual and customary services."[48]

Takeda does not dispute either point. Rather, Takeda argues that Painters' claims are atypical because they are subject to "unique defenses relating to [Painters'] failure to preserve relevant documents."[49] Specifically, Takeda accuses Painters of spoilation by failing to ensure that Prime Therapeutics preserved relevant documents, as Painters did not preserve documents on its own.[50] Takeda also says that Prime Therapeutics testified that it did not receive a litigation hold notice, so it has documents and formularies reaching back to only 2009.[51]

When a class representative destroys evidence, the Court may deem her claim to be atypical if that conduct threatens to become the focus of the litigation. *See Doyle v. Chrysler Grp. LLC*, 2014 WL 7690155, at *3 (C.D. Cal. Oct. 9, 2014), *rev'd and remanded on different grounds*, 663 F. App'x 576 (9th Cir. 2016). However, the Court concludes that Painters cannot be accused of spoilation because ***it*** did not destroy or dispose of any documents—Prime Therapeutics did. Painters provides evidence of its diligent efforts to

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46 Sealed Motion to Certify 7:24-27.

47 *Id.* at 8:16-21.

48 *Id.* at 8:28-9:3.

49 Sealed Opposition 37:15-16.

50 *Id.* at 37:23-38:4; Sealed Motion to Certify 8:16-17.

51 Sealed Opposition 38:3-10.

preserve its documents, to notify Prime Therapeutics of the lawsuit (when Takeda, ironically, did not), and even to subpoena Prime Therapeutics.[52]

Moreover, Takeda gives little if any explanation for why the lost documents—specifically, Prime Therapeutics' drug formularies from 2005 to 2009—even matter.[53] Painters claims that it has the data showing how much it paid for Actos prescriptions, rendering the information in the formularies duplicative.

Therefore, the Court is doubtful that the lost formularies would become the focus of the lawsuit. In fact, if that information was so important, the Court would have expected the issue to arise during the hearing on the Motion to Certify. It did not. Thus, the Court is not persuaded that the lost formularies render Painters' claims atypical. Rule 23(a)(3) is satisfied with respect to typicality.

4. Adequacy

Rule 23(a)(4) requires that the class representative "fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). Takeda makes two arguments why Painters is an inadequate class representative.

First, Takeda contends that Painters has abandoned allegedly viable claims because (1) it narrowed the period of the class by amending the end date to September 2010; and (2) it declined to appeal its excess price theory of damages.[54] Because those "tactical decisions potentially jeopardize the rights of absent class members," says Takeda, "class certification should be denied."[55]

Takeda's argument is weak and easily surmounted. "A strategic decision to pursue those claims a plaintiff believes to be most viable does not render her inadequate as a class representative." *Todd v. Tempur-Sealy Int'l, Inc.*, 2016 WL 5746364, at *5 (N.D. Cal. Sept. 30, 2016). Takeda offers no compelling reason why narrowing the class definition—as Painters did here—jeopardizes the rights of absent class members.[56] If anything, the new timeframe better aligns with the data unearthed in discovery, which

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52 Sealed Reply 2:25-3:16.

53 *See* Sealed Opposition 38:5-10 (asserting that the loss of formularies has impacted the litigation, without identifying the impact or explaining why that information matters).

54 *Id.* at 35:23-36:4.

55 *Id.* at 36:5-6.

56 *See generally id.*

undergirds Plaintiffs' theory. Pruning unviable elements from one's case is a hallmark of competence, not inadequacy.[57]

Moreover, Takeda moved to dismiss the excess price theory with prejudice and ***won***.[58] Takeda now asserts that Plaintiffs' failure to revive that theory on appeal renders Painters an inadequate representative,[59] but Takeda offers no authority for the proposition that declining to appeal constitutes abandonment rather than an exercise of discretion.[60] *Cf. In re Conseco Life Ins. Co. LifeTrend Ins. Sales & Mktg. Litig.*, 270 F.R.D. 521, 532 (N.D. Cal. 2010) ("Plaintiffs are permitted to press a theory of contract liability that affords them the best chance of certification and of success on behalf of the class" in view of "changes occasioned by the issuance of the regulatory settlement."). Indeed, the facts here are distinguishable from the cases that Takeda cites, in which the class representative took some affirmative action to waive or abandon certain claims. *See, e.g.*, *Clark v. Experian Info. Sols., Inc.*, 2001 WL 1946329, at *3 (D.S.C. Mar. 19, 2001) (the plaintiffs abandoned their claims); *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544, 550 (D. Minn. 1999) (the plaintiffs tried to "reserve" personal injury and damage claims); *Drimmer v. WD-40 Co.*, 2007 WL 2456003, at *3 (S.D. Cal. Aug. 24, 2007), *aff'd*, 343 F. App'x 219 (9th Cir. 2009) (the plaintiff's "own conduct militates against finding that he adequately represents the class" when he "refuses to seek all available remedies even for himself").

Second, Takeda lambasts Painters as "stunningly unaware of what has been happening in this litigation since it was filed."[61] But in support of that accusation, Takeda can cite only a lapse of memory by Painters' fund counsel during a live deposition regarding certain details of the litigation.[62] While mildly unflattering for Painters, it is too much of a stretch for Takeda then to equate that circumstance to a case in which the class representative "ceded all control to his counsel."[63] *Azoiani v. Love's Travel Stops & Country Stores, Inc.*, 2007 WL 4811627, at *2 (C.D. Cal. Dec. 18, 2007).

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57 Sealed Reply 5:22-25.

58 In Chambers Order Partially Granting Mot. to Dismiss [ECF No. 140] 2.

59 Sealed Opposition 35:25-27.

60 *See id.* at 34:25-35:22 (where none of the cases that Takeda cites stands for the proposition that failing to appeal a claim dismissed with prejudice constitutes abandonment for the purposes of determining adequate representation under Rule 23(a)(4)).

61 *Id.* at 36:21-22.

62 *See, e.g.*, *id.*, Ex. G. Dep. Tr. of Rule 30(b)(6) Designee Roger Stelljes [ECF No. 248-4] 38:20-25 (where the fund's counsel could not remember if the class was shortened from September 2010 or 2011).

63 Sealed Opposition 36:22-37:12.

Crucially, Takeda does not assert that Painters' interests are misaligned with those of the other class members. *See, e.g.*, *Crawford v. Honig*, 37 F.3d 485, 487 (9th Cir. 1994), *as amended on denial of reh'g* (Jan. 6, 1995) (adequacy depends on the qualifications of the representative, "an absence of antagonism, a sharing of interests between representatives and absentees, and the unlikelihood that the suit is collusive") (internal quotations and citations omitted). The Court therefore concludes that the adequacy requirement is satisfied. *See* Fed. R. Civ. P. 23(a)(4).

In summary, each of the requirements under Rule 23(a) is met for the National TPP Class.

B. Rule 23(b) Requirements

The proposed class must also meet one of three prongs set forth in Rule 23(b). Plaintiffs focus on the third prong, which requires both that a class action is the superior method of adjudication and that common issues of law or fact predominate over individualized issues. *See* Fed. R. Civ. P. 23(b)(3).

1. Superiority

Plaintiffs argue that a class action is superior because it would be uneconomical to litigate many of the claims for individual TPPs separately, in view of the staggering costs of litigation and the barriers to access the IQVIA data needed to establish causation.[64] Takeda responds that trial will be unmanageable if the Court certifies the class, given the myriad witnesses and volume of evidence involved. Takeda points to the five-week trial in *In re Neurontin Mktg. & Sales Pracs. Litig.*, 2011 WL 3852254, at *2 (D. Mass. Aug. 31, 2011), as a benchmark.[65]

Notwithstanding the enormous logistical hurdles of a five-week trial, the alternative would be far less efficient. With thousands of TPPs, there could be hundreds or thousands of individual lawsuits. Even if each of those trials is short, the cumulative amount of time and resources expended on all of those proceedings—by both the judicial system and the parties—would be greater in the aggregate. One supposed "nightmare" trial is preferable to many hundreds of shorter ones.[66] The class action form is far superior here. *See* Fed. R. Civ. P. 23(b)(3).

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64 Sealed Motion to Certify 36:9-18.

65 Sealed Opposition 33:21-34:18.

66 *Id.* at 34:16.

2. Predominance

In this lawsuit, the battle over certification is waged in the trenches of the second prong of Rule 23(b)(3): predominance. In view of the quantity of briefing on this topic and the complexity of the factual matters involved, the Court will proceed claim by claim, element by element, endeavoring to conduct a "rigorous analysis" to determine whether common questions of law and fact predominate over Plaintiffs' claims. *See Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013).

The predominance inquiry tests "whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 623 (1997). "Considering whether questions of law or fact common to class members predominate begins, of course, with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011) (internal quotations omitted).

For the National TPP Class, Plaintiffs assert civil RICO claims against Takeda and Lily under 18 U.S.C. § 1962(c) and derivatively under § 1962(d).[67] To establish those claims, Plaintiffs must show (1) that a RICO violation occurred; and (2) that the class members have standing. *Painters & Allied Trades*, 943 F.3d at 1248.

After those issues have been characterized as common or individual, "courts then loosely compare the issues subject to common proof against the issues subject solely to individualized proof to assess whether the common issues predominate." 2 W. Rubenstein, *Newberg on Class Actions* § 4:50 (5th ed. 2021) ("Rubenstein"). That final step "is more of a qualitative than quantitative analysis." *Id.* One indication that common issues predominate is if adding more plaintiffs to the class only minimally affects the amount of evidence to be introduced. *See id.* Another indication is if individual factual determinations "can be accomplished using computer records, clerical assistance, and objective criteria." *Id.* But if the resolution of an issue "breaks down into an unmanageable variety of individual legal and factual issues leading to an inordinate number of evidentiary hearings," then common questions do not predominate. *Kristensen v. Credit Payment Servs.*, 12 F. Supp. 3d 1292, 1306 (D. Nev. 2014).

a. Civil RICO Violation

To demonstrate a civil RICO violation, "a plaintiff must prove that the defendant engaged in (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Painters & Allied Trades*, 943 F.3d at 1248 n.5.

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[67] Amended Complaint ¶¶ 231-259.

i. Conduct

Plaintiffs argue that questions of conduct are common to the class because evidence of conduct all stems from the behavior of Takeda and Lilly.[68] The Court agrees. "Proving the first element of a RICO violation in this case would involve common questions about the activities" of Takeda and Lilly and whether they "participated or engaged in conduct" with each other. *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d 241, 269 (3d Cir. 2009). Such evidence would not necessarily vary based upon the number of TPPs in the class. Even if including some TPPs in the class (and not others) would force Plaintiffs to extend the timeframe of the class period,[69] the locus of the evidence would nonetheless be Takeda and Lilly. Thus, common questions predominate with respect to the first element of a civil RICO violation.

Lilly suggests that the evidence will not bear out Plaintiffs' allegations regarding its conduct (as opposed to Takeda's conduct), especially in the years after 2006, when Lilly stopped promoting Actos.[70] But that concern is immaterial at this stage of the litigation. Whether the evidence will support Plaintiffs' claims is a matter for trial or summary judgment; it is peripheral to the question of whether (or not) the issue is common to the class.[71] *See Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 459 (2013) (holding that "Rule 23(b)(3) requires a showing that *questions* common to the class predominate, not that those questions will be answered, on the merits, in favor of the class") (emphasis in original); *Olean*, 31 F.4th at 667 (observing that district courts are "limited to resolving whether the evidence establishes that a common question is *capable* of class-wide resolution, not whether the evidence in fact establishes that plaintiffs would win at trial") (emphasis original).

ii. Enterprise

Plaintiffs contend that the second element of a RICO violation—the existence of an enterprise—also involves common evidence.[72] *See In re Ins. Brokerage Antitrust Litig.*,

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68 Sealed Motion to Certify 11:9-12.

69 Imagine, for example, some cluster of TPPs started reimbursing for Actos prescriptions only at the end of the class period, rather than continuously throughout the period.

70 *See* Sealed Joinder 5:1-15.

71 Sealed Reply to Joinder 1:16-27. Additionally, the MDL Court found that Lilly "continued to collect a residual fee based upon the scope and success of its efforts during the official term of the Co–Promotion Agreement" for three years after Lilly ceased actively to promote Actos. *In re Actos (Pioglitazone) Prod. Liab. Litig.*, 2014 WL 46579, at *9 (W.D. La. Jan. 6, 2014). Plaintiffs contend that such a finding illustrates how they would succeed on the merits for the element of conduct. *See* Sealed Reply to Joinder 2:1-19.

72 Sealed Motion to Certify 11:12-15.

579 F.3d at 269–70. Under the RICO statute, an enterprise is defined as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). On its face, it appears that the question of whether Takeda or Lilly was "part of an association-in-fact enterprise operating an alleged scheme to defraud the class members" is one that "can be resolved on a class-wide basis." *Negrete v. Allianz Life Ins. Co. of N. Am.*, 287 F.R.D. 590, 610 (C.D. Cal. 2012); *see also Just Film, Inc. v. Buono*, 847 F.3d 1108, 1122 n.3. (9th Cir. 2017) (whether the defendants were "part of an enterprise" was an issue to be "resolved on a classwide basis").

In response, Takeda and Lilly assert that their evolving relationship from 1999 through 2010 precludes Plaintiffs from using common proof to establish that a RICO enterprise existed.[73] But that argument muddies the inquiry. Even if Takeda and Lilly's relationship changed over time, the evidence needed to prove the existence of an enterprise would not vary by TPP—it would remain common to the class. Common evidence need not be evidence that holds true or applies equally across periods of time; it can refer to any or all evidence that answers a question common to the class. *See Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (observing that a common question is one where the same evidence will suffice for each member to make a *prima facie* showing ***or*** the issue is susceptible to generalized, class-wide proof); *see also Does I v. Gap, Inc.*, 2002 WL 1000073, at *7 (D. N. Mar. I. May 10, 2002) (holding that common issues predominate in a claim for a civil RICO violation where "common evidence" could prove the existence of a RICO enterprise). Thus, common questions of law and fact predominate over the second element of a civil RICO violation.[74]

iii. Pattern of Racketeering Activity

Lastly, Plaintiffs argue that the third and fourth elements of a RICO violation "would encompass common questions . . . including whether activities that constitute racketeering were taking place through the enterprise . . . and whether these racketeering activities were recurring such that a pattern could be established."[75] *In re Ins. Brokerage*

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[73] Sealed Opposition 30:9-10; Sealed Joinder 4:9-25.

[74] Additionally, the parties dispute whether Takeda and Lilly's prior stipulation, *see* Motion to Certify, Ex. 9 [ECF No. 229-10], means that they conceded the argument that the existence of an enterprise is one common to the class. *Compare* Sealed Motion to Certify 11:12-15 *with* Sealed Opposition 30:24-31:2 *and* Sealed Joinder 4:9-25. Whether Takeda and Lilly conceded that point is moot because the Court concludes that common issues predominate over the first and second elements of a civil RICO violation.

[75] Sealed Motion to Certify 11:15-19.

Antitrust Litig., 579 F.3d at 270. The alleged racketeering activity involves mail fraud and wire fraud under 18 U.S.C. § 1341 and § 1343, respectively.[76]

Takeda and Lilly attack this contention from two angles. First, they argue that proving racketeering by means of mail and wire fraud would require common evidence showing that they intended to "deceive *and* cheat."[77] *United States v. Miller*, 953 F.3d 1095, 1101 (9th Cir. 2020) (emphasis original). Takeda and Lilly say that the evidence against them of fraud and deception varies depending on the time-period because their product labels changed.[78] That nuance matters because statements are false and misleading only if such is the case "***at the time they were made***, as required in a civil RICO action based on mail and wire fraud." *United Food & Com. Workers Cent. Pennsylvania & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (emphasis added).

Takeda and Lilly's argument is unpersuasive. While the product labels for Actos may have changed from 1999 to 2011, they would have changed for all members of the class at the same time. That fact distinguishes the circumstances here from the case that Takeda cites,[79] in which the defendant allegedly violated New York consumer protection laws by, *inter alia*, failing to disclose certain fees, terms, and conditions on the various websites through which it sold video games. *See Williams v. Oberon Media, Inc.*, 2010 WL 8453723, at *1 (C.D. Cal. Apr. 19, 2010), *aff'd*, 468 F. App'x 768 (9th Cir. 2012). There, "the content and format of those websites varie[d] from website to website." *Id.* at *9. As a result, the district court determined that it would need to engage in a customer-by-customer inquiry to determine which disclosures any individual class member read. *Id.* In contrast, Takeda and Lilly have not explained why Actos product labels would differ from TPP to TPP. If, for certain periods of time, the product labels were deemed not false or misleading, then that would hold true for all TPPs purchasing Actos in that timeframe, effectively shortening or redrawing the class period eligible for damages. But

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76 Amended Complaint ¶ 239.

77 Sealed Opposition 9:28-10:5; *see also* Sealed Joinder 3:16-27.

78 Sealed Opposition 28:7-8; *see also id.* at 27:19-22 ("Simply put, the evidence as to whether Defendants committed a RICO violation (and Defendants' defenses to such allegations) is not common for all class members, but varies based on when the underlying Actos prescription was filled.").

79 *Id.* at 28:14-17. Takeda cites two other cases, but the Court also finds them distinguishable. *See id.* at 28:17-29:1 (citing *Reitman v. Champion Petfoods USA, Inc.*, 830 F. App'x 880, 881 (9th Cir. 2020) (affirming the district court's denial of class certification where each bag of the defendant's dog food contained different information depending on the packaging), and *Cabral v. Supple LLC*, 608 F. App'x 482, 483 (9th Cir. 2015) (vacating certification where the defendant made different statements about its product through different advertising channels)).

that scenario would not require individualized hearings. The evidence needed to resolve the inquiry would remain "a common body of evidence," even if the evidence may implicate individual TPPs (or temporal clusters of TPPs) differently. *Olean*, 31 F.4th at 666.

Second, Takeda argues that the changing state of scientific knowledge precludes Plaintiffs from establishing the element of scienter with common proof.[80] Takeda cites *Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 453 (E.D. Pa. 2000), and *In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 220 (E.D. La. 1998), for support.[81] Again, the Court concludes that evidence of scienter would involve common elements because Takeda and Lilly's scientific knowledge would not vary by individual TPP. Evidence of scienter would necessarily focus on what Takeda and Lilly knew, not what the individual TPPs knew.[82] *See, e.g.*, *Broomfield v. Craft Brew All., Inc.*, 2018 WL 4952519, at *13 (N.D. Cal. Sept. 25, 2018) (holding that the question of the defendant's "state of mind is . . . common to the class"); *cf. In re Bofl Holding, Inc. Sec. Litig.*, 2021 WL 3742924, at *4 (S.D. Cal. Aug. 24, 2021) (holding, in the context of securities fraud, that "the defendant's scienter [is an] issue[] that would require the same proof for any class member"); *Takiguchi v. MRI Int'l, Inc.*, 2016 WL 1091090, at *7 (D. Nev. Mar. 21, 2016) (holding that evidence of scienter is "clearly susceptible to classwide proof"). Thus, common evidence would predominate over the third and fourth elements of a RICO violation and any respective defenses put forward by Takeda or Lilly.

In conclusion, common questions of fact predominate over each element of the civil RICO violation.

b. Civil RICO Standing

To allege civil RICO standing under 18 U.S.C. § 1964(c), a "plaintiff must show: (1) that his alleged harm qualifies as injury to his business or property; and (2) that his harm was by reason of the RICO violation." *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 972 (9th Cir. 2008) (internal quotations omitted). The Supreme Court has interpreted the phrase "by reason of" in 18 U.S.C. § 1964(c) to require both proximate and but-for causation. *See Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992).

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80 *Id.* at 29:2-8.

81 *Id.* at 29:9-18.

82 Furthermore, neither *Sanneman* nor *Ford Motor Co. Vehicle Paint Litig.* provides any reasoning or explication regarding how a defendants' changing scienter over time means that common questions do not predominate. If anything, a defense that Takeda lacked scienter in 2000, but had it in 2004, would necessarily rely on evidence common to a class of TPPs that purchased Actos in that time frame.

i. Injury

To satisfy the element of injury, Plaintiffs must show that "'damages are capable of measurement on a classwide basis,' in the sense that the whole class suffered damages traceable to the same injurious course of conduct underlying the plaintiffs' legal theory." *Just Film, Inc.*, 847 F.3d at 1120 (citing *Comcast Corp.*, 569 U.S. at 34). But the presence of individualized variation in the damages does not, by itself, defeat certification. *See Leyva v. Medline Industries Inc.*, 716 F.3d 510, 514 (9th Cir. 2013). The Court must determine whether common questions "predominate[] over any individual questions, including individualized questions about injury or entitlement to damages." *Olean*, 31 F.4th at 669.

Takeda argues that the National TPP class definition includes some uninjured TPPs and that their presence is a reason to reject certification, as their inclusion in the class generates the need for individualized analysis.[83] *See Ruiz Torres v. Mercer Canyons Inc.*, 835 F.3d 1125, 1138 (9th Cir. 2016) (noting that the class should not be "defined so broadly as to include a great number of members who for some reason could not have been harmed by the defendant's allegedly unlawful conduct") (internal citations omitted). Specifically, Takeda highlights three "types" of uninjured TPPs.[84] The Court reviews each in turn.

(a) Inevitable Actos Prescriptions

The first type of uninjured class members are those TPPs that paid for Actos prescriptions that would have been written anyway, fraud be damned.[85] Takeda pounces on the remarks of Plaintiffs' expert witness—Comanor—when he states that "a good number of Actos prescriptions were dispensed that would have occurred even in the absence of the Defendants' misconduct."[86] In fact, Comanor estimates that around 40% of the Actos prescriptions would have still been written (and, thus, would have been reimbursed), even if there was full awareness of the bladder cancer risks.[87]

Plaintiffs seek to overcome that criticism by including only those TPPs in the class that paid for at least five Actos prescriptions during the class period. In his report, Comanor concluded that 56.77% of Actos prescriptions during the class period were

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83 *See* Sealed Opposition 10:10-15:11.

84 *Id.* at 11:11.

85 *Id.* at 11:12-13 & 12:2-13:20.

86 *Id.* at 12:4-6 (quoting Motion to Certify 31:20-22).

87 Sealed Opposition 19:4-7.

fraudulently induced.[88] Taking Comanor's analysis at face value, the odds that any given prescription, plucked randomly out of the class period, was induced by fraud would be 56.77%.[89] As a result, any TPP that paid for at least five Actos prescriptions has, statistically, a 98.5% chance of suffering an injury from Takeda and Lilly's alleged concealment of the bladder cancer risks.[90] While it is not known at this time which specific TPPs managed to avoid paying for any fraudulently induced prescriptions entirely,[91] one would expect—statistically speaking—that Takeda and Lilly could dispute injury upon that basis for only about 1.5% of the class. And even though those disputes would likely turn on individualized evidence specific to those TPPs, common evidence of injury would still be expected to apply to the other 98.5% of the class. "That the defendant might attempt to pick off the occasional class member here or there through individualized rebuttal does not cause individual questions to predominate." *Olean*, 31 F.4th at 668.

This conclusion is valid even when taking into account the temporal variations in Comanor's probability scores, since the years when the odds of fraudulently induced prescriptions were lowest also tended to be the years when total volumes of prescriptions were the lowest.[92] For example, for 2000, Comanor estimated that 88.3% of Actos prescriptions and Actos combination treatments were fully informed of the bladder

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88 The Court takes Comanor's report at face value and does not prejudge its accuracy. *See* Expert Report of William S. Comanor (the "Comanor Report") [ECF No. 234-6]. While the Court found his testimony to be admissible for the purpose of class certification, it is up to the finder of fact to weigh Comanor's testimony in view of any cross-examination or contradicting evidence or testimony from Takeda's experts. Importantly, Takeda and Lilly do not provide a competing regression analysis. Instead, Takeda and Lilly offer arguments and expert testimony why they believe that Comanor's analysis is flawed. *See, e.g.*, Defs.' Mot. to Exclude William S. Comanor [ECF No. 249]; *see also* Expert Report of James W. Hughes on Class Certification (the "Hughes Report") [ECF No. 248-5] (critiquing the Comanor Report methodologically, but refraining from offering a competing analysis). Comanor's probability scores are the only ones that the Court has before it.

89 The Court notes that 56.77% is the ***average*** probability of a fraudulently induced prescription across the class period. Plaintiffs acknowledge that the probability changes over time. *See* Not. of Lodging of Pls.' PowerPoint for Hr'g on Pls.' Motion to Certify [ECF No. 305] 67. The probability ranges from as low as 11.7% in the year 2000 to as high as 70.6% in 2010. *See* Comanor Report 64 (providing a table of the share of "fully informed" prescriptions for Actos and Actos combinations).

90 Sealed Reply 9:28-10:9. The math is relatively straightforward. Taking Comanor's summary statistics as valid, the chance that a TPP paid for five Actos prescriptions—and that ***none*** was induced by fraud—would be $(1 - 0.5677)^5$, or about 1.5%.

91 *See* Defendants' Supplemental Brief 9:22-10:8.

92 *See* Comanor Report 64.

cancer risks, and, thus, they would have still been prescribed.[93] That year there were 4,459,950 total Actos prescriptions and Actos combination treatments, of which 3,938,256 (or 88.3%) were therefore fully informed. But those 3.9 million prescriptions represent only about 3% of the total number of Actos prescriptions and Actos combination treatments reimbursed during the class period. Moreover, the data shows that Actos prescriptions grew steadily each year. So even though the odds were better that a TPP was uninjured from prescriptions arising from the early years of the class period, those years saw fewer total prescriptions. Thus, the number of uninjured TPPs appears to be *de minimis* even when temporal variations are considered, and it is more likely than not that common questions of fact would predominate over individualized ones when it comes to injury.[94]

Takeda tries to throw another wrench into the probability analysis by arguing that individualized data would be needed to determine whether any individual TPP's five (or more) payouts were for "independent" prescriptions or merely for refills.[95] While that theory has some superficial appeal, it does not survive scrutiny. Plaintiffs point out that both their experts and Takeda's expert—Dr. James W. Hughes—successfully used the same IQVIA plan-level data to screen out TPPs that did not fall within the class definition when filtering for independent prescriptions.[96] Because the IQVIA data facilitates individual determinations, Plaintiffs' approach is a textbook example of how the use of "computer records, clerical assistance, and objective criteria" can obviate the need for an evidentiary hearing on each claim. Rubenstein § 4:50. The Court is persuaded that common questions of fact still predominate.

(b) More Costly Alternatives

A second type of uninjured TPPs is those "that would have paid more for an alternative treatment, had they not reimbursed for Actos."[97] After all, there are patients who switched from Actos to another drug, and, in some instances, those patients' doctors

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93 It is worth noting that 88.3% is the highest probability (and, thus, the least favorable probability to Plaintiffs) of any given year that a prescription was deemed "fully informed." *Id.* The average probability of a fully informed prescription during the class period is about 43% (that is, one minus 57%—the average chance that the prescription was due to fraud).

94 Even if the number of uninjured class members was more than *de minimis*, *Olean* clarified that that defect is not necessarily a bar to certification. *Olean*, 31 F.4th at 669 (rejecting the argument "that Rule 23 does not permit the certification of a class that potentially includes more than a de minimis number of uninjured class members").

95 Sealed Opposition 13:8-20; Defendants' Supplemental Brief 10:8-15.

96 *See* Sealed Reply 11:14-21; *see also* Plaintiffs' Supplemental Brief 10:1-9.

97 Sealed Opposition 14:1-2.

prescribed more expense alternatives.[98] Understanding whether a patient would have moved from Actos to a different drug, says Takeda, is an analysis "necessarily unique to each TPP, based on the individual patient prescription decision that underlies the TPP's claims data."[99]

Close scrutiny reveals cracks in that argument. Although Takeda implies that this offset issue is rampant throughout the class, Takeda never identifies how many TPPs are (or would be) affected.[100] Takeda only regurgitates the number from the Hughes Report identifying how many ***patients*** switched from Actos to another regimen[101]—about 30%.[102] But that 30% figure says nothing about the number of ***TPPs*** affected by higher alternative costs. And in fact, the Court has reason to believe that switching costs may affect only a *de minimis* number of TPPs. Hughes estimated that only 14.4% of the patients who switched treatments from Actos chose a new treatment equal to or greater in cost than their prior Actos prescription.[103] Doing the math, 14.4% of 30.6% of patients is about 4% of total patients in the sample population. In other words, only about 4% of the patients switched from Actos to an equally or more expensive drug.

How those patients are distributed across the class of TPPs is unknown to the Court at this time. But the answer must lie between one of two extremes: either those patients are maximally distributed across the TPP class, or they are maximally concentrated in one TPP (or perhaps some handful). The Court reviews each scenario in turn.

(1) Distribution Across the TPPs

In the first scenario, it appears extremely unlikely that ***any*** TPP would count as uninjured (when those TPPs were likely reimbursing many other patients' fraudulently induced prescriptions at the same time), thus directly undermining Takeda's argument

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98 For context, Actos is often understood as a second-line treatment drug. That is, patients usually start with a different drug, like Metformin, before trying Actos. *See* Reporter's Tr. of Mot. Proceedings (the "Hearing Transcript") [ECF No. 312] 11:8-12:4 & 40:7-15.

99 Sealed Opposition 15:3-5.

100 *Id.* at 15:6-11.

101 *Compare id.* 15:7-8 (citing the Hughes Report: "more than 30% of patients paid more for their diabetes treatment after they stopped using Actos") *with* Hughes Report ¶ 158 (observing that "26.1 percent of all Actos patients switched to an alternative branded monotherapy, and an additional 4.5 percent of patients switched to a combination therapy").

102 Sealed Opposition 15:7.

103 Hughes Report ¶ 160 (stating that, of the patients who transitioned from Actos to alternative treatments, only 14.4% paid for new regimens that were "equally or more expensive for the TPP").

that individualized questions of injury would overwhelm common ones. Moreover, any variance in the distribution of those patients would be a factor to consider only in calculating ***damages***, which does not disturb predominance. *See* Rubenstein § 4:54 (observing that "courts in every circuit have uniformly held that the 23(b)(3) predominance requirement is satisfied despite the need to make individualized damage determinations").

(2) Concentration in a Few TPPS

In the second scenario, common questions of fact would still predominate, since the evidence would—at most—give Takeda the ability to "pick off the occasional class member here or there," which "does not cause individual questions to predominate."[104] *Halliburton Co.*, 573 U.S. at 276. That ability to pick off a few class members, of course, also assumes that the avoidance of ***economic loss*** is sufficient to render a TPP uninjured. Plaintiffs directly challenge that assumption, arguing that the act of paying for fraudulently induced prescriptions—even when the alternatives are more expensive—is an injury in and of itself.[105] The Court agrees. "To the extent that class members were relieved of their money by [defendant's] deceptive conduct—as Plaintiffs allege—they have suffered an 'injury in fact.'" *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012), *overruled on other grounds by Olean*, 31 F.4th at 682 n.32 (9th Cir. 2022). Again, whether the net economic loss is zero (or negative) is a question of ***damages***, not injury. *See Olean*, 31 F.4th at 679; *Painters & Allied Trades*, 943 F.3d 1251 n.7 (describing that question as a "damages question for another day"). Therefore, the presence of more costly alternative medicines is not a reason, in this case, to believe that individualized questions predominate over the element of injury.

(c) TPPs That Settled

A third and final type of uninjured TPPs is those that already settled.[106] While the Court can understand how their inclusion could have raised individualized issues, the issue is now moot. Plaintiffs have amended the putative National TPP class definition to exclude those TPPs.[107]

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[104] The Court hypothetically referred to this scenario as the Kansas City example during the hearing. Hearing Transcript 49:20-51:22. For instance, if all of those patients and prescribers lived in one city, and all of those prescriptions were reimbursed by one TPP, then Takeda will have succeeded in removing only that one TPP from the class.

[105] *See* Sealed Reply 12:9-13:3.

[106] Sealed Opposition 11:24-12:1.

[107] *See* Sealed Reply 1:26-2:3 (amending the National TPP class to exclude those TPPs that had already settled their claims). At the hearing, counsel for Plaintiffs averred that roughly 15 to

In summary, Takeda fails to persuade the Court that the question of injury cannot be resolved through Plaintiffs' common body of evidence. Furthermore, because class damages can be calculated formulaically in a manner consistent with Plaintiffs' theory of liability, Plaintiffs have met their burden to demonstrate predominance. *See Comcast Corp.*, 569 U.S. at 35; *see also* Rubenstein § 4:54 (discussing individual damages versus common liability).

ii. Causation

(a) Proximate Causation

Although the causation analysis includes both but-for and proximate causation, *see Holmes*, 503 U.S. at 268, neither Takeda nor Lilly challenges the idea that common issues predominate proximate causation.[108] Instead, Takeda and Lilly attack the idea that common issues of law and fact predominate over but-for causation. Accordingly, the Court regards Rule 23(b)(3)'s predominance requirement as satisfied with respect to the element of proximate causation.

(b) But-For Causation

To establish but-for causation under the "quantity-effect theory," *see Painters & Allied Trades*, 943 F.3d at 1247, Plaintiffs need to prove that Takeda and Lilly's fraudulent concealment of Actos's bladder cancer risk caused TPPs to pay for additional quantities of the drug—more than they would have otherwise paid, had they known the risks. As evidence, Plaintiffs offer Comanor's regression analysis, as well as direct evidence of internal company emails, marketing studies, and other testimony.[109]

Plaintiffs point to several out-of-circuit cases for the proposition that a statistical regression, like Comanor's analysis, can establish but-for causation for a civil RICO claim, especially when used in tandem with other circumstantial or direct evidence.[110] *See, e.g.*, *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 30 (1st Cir. 2013) ("*Neurontin I*") (affirming a jury verdict and bench trial where a regression analysis determined that

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20 TPPs settled, which would not disturb the numerosity requirement discussed in Part III.A.1 above. Hearing Transcript 6:13-20.

108 *See generally* Sealed Opposition; Sealed Joinder; *see also* Sealed Reply 9:18-19. As the Ninth Circuit already reasoned, if a TPP can establish that Takeda and Lilly engaged in racketeering to conceal the risk of bladder cancer and that the TPP purchased at least one additional Actos prescription because of that conduct (*i.e.*, but-for causation), then the injury is sufficiently "direct" to satisfy proximate causation. Sealed Motion to Certify 32:28-33:4 (citing *Painters & Allied Trades*, 943 F.3d at 1251).

109 Sealed Motion to Certify 19:4-22:19.

110 *Id.* at 12:21-16:10.

"three out of ten Neurontin prescriptions written by neurologists for migraine would not have been written or filled but for the alleged misconduct"); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 51, 57 (1st Cir. 2013) ("*Neurontin II*") (holding that the statistical evidence that "Aetna presented on but-for causation—that in the absence of Pfizer's alleged fraud, Aetna would have paid for fewer off-label prescriptions of Neurontin—survives summary judgment"); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 60, 68 (1st Cir. 2013) ("*Neurontin III*") (holding that the "plaintiffs need not prove causation through the testimony of individual doctors" and that the "combination of the aggregate evidence and the circumstantial evidence" was enough to overcome summary judgment).

In 2019, the First Circuit reaffirmed the approach that it forged in the *Neurontin* cases to establish but-for causation.[111] *See In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 14 (1st Cir. 2019) (reversing the district court's entry of summary judgment) ("*Celexa*"). In *Celexa*, Painters sued Forest Laboratories and Forest Pharmaceuticals for a civil RICO violation regarding sales of Celexa and Lexapro. *See id.* at 5. Painters sued on behalf of itself and a putative class of nationwide TPPs. *See id.* at 7. While the case was before the district court, Painters' expert, Dr. Meredith Rosenthal, conducted the same regression analysis from the *Neurontin* cases "to examine whether the fraudulent, off-label promotion in this case caused physicians to write additional off-label prescriptions." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 315 F.R.D. 116, 126 (D. Mass. 2016), *aff'd*, 915 F.3d 1 (1st Cir. 2019). At the time, the district court expressed doubts about the ability of Rosenthal's causation analysis to satisfy Rule 23(b)(3)'s predominance requirement.[112] *See id.* at 127. The district court ultimately denied class certification, in part because it determined that individualized questions predominated over issues of causation. *See id.* at 128. But importantly, the district court also denied certification for reasons relating to the statute of limitations. *See id.* at 129–30.

On appeal, the First Circuit affirmed the district court's denial of class certification, but, only narrowly—on statute of limitation grounds. *See Celexa*, 915 F.3d. at 14–17. In *dicta*, the First Circuit remarked that it was "not clear why those issues to which the district court pointed would preclude certification of such a class" when "Painters' clinical and statistical evidence, if believed, could establish causation and

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111 *Id.* at 16:1-17:14.

112 Importantly, the district court directed its skepticism toward an assumption embedded in Rosenthal's model. *See Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 315 F.R.D. at 127. That assumption is not relevant here, because Rosenthal was modeling the relationship between promotional spending and sales. *See id.* at 126.

injury at least for any TPP who paid for more than a handful of different patients' prescriptions." *Id.* at 14.

Lastly, Plaintiffs discuss *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015) ("Sergeants"), in which the Second Circuit noted in *dicta* that "it may be possible for a class of plaintiffs to prove the causation element of a pharmaceutical fraud claim such as this one with generalized proof," even though the plaintiffs "failed to offer such proof" in that case. *Id.* at 74–75.

Celexa, *Sergeants*, and the *Neurontin* cases give the Court confidence that evidence common to the class—*e.g.*, a regression model, academic papers, internal corporate studies, and emails from Takeda's and Lilly's employees—can be used to establish but-for causation under a quantity-effect theory for a single TPP or even for a class of them. But whether common evidence can ***establish*** but-for causation is a separate issue from whether common questions of fact ***predominate*** over that same inquiry. It remains an open question whether a class of TPPs may successfully leverage common evidence of the kind offered here (and discussed in *Celexa* and in the *Neurontin* cases) without running into the need for individualized analysis—or, at least, without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones.

Of the *Neurontin* cases, only *Neurontin III* considered a motion to certify a class. *See Neurontin III*, 712 F.3d at 63. There, the district court initially denied class certification. *See In re Neurontin Mktg. & Sales Pracs. Litig.*, 2011 WL 1882870, at *5 (D. Mass. May 17, 2011) (holding that a class action would be "unmanageable" where "a factfinder would have to perform a granular doctor-by-doctor analysis" in order "to differentiate those prescriptions that were caused by fraud from those that were attributable to non-fraudulent off-label marketing or other independent factors"). The First Circuit vacated the denial of class certification, but only because the district court rested its decision on the belief that a statistical regression analysis "could not provide proof of causation or damages." *Neurontin III*, 712 F.3d at 70. Neither *Celexa* nor *Neurontin III* concluded that common questions predominated over Plaintiffs' approach to but-for causation. Vacating a denial of certification is not tantamount to an endorsement of Plaintiffs' view.[113] The same goes for *dicta* that offers only glimmers of hope.[114] *See, e.g.*, *Celexa*, 915 F.3d. at 14; *Sergeants*, 806 F.3d at 74–75.

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[113] Intriguingly, after the First Circuit remanded the case, the district court hinted that it would likely grant the motion for class certification. *See* Motion to Certify, Ex. 10 [ECF No. 229-11] 35:19-25. But the parties settled before the district court could issue its ruling. *See* Motion to Certify, Ex. 3 [ECF No. 229-4].

[114] Sealed Opposition 16:12-16 (remarking on Plaintiffs' reliance on *dicta*).

Takeda marshals its own authority regarding but-for causation, citing *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135–36 (2d Cir. 2010) ("*Zyprexa*").[115] The Second Circuit declined to certify a class of nationwide TPPs based upon the quantity-effect theory[116] where the district court had noted that "the evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations, and thus would not have written 'excess' prescriptions as identified by the plaintiffs." *Id.* at 136. The Second Circuit concluded that the independent actions of physicians made "general proof of but-for causation impossible." *Id.*

Although the First Circuit and Ninth Circuit have subsequently spurned the idea expressed in *Zyprexa* that a plaintiff needs individual proof of physicians' decision-making,[117] *Zyprexa* nevertheless unearths a key flaw with Plaintiffs' predominance argument. Namely, Takeda or Lilly could still depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation, as those physicians might testify that they would have continued to prescribe Actos, notwithstanding the bladder cancer risk. And even if Plaintiffs present evidence that such testimony is "unreliable," a trier of fact could nonetheless rely on the physicians' testimony to qualify, discredit, or reject Plaintiffs' common evidence of but-for causation (*e.g.*, Comanor's regression analysis). *See Neurontin I*, 712 F.3d at 29. Since the number of testifying physicians would likely increase with the number of TPPs in the class, and that testimony would be linked to specific TPPs, such evidence would constitute individualized evidence. With so many individual TPPs in the class, a real and significant risk exists that individualized factual determinations would swamp common ones on the question of but-for causation.[118]

Plaintiffs gloss over that issue by repeatedly insinuating that they must prove only a *prima facie* case with common evidence,[119] but the predominance question is not limited

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115 *Id.* at 18:1-19:11.

116 For context, the Second Circuit in *Zyprexa* also reversed the district court's certification of a class of TPPs based upon the "excess price theory," which posits that the TPPs overpaid for Zyprexa prescriptions because the manufacturer's misrepresentations artificially inflated the price of the drug.

117 *See Neurontin I*, 712 F.3d at 45 (noting that a tort plaintiff need not prove a series of negatives); *Neurontin III*, 712 F.3d at 68 (holding that the "plaintiffs need not prove causation through the testimony of individual doctors"); *Painters & Allied Trades*, 943 F.3d at 1257 (expressing concern that manufacturers could "hide behind prescribing physicians and pharmacy benefit managers" if prescribing physicians' and pharmacy benefit managers' decisions constituted an intervening cause to sever the chain of proximate cause); *see also id.* at 1258 (crediting allegations of survey data showing that 75% of responding physicians lost considerable interest in an oral anti-diabetic drug once they learned that it carried a risk of bladder cancer).

118 Sealed Opposition 21:27-22:4.

119 *See, e.g.*, Sealed Motion to Certify 3:1-4, 10:23-25, 11:21-22, 12:2-4, & 32:15-17; Sealed Reply 14:20-15:4 & 15:20-22.

merely to Plaintiffs' case-in-chief. Affirmative defenses, too, must be considered. *See Dukes*, 564 U.S. at 367 (holding that a class cannot be certified on the premise that a defendant "will not be entitled to litigate its statutory defenses to individual claims"); *see also Tyson*, 577 U.S. at 457 (noting that the petitioner's reliance on the respondents' representative evidence "did not deprive petitioner of its ability to litigate individual defenses"). Moreover, the *Neurontin* cases do not come to the rescue, since they concluded that doctor-by-doctor testimony was best left for the trier of fact to weigh and decide.[120] *See, e.g.*, *Neurontin I*, 712 F.3d at 45–46; *Neurontin II*, 712 F.3d at 58; *Neurontin III*, 712 F.3d at 69. In other words, rather than eschewing individualized evidence like testimony from the prescribing physicians, the *Neurontin* cases reserved it for the jury to consider.

At this point, one might conclude that individualized questions of fact predominate over common questions—at least, when it comes to but-for causation. But that conclusion is premature. It is not clear that Takeda or Lilly will—or even can—avail themselves of a TPP-by-TPP causation defense using doctor-by-doctor testimony. To sustain an affirmative defense, a defendant must have evidence. Transitively, then, the availability of evidence matters for the purposes of determining predominance. For example, in *Tyson*, the Supreme Court noted that:

> respondents sought to introduce a representative sample to fill an evidentiary gap created by the employer's failure to keep adequate records. If the employees had proceeded with 3,344 individual lawsuits, each employee likely would have had to introduce Mericle's study to prove the hours he or she worked. Rather than absolving the employees from proving individual injury, the representative evidence here was a permissible means of making that very showing. Reliance on Mericle's study did not deprive petitioner of its ability to litigate individual defenses. Since there were no alternative means for the employees to establish their hours worked, petitioner's primary defense was to show that Mericle's study was unrepresentative or inaccurate. That defense is itself common to the claims made by all class members.

Tyson, 577 U.S. at 456-57. Implicit in that reasoning is the idea that the question of predominance did not hinge on what evidence was ***theoretically*** available, but instead on what evidence was ***actually*** adduced to support the parties' claims and defenses. *Accord Huntsman v. Sw. Airlines Co.*, 2021 WL 391300, at *11 (N.D. Cal. Feb. 3, 2021) (synthesizing *Tyson* and other authorities to hold that the mere existence of an affirmative defense does not defeat class certification); *see also* Rubenstein § 4:55 (observing that the

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[120] Sealed Opposition 21:11-27.

general rule, "regularly repeated by courts in many circuits," is that courts traditionally have been "reluctant to deny class action status under Rule 23(b)(3) simply because affirmative defenses may be available against individual members").

In reviewing the docket, the Court notes that most of the evidence related to the element of but-for causation (from either party) is common to the class. Excerpts of two depositions, each of a prescribing physician, constitute the only exception.[121] Those excerpts are the only individualized evidence that Takeda or Lilly submitted in relation to the element of but-for causation on the Motion to Certify. In contrast, Plaintiffs supply a mountain of evidence regarding but-for causation that is common to the class; *e.g.*, Comanor's regression model, internal email conversations, academic studies, data regarding physician information requests, and the results of Takeda's internal investigations.[122] As the tally stands, individualized issues would not predominate over but-for causation if the trial was held today. While the Court could speculate whether Takeda or Lilly will depose (or even can depose) many prescribing physicians, it is not this Court's role to make decisions on conjecture. The Court conducts a "rigorous analysis" of the issues and evidence as they stand to determine whether Rule 23 has been satisfied. *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161 (1982). It refrains from speculating whether the dearth of physician testimony is the result of a tactical decision or a matter of unavailability. Accordingly, the Court concludes that Plaintiffs have shown, by the preponderance of the evidence, that common questions of fact predominate over the element of but-for causation.

C. Conclusion for the National TPP Class

The Court is persuaded that the National TPP Class can be certified. Plaintiffs easily satisfy the four requirements of Rule 23(a). Plaintiffs also satisfy the superiority prong of Rule 23(b)(3). When it comes to predominance under Rule 23(b)(3), Plaintiffs handily show, by a preponderance of the evidence, that common questions of law and fact predominate over five of the seven underlying elements to their civil RICO claims. *Olean*, 31 F.4th at 665. Only two elements provoke any trepidation, and both relate to civil RICO standing: injury and but-for causation. 18 U.S.C. § 1964(c). Nonetheless, this Court concludes that Plaintiffs eke out a victory on both.

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121 *See* Opposition, Ex. D. Dep. of Bolanle T. Oyeyipo, MD (the "Oyeyipo Deposition") [ECF No. 247-5]; *see also* Opposition, Ex. E. Remote Video Dep. of Cathy Stotz (the "Stotz Deposition") [ECF No. 247-6].

122 *See* Sealed Motion to Certify 19:2-31:7 (describing common evidence on causation); *see also* Sealed Reply 15:5-18 (highlighting common evidence of internal marketing surveys and evidence of increases in physician information requests).

With respect to injury, the Court is persuaded that common questions are more likely to predominate than not for three reasons. First, the way that Plaintiffs define the class statistically limits the number of uninjured TPPs to a *de minimis* level. Second, the data from the regression model (which appears highly unique to this case) shows that variations in the probability of fraudulently induced prescriptions are still unlikely to generate large clusters of uninjured TPPs, given their timing with prescription volumes. And third, as even Takeda and Lilly acknowledge,[123] the Ninth Circuit foreclosed their argument that the presence of uninjured class members is a *per se* reason to deny certification. *See Olean*, 31 F.4th at 669.

Lastly, with respect to but-for causation, the Court recognizes and considers the possibility that an individualized but-for causation analysis could overwhelm a common analysis. But in view of the sparse rebuttal evidence in the record animating that defense, the Court refrains from giving undue weight to the theoretical at the expense of the concrete. Thus, predominance for Rule 23(b)(3) is established for each element of Plaintiffs' civil RICO claims. And even if individualized questions of fact did outnumber common ones on the question of but-for causation, the bulk of the questions raised by Plaintiffs' civil RICO claims would be resolved with common evidence. On balance, the Court finds it appropriate to **GRANT** Plaintiffs' Motion to Certify as it relates to the National TPP Class. Painters is an appropriate class representative, and its counsel of record have demonstrated their competence to serve as Class Counsel.

IV. THE CALIFORNIA CONSUMER CLASS

Plaintiffs also seek to certify a class of California consumers, with Snyder named as the putative class representative. Plaintiffs define that class as:

> All consumers and entities in the State of California, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, i.e., when the drug was approved, and the present. Excluded from the California Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.[124]

On behalf of the California Consumer Class, Plaintiffs assert three claims against Takeda and Lilly: (1) a claim seeking relief under California's Consumer Legal Remedies Act (the "CLRA"), *see* Cal. Civ. Code §§ 1750, *et seq.*; (2) a claim for remedies pursuant to

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123 Defendants' Supplemental Brief 8:27-28.

124 Amended Complaint ¶ 223.

California's Unfair Competition Law (the "UCL"), *see* Cal. Bus. & Prof. Code §§ 17200, *et seq.*; and (3) a claim seeking remedies under California's False Advertising Law (the "FAL"), *see* Cal. Bus. & Prof. Code §§ 17500, *et seq.*[125]

As discussed below, Takeda and Lilly make a weak typicality challenge. *See* Fed. R. Civ. P. 23(a)(3). Otherwise, Takeda and Lilly concede that Plaintiffs satisfy the Rule 23(a) requirements. Like the National TPP Class discussed in Part III above, the battle over certification largely turns on the issue of predominance. *See* Fed. R. Civ. P. 23(b)(3).

A. Rule 23(a) Requirements

1. Numerosity, Commonality, and Adequacy

Plaintiffs assert that there are "hundreds of thousands, if not millions, of consumers who purchased Actos within the State of California between July 1, 1999 and September 17, 2010."[126] And Snyder herself declares that she has no conflict of interest with any of those putative members of the California Consumer Class.[127] Additionally, Plaintiffs argue that there are issues of law and fact common to the putative California Consumer Class regarding Takeda and Lilly's alleged violations of California consumer protection laws.[128]

Takeda and Lilly do not contest any of those arguments or averments.[129] In view of those concessions, the Court concludes that the numerosity, commonality, and adequacy elements satisfied. *See* Fed. R. Civ. P. 23(a)(1), (2), & (4).

2. Typicality

Plaintiffs allege that Snyder sustained the injury of purchasing Actos without a full and accurate knowledge of its risks.[130] Snyder herself declares that she would "never have purchased and ingested the drug" had she known that Actos was associated with an increased risk of bladder cancer.[131] For those reasons, Plaintiffs suggest that Snyder—and the injury that she sustained—are typical of the class. *See* Fed. R. Civ. P. 23(a)(3); *see also*

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125 *Id.* at ¶¶ 260-88. Those claims are pled as Counts III, IV, and V, respectively.

126 Sealed Motion to Certify 37:5-14.

127 *Id.* at 38:12-15.

128 *Id.* at 37:15-28.

129 *See generally* Sealed Opposition & Sealed Joinder.

130 Sealed Motion to Certify 38:1-3.

131 Decl. of Annie Snyder (the "Snyder Declaration") [ECF No. 229-50] ¶ 9.

Ellis, 657 F.3d at 984 (reiterating that the test of typicality "is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct") (internal citations and quotations omitted).

Writing separately, Lilly argues that Snyder is not typical of the class for two reasons. First, Lilly observes that Snyder began purchasing Actos in May 2009—three years after Lilly stopped promoting the drug.[132] Lacking unilateral control to change the labels and to cure any omissions after the co-promotion ended,[133] Lilly insinuates that Snyder faces "additional, unique legal hurdles in pursuing claims against Lilly as compared to putative class members who paid for Actos during the term of the co-promotion agreement."[134] But that argument is a red herring because Snyder alleges liability under the CLRA, UCL, and FAL based upon a decades-long conspiracy, for which Lilly received royalties after its co-promotion with Takeda ended.[135]

Second, Lilly points out that Snyder's physician, Dr. Cathy Stotz, testified that she believed that Actos was the right medical choice for Snyder.[136] But that argument is yet another red herring: Stotz's *post hoc* beliefs regarding the propriety of the treatment are immaterial to the typicality of Snyder's injury.[137] If Snyder had known about the bladder cancer risks, Snyder avers that she would not have pursued the treatment, notwithstanding her physician's recommendation.[138] *See Guido v. L'Oreal, USA, Inc.*, 284 F.R.D. 468, 479 (C.D. Cal. 2012), *on reconsideration*, 2012 WL 2458118 (C.D. Cal. June 25, 2012) (finding typicality satisfied when the named plaintiff "testified that she would not have purchased Serum or would have paid less for Serum had she known it had flammable characteristics").

In summary, Snyder meets the typicality requirement as a putative class representative. *See* Fed. R. Civ. P. 23(a)(3). Other California consumers ostensibly

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132 Sealed Joinder 8:15-18.

133 *Id.* at 9:1-10.

134 *Id.* at 9:11-13. Curiously, though, Lilly does not identify what those unique legal hurdles might be. *See generally id.*

135 Sealed Reply to Joinder 6:5-24.

136 Sealed Joinder 9:13-19.

137 It also strikes the Court that ***many*** physicians would be reluctant to reverse their earlier recommendations, *see, e.g.*, *Neurontin I*, 712 F.3d at 29 (discussing the phenomenon), which, ironically, would make Snyder's experience even more typical.

138 *See* Sealed Reply to Joinder 7:1-6 (citing Snyder Declaration ¶¶ 7-9).

would have been injured by the same omissions from Takeda and Lilly. Neither the timing nor Snyder's physician's belief is a bar to that finding.

B. Rule 23(b) Requirements

Like they did with the National TPP class, here Plaintiffs elect to meet the mandates of Rule 23(b) by attempting to show that the California Consumer Class satisfies the third prong; *i.e.*, superiority and predominance. *See* Fed. R. Civ. P. 23(b)(3).

1. Superiority

Plaintiffs argue that it would be "unrealistic to expect millions of California consumers to engage in a multiyear litigation against Takeda and Lilly to recover a meager refund."[139] Takeda and Lilly wisely concede the point. As with the National TPP class, the Court finds that the class action form would be superior to alternative methods in this instance.

2. Predominance

Plaintiffs argue that their CLRA, UCL, and FAL claims focus on Takeda and Lilly's misconduct, and, thus, common issues predominate. Specifically, Plaintiffs contend that Takeda and Lilly made material omissions about Actos's bladder cancer risk, which caused the members of the California Consumer Class to sustain economic injuries.[140] The Court evaluates predominance for each of those claims. *See Comcast Corp.*, 569 U.S. at 35.

a. CLRA

The CLRA makes unlawful various "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale . . . of goods . . . to any consumer." Cal. Civ. Code § 1770(a). Here, Plaintiffs allege that Takeda and Lilly's omission of Actos's bladder cancer risk constituted two such proscribed practices under the CLRA: namely, misrepresenting the "certification" of safety in violation of Cal. Civ. Code § 1770(a)(2) and misrepresenting the "standard, quality, or grade" of the drug in violation of Cal. Civ. Code § 1770(a)(7).[141]

Relief under the CLRA is "limited to '[a]ny consumer who suffers any damage as a result of the use or employment by any person of a method, act, or practice' unlawful

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139 Sealed Motion to Certify 45:6-8.

140 *Id.* at 38:18-45:2.

141 Amended Complaint ¶ 264.

under the act." *Massachusetts Mut. Life Ins. Co. v. Superior Ct.*, 97 Cal. App. 4th 1282, 1292 (2002), *as modified on denial of reh'g* (May 29, 2002) (citing Cal. Civ. Code § 1780(a)). Thus, Plaintiffs must "show not only that a defendant's conduct was deceptive but that the deception ***caused*** them harm." *Id*. (emphasis added). In other words, the California Consumer Class must have relied on Takeda or Lilly's omissions. Additionally, Plaintiffs must demonstrate an "actual injury as to each class member." *Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 155 (2010), *as modified on denial of reh'g* (Feb. 8, 2010) ("*Steroid*"). "[B]oth the named plaintiff and unnamed class members must have suffered some damage caused by a practice deemed unlawful under Civil Code section 1770." *Id.* at 156. Accordingly, the Court evaluates whether common questions predominate over the elements of causation and Plaintiffs' reliance, Plaintiffs' injury, and Takeda or Lilly's obligation to disclose the risks—*i.e.*, their deceptive conduct.[142]

i. Deceptive Conduct

The Court begins with the easiest element to evaluate. Similar to the element of a civil RICO violation that the Court considered in connection with the National TPP Class, *see supra* Part III.B.2.a.i, the Court agrees with Plaintiffs that questions of deception are ones susceptible to common class-wide proof for the California Consumer Class, since the inquiry turns on evidence of what Takeda and Lilly knew and what they failed to disclose. *See Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 481 (C.D. Cal. 2012) (holding that evidence of the defendant's senior management's desire "to eliminate references to odor problems" in its product's labeling constituted common evidence that could establish deceptive conduct). Thus, common evidence would resolve this element—predominance is established.

ii. Causation and Reliance

In contrast, a muddled mix of common and individualized evidence would be needed to resolve the elements of causation and reliance. Causation "may be established" on a class-wide basis ***if*** a material misrepresentation or omission has been

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142 Where, as here, Plaintiffs' CLRA claim is premised on an "omission," the omission must be either: (1) "contrary to a representation actually made by the defendant"; or (2) "an omission of a fact the defendant was obliged to disclose." *Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 835 (2006). An obligation to disclose exists for the purposes of a CLRA claim based upon "failure to disclose a fact" in any of "four circumstances": "(1) when the defendant is the plaintiff's fiduciary; (2) when the defendant has exclusive knowledge of material facts not known or reasonably accessible to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; [or] (4) when the defendant makes partial representations that are misleading because some other material fact has not been disclosed." *Collins v. eMachines, Inc.*, 202 Cal. App. 4th 249, 255 (2011), *as modified* (Dec. 28, 2011).

made to the entire class. *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 129 (2009) ("*Vioxx*"); *see also Stearns*, 655 F.3d 1022 (noting that the rule applies to cases regarding omissions) (citing *McAdams v. Monier, Inc.*, 182 Cal. App. 4th 174, 184 (2010)). "That the defendant can establish a lack of causation as to a handful of class members does not necessarily render the issue of causation an individual, rather than a common, one." *Vioxx*, 180 Cal. App. 4th at 129.

Materiality is "generally judged by a reasonable man standard." *Steroid*, 181 Cal. App. 4th at 157 (internal quotations omitted). "[H]owever, if the issue of materiality or reliance is a matter that would vary from consumer to consumer, the issue is not subject to common proof, and the action is properly not certified as a class action." *Vioxx*, 180 Cal. App. 4th at 129 (citing *Caro v. Procter & Gamble Co.*, 18 Cal. App. 4th 644, 668 (1993) (affirming denial of class certification where the materiality of the defendant's representations regarding the freshness of its orange juice varied from consumer to consumer, since not all consumers believed the defendant's statements and thus were not induced "to alter [their] position to [their] detriment")).

To their credit, Plaintiffs offer some compelling common evidence of materiality; *e.g.*, the wave of physician information requests ("PIRs") came in the wake of the bladder cancer risk disclosures and Lilly's concession that bladder cancer risks would be a "serious thing" for a healthcare professional.[143]

But as Lilly argued at the hearing, the materiality of that bladder cancer risk to patients' diabetes prognoses is highly individualized. Moreover, some medicines and treatment regimens would be ineffective; some patients would have no other option other than Actos, notwithstanding the bladder cancer risks.[144] Those determinations necessarily reside with the patients and their physicians. Even Comanor recognized that reality.[145] Therefore, the question of whether Takeda or Lilly's omissions were material to the choices of any physician-patient tandem is an individualized one. And unlike the National TPP Class—where Plaintiffs could establish a *prima face* case with extant

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[143] *See* Sealed Motion to Certify 42:24-43:2 (pointing out that Lilly conceded that bladder cancer risks would be a "serious thing" for a healthcare professional and noting a wave of PIRs that came in the wake of the disclosures). While PIRs in aggregate serve as common evidence, PIRs could also serve as individualized evidence: many physicians expressed concerns, but others did not, and even more would not have changed their prescription.

[144] Hearing Transcript 123:3-127:18 (using the case of the named class representative as an example, wherein her physician testified that there was no other option but to choose Actos).

[145] *See, e.g.*, Ex. A. Remote Video Dep. of Dr. William S. Comanor [ECF No. 248-2] 109:20-23 (observing that the decision to prescribe lies with the physician and patient) & 192:18-193:6 ("Q: Okay. As you sit here, you can't say what an individual physician would do with respect to any particular patient and their prescribing diabetes medications? A: That is obviously correct.").

common evidence (before even considering Takeda's or Lilly's possible affirmative defenses)—the Court struggles to see how Plaintiffs can circumvent that individualized, case-by-case materiality analysis for the California Consumer Class.[146]

Plaintiffs also rely heavily on the "presumption" of reliance.[147] *See Davis-Miller v. Auto. Club of S. California*, 201 Cal. App. 4th 106, 125 (2011), *as modified* (Nov. 22, 2011) (noting that, unlike the UCL and FAL, the CLRA requires "an additional showing of reliance"). But that presumption does not necessarily apply here. In *Vioxx*, the plaintiffs sought to certify a class upon the basis of alleged misrepresentations and omissions in "Merck's direct-to-consumer advertisements," which "did not address the cardiovascular risks at all." *Vioxx*, 180 Cal. App. 4th at 123. In view of the individualized issues regarding Vioxx's effectiveness and safety, the trial court concluded that the plaintiffs could not establish materiality and reliance with respect to the CLRA on a classwide basis. *See id*. at 126. The California Court of Appeals affirmed:

> [P]hysicians consider many patient-specific factors in determining which drug to prescribe, including the patient's history and drug allergies, the condition being treated, and the potential for adverse reactions with the patient's other medications—in addition to the risks and benefits associated with the drug. When all of these patient-specific factors are a part of the prescribing decision, the materiality of any statements made by Merck to any particular prescribing decision cannot be presumed. All of this evidence supports the trial court's conclusion that whether Merck's misrepresentations were material, and therefore induced reliance, is a matter on which individual issues prevailed over common issues, justifying denial of class certification with respect to the CLRA claim

Vioxx, 180 Cal. App. 4th at 134. The cardiovascular risks in *Vioxx* and the bladder cancer risks here both strike the Court as serious considerations—ones that most reasonable physicians and patients would evaluate before choosing an appropriate healthcare regimen.

But materiality is found only where the omission of those risks "would have been important to the decision-making process." *Krueger v. Wyeth, Inc.*, 2011 WL 8971449, at

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[146] Important here to the Court's decision is the relative quantum of evidence. Whereas Plaintiffs adduced mountains of common evidence for the National TPP class, they fail to do so for the California Consumer Class. For example, Plaintiffs do not have large numbers of consumers who were surveyed regarding their opinions, nor do Plaintiffs have evidence of a large number of consumers seeking refunds. The quantum of evidence on each side with respect to this class is far closer to parity.

[147] *See* Sealed Reply 22:24-25.

*9 (S.D. Cal. Mar. 30, 2011) ("*Krueger I*"); *see also In re Vioxx Consolidated Class Action*, 2009 WL 1283129 (Cal. Super. Apr. 30, 2009) ("[t]o determine whether the cardiac risks posed by Vioxx were material to any given class member requires an examination of the member's medical needs and history"). That aspect of materiality implicates a further individualized analysis. As Stotz's testimony illustrates,[148] medical decisions are unique. Some risks may not be all that important to the decision-making process when a patient faces a debilitating and life-threatening disease. The Court is loath to insert itself into the doctor's office and impose its judgment onto physicians and their patients, blanketly concluding on behalf of all "reasonable persons" that some risks matter (*i.e.*, bladder cancer risk) and that some do not (*i.e.*, untreated or mismanaged diabetes). After all, *sola dosis facit venenum*—the dose makes the poison. *See* Lothar Determann, *Healthy Data Protection*, 26 Mich. Tech. L. Rev. 229, 277-78 n.245 (2020) ("Pracelsus [*sic*, Paracelsus] said, 'Sola dosis facit venenum' (all things are poison and nothing is without poison; only the dose makes a thing not a poison) (citation omitted)). And indeed, Comanor's own model suggests that 40% of Actos purchases would have been made even if full information of the risks was known.[149] Forty percent is not a trivial amount, even post-*Olean*.

For the same reasons as the court in *Vioxx*, the Court here concludes that individualized questions of fact predominate over causation and reliance with respect to Plaintiffs' CLRA claim. *See also Stearns*, 655 F.3d at 1024 (affirming the denial of class certification for a CLRA claim where there were "myriad reasons" why a consumer might not have been misled by an omission on the defendant's website, and yet "all of those people would have been swept willy-nilly into the class"); *cf. Steroid*, 181 Cal. App. 4th at 159–60 (distinguishing *Vioxx* by asserting that "there is no impediment to establishing reliance on a classwide basis for the CLRA claim in this case because it can be established by showing that the alleged misrepresentation—that the androstenediol products were legal—was material").[150]

iii. Actual Injury

"A CLRA claim warrants an analysis different from a UCL claim because the CLRA requires each class member to have an actual injury caused by the unlawful

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148 *See generally* Stotz Deposition; *see also* Oyeyipo Deposition.

149 Sealed Opposition 42:23-25.

150 Plaintiffs also rely on *Krueger I*, but that case is distinguishable on the facts. The court there explained that "the drug in Vioxx ultimately performed as advertised, but with an undisclosed side effect," whereas in *Krueger I*, the drug "did not perform as advertised." *Krueger I*, 2011 WL 8971449, at *8. Here, Plaintiffs say that Actos performed as advertised but that it posed an undisclosed risk of bladder cancer. That allegation makes this case closer to *Vioxx* than *Krueger I*.

practice." *Stearns*, 655 F.3d at 1022. Injury is conflated, though, with the reliance inquiry. *See Steroid*, 181 Cal. App. 4th at 156–57. As discussed above, individualized questions predominate over the question of reliance. Therefore, individualized questions predominate over the element of injury as well.

b. UCL and FAL

The UCL proscribes unfair competition, described as "unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. "Thus, there are three varieties of unfair competition: practices which are unlawful, unfair or fraudulent." *Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 837 (2006), *as modified* (Nov. 8, 2006). Plaintiffs allege violations of all three varieties, although each allegation arises from essentially the same deceptive and misleading conduct.[151]

Similarly, the FAL prohibits the dissemination of any advertising "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof. Code § 17500. Consistent with their UCL claim, Plaintiffs allege that Takeda and Lilly advertised on its packaging and through various media outlets in a manner that misstated Actos's bladder cancer risk.[152]

To state a claim under either the UCL or the FAL, "it is necessary only to show that 'members of the public are likely to be deceived.'" *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002). Whereas a "fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied upon by a victim who incurs damages," none of those elements is required to state a claim for relief under the UCL or the FAL. *Day v. AT & T Corp.*, 63 Cal. App. 4th 325, 332 (1998). While the UCL focuses "on the defendant's conduct, rather than the plaintiff's damages, in service of the statute's larger purpose of protecting the general public against unscrupulous business practices," *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009), predominance is not necessarily automatic in every UCL or FAL case. "For example, it might well be that there was no cohesion among the members because they were exposed to quite disparate information from various representatives of the defendant." *Stearns*, 655 F.3d at 1020.

Takeda first challenges the idea that common evidence predominates over the California Consumer Class members' exposure to its omissions. Takeda argues that it is unlikely that each member of the California Consumer Class viewed the product label,

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151 *See* Amended Complaint ¶¶ 271-81.

152 *Id.* at ¶ 285.

especially when the labels are often directed at physicians.[153] To wit, Snyder testified that she read labels sometimes, but not every time.[154] Plaintiffs counter by asserting that the fraud lasted a decade, thus making the facts here analogous to the tobacco industry's decades-long deceptive advertising campaign.[155] *See Tobacco II*, 46 Cal. 4th at 324–27. But while the duration of Takeda's alleged malfeasance shares an order of magnitude with that of the tobacco industry in *Tobacco II* (*i.e.*, decades rather than months or years), product labels for a specific oral antidiabetic medication do not share the same level of ubiquity as cigarette advertisements. *See id.* at 327 (describing the tobacco industry's technique of "saturation advertising"); *see also Mazza*, 666 F.3d at 596 ("In the absence of the kind of massive advertising campaign at issue in *Tobacco II*, the relevant class must be defined in such a way as to include only members who were exposed to advertising that is alleged to be materially misleading.").

Furthermore, Plaintiffs cannot simply assume that every patient who took Actos was instantly exposed to misleading statements, especially when Plaintiffs' own expert's model accounts for a lag in the time it takes for information to be disseminated.[156] That empirical fact suggests that Plaintiffs are not entitled to a presumption. Indeed, "*Tobacco II* does not stand for the proposition that a consumer who was never exposed to an alleged false or misleading advertising or promotional campaign is entitled to restitution." *Pfizer Inc. v. Superior Ct.*, 182 Cal. App. 4th 622, 632 (2010). The availability of some common evidence—which at best indicates that some physicians were aware of the omission[157]—does not obviate the need for individualized evidence.

Second, Takeda contends that the materiality of the misleading omissions would also vary patient by patient.[158] As discussed earlier, *see supra* Part IV.B.2.a.ii, the Court agrees that individualized issues are likely to predominate, especially when at least 40% of the class would have continued to purchase Actos after being fully informed of the bladder cancer risks, according to the Plaintiffs' expert.

Third, Takeda argues that the modification of the class period—back to 2010—triggers statute-of-limitation issues for Plaintiffs' CLRA and FAL claims.[159] *See Yumul v.*

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153 Sealed Opposition 41:3-15.

154 Opposition, Ex. I [ECF No. 238-10] 63:3-24.

155 Sealed Reply 22:25-23:12.

156 *See* Sealed Opposition 42:9-18.

157 Sealed Motion to Certify 40:2-9 (discussing Takeda's studies and interviews of prescriber awareness of bladder cancer risks).

158 Sealed Opposition 42:19-43:11.

159 *Id.* at 44:21-45:22.

Smart Balance, Inc., 733 F. Supp. 2d 1117, 1130 (C.D. Cal. 2010) (explaining that CLRA and FAL claims are subject to a three-year statute of limitations and that UCL claims are subject to a four-year statute of limitations). Those issues, says Takeda, raise "substantial individual questions that vary among class members." *O'Connor v. Boeing N. Am., Inc.*, 197 F.R.D. 404, 414 (C.D. Cal. 2000). Plaintiffs reply that the "discovery rule" applies here, which has the effect of postponing the accrual of the claims.[160] *See Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1024 (9th Cir. 2008) (citing *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397 (1999)).

"In order to invoke this special defense to the statute of limitations, the plaintiff must specifically plead facts which show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Saliter v. Pierce Bros. Mortuaries*, 81 Cal. App. 3d 292, 297 (1978). Since this case was filed on July 23, 2014,[161] Plaintiffs would need to invoke the discovery rule for any California Consumer Class member who discovered (or could have discovered) the misleading omissions prior to July 23, 2011—at least with respect to the CAL and CLRA claims.[162]

While the Court need not now adjudicate the merits of this defense, it must consider whether evidence common to the class, or evidence particular to individual class members, would predominate in resolving the inquiry. Ironically, Takeda and Lilly appear more likely to avail themselves of evidence common to the class to overcome the discovery rule defense—*e.g.*, the FDA's announcement on September 17, 2010, that it was conducting an on-going safety review of Actos for bladder cancer risk;[163] the American Diabetes Association's publication of studies of pioglitazone use and bladder cancer on April 22, 2011;[164] the European Medicines Agency's June 9, 2011, announcement that it was suspending Actos;[165] and the FDA's June 15, 2011, safety announcement informing the public of the links between Actos use and bladder cancer.[166] On the other hand, individualized evidence—such as patient or prescriber testimony—would likely be needed to show that any given California Consumer Class member "was not negligent in failing to make the discovery sooner" in view of those announcements or

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160 Sealed Reply 25:4-10.

161 *See* Compl. [ECF No. 1].

162 The parties acknowledge that the UCL claim is not at issue here. *See* Sealed Opposition 45:20-22; Sealed Reply 25:28. Given the UCL's four-year limitations period, the cutoff date would be July 23, 2010.

163 Second Amended Complaint ¶ 94.

164 *Id.* at ¶ 96.

165 *Id.* at ¶ 97.

166 *Id.* at ¶ 99.

that they "had no actual or presumptive knowledge of facts sufficient to put [them] on inquiry." *Bedolla v. Logan & Frazer*, 52 Cal. App. 3d 118, 129 (1975). While Plaintiffs make clear that they intend to point to the August 2011 Actos product label's inclusion of the bladder cancer risk (which is common evidence),[167] the Court is skeptical that individual testimony could be entirely avoided, should Plaintiffs avail themselves of the discovery rule.

c. Damages

If Plaintiffs prevail on their claims for the California Consumer Class, then they would be entitled to only those damages resulting from their theory of liability—in this case, restitution. *See Comcast Corp.*, 569 U.S. at 35. "It follows that a model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory." *Id.* Calculations "need not be exact," so long as they are "consistent" with Plaintiffs' liability case. *Id.* "And for purposes of Rule 23, courts must conduct a 'rigorous analysis' to determine whether that is so." *Id.* (citing *Dukes*, 564 U.S. at 351).

Plaintiffs presented a model for the National TPP Class, but they do not do so for the California Consumer Class. Rather, Plaintiffs merely allude to a methodology described in another case. Plaintiffs say that Comanor is ready and willing to perform an analysis using the methodology similar to the one performed in *Krueger v. Wyeth, Inc.*, 396 F. Supp. 3d 931 (S.D. Cal. 2019) ("*Krueger II*").[168] But that analysis remains a mere proposal.[169]

While the methodologies described in *Krueger II* appear sound in principle, the Court is skeptical that Plaintiffs have met their burden here. Plaintiffs cite no authority suggesting that they may provide merely a ***proposal*** for a model calculating damages.[170] The Court cannot conduct a rigorous analysis of a plan written, so to speak, on a paper napkin. Comanor would need to apply the methodologies to the facts and data in this case to show that they are consistent with Plaintiffs' theory of liability. *See Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 989 (9th Cir. 2015) (requiring that damages be computed even if only an approximation for the purposes of restitution under California law). In other words, Plaintiffs are obligated to show that their damages ***are*** measurable, not that they ***could be***. *See Daniel F. v. Blue Shield of California*, 305 F.R.D.

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167 *See* Sealed Reply 25:12-22.

168 *Id.* at 24:8-25:2.

169 Hearing Transcript 69:23-70:20 (emphasizing that Comanor "proposes" following the methodology of Rosenthal in *Krueger II*, not that Comanor performed it).

170 *See* Sealed Motion to Certify 43:9-5:2 & Sealed Reply 24:7-25:2.

115, 128 (N.D. Cal. 2014). That burden may be easy to satisfy, but it nonetheless remains Plaintiffs' burden to satisfy, as the movant for class certification. Because Plaintiffs have not done so, the Court must decline to certify the California Consumer Class. *See Kim v. Benihana, Inc*, 2022 WL 1601393, at *12 (C.D. Cal. Mar. 25, 2022) (denying class certification where the plaintiff did not present a damages model).

C. Conclusion for the California Consumer Class

Like the National TPP Class discussed in Part III above, the Court is persuaded that the California Consumer Class easily meets the four requirements of Rule 23(a). The California Consumer Class also satisfies the superiority prong of Rule 23(b)(3). But when it comes to predominance, the role of individualized evidence appears far more prominent, even though it varies slightly from claim to claim.

A mix of common and individualized evidence would likely come into play with respect to materiality, exposure, and the statute of limitations. Saying ***exactly*** how much, though, is unclear. With far less evidence submitted to the Court with respect to the California Consumer Class, predicting the precise proportions of individual and common evidence needed to resolve the inquiries appears especially challenging. But at a minimum, the importance of materiality to the element of reliance—which traverses the CLRA, UCL, and FAL claims—transitively amplifies the importance of any evidence related to that inquiry. On that element, the Court foresees a potentially far greater need for individualized testimony, should Takeda and Lilly be able to marshal it.

The California Consumer Class also differs from the National TPP Class in that, for the latter class, Plaintiffs offer a compelling regression analysis to circumvent individualized evidence on the element of injury with respect to Plaintiffs' civil RICO claims. In contrast, Plaintiffs do not offer such a solution for their UCL, FAL, or CLRA claims. Plaintiffs instead rely on California law to provide them with a presumption of reliance, but, as discussed, the facts here are too dissimilar from those in *Tobacco II* to warrant a finding in Plaintiffs' favor.

Lastly, the Court is unpersuaded by Plaintiffs' perfunctory efforts regarding their damages model. Until a model is constructed, or an analysis is performed, Plaintiffs receive a grade of "incomplete" with respect to damages and the predominance inquiry under Rule 23(b)(3). That missing piece—in tandem with the milieu of individualized questions discussed above—tips the balance against certifying the California Consumer Class for all three of Plaintiffs' claims.

V. DISPOSITION

For the foregoing reasons, the Court hereby **ORDERS** as follows:

1. Plaintiffs' Motion to Certify is **GRANTED in part** and **DENIED in part**:

a. The National TPP Class is **CERTIFIED**. Painters is preliminarily **APPOINTED** as class representative. R. Brent Wisner, Michael L. Baum, and Christopher L. Coffin are also preliminarily **APPOINTED** as Class Counsel.

b. The Court declines to certify the California Consumer Class.

2. The parties are **DIRECTED** to confer forthwith and to file no later than June 16, 2023, a Joint Status Report that provides the Court with their jointly proposed case schedule or, if the parties cannot agree, their respective competing proposed case schedules and the reasons for their disagreement.

3. A Scheduling Conference is **SET** for June 30, 2023, at 11:00 a.m. in Courtroom 9D of the Ronald Reagan Federal Building and U.S. Courthouse, 411 W. 4th Street, Santa Ana, California.

4. Class Counsel is **DIRECTED** to propose a comprehensive notice plan for the National TPP Class.

IT IS SO ORDERED.

Dated: May 24, 2023

John W. Holcomb
UNITED STATES DISTRICT JUDGE