UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE XYREM (SODIUM OXYBATE) ANTITRUST LITIGATION

Case No. 20-md-02966-RS

ORDER GRANTING CLASS CERTIFICATION, DENYING *DAUBERT* MOTION, AND GRANTING MOTION FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT

I. INTRODUCTION

Plaintiffs in this multidistrict litigation have moved for certification of two classes: a damages class under Federal Rule of Civil Procedure 23(b)(3), and an injunctive relief class under Rule 23(b)(2). In addition to opposing class certification, Defendants have filed a motion to exclude portions of Plaintiffs' expert testimony. Finally, Plaintiffs seek preliminary approval of a class settlement with two of the Defendant corporations. For the reasons discussed below, both proposed classes pass muster under Rule 23 and both will be certified, except as to Xywav prescriptions. Defendants' *Daubert* motion raises issues that go to the weight of Plaintiffs' expert testimony, rather than its admissibility, and that motion will therefore be denied. Finally, the proposed Settlement Class satisfies the criteria for preliminary approval under Rule 23(e), and that motion accordingly will be granted.

II. BACKGROUND

The factual background of this litigation has been thoroughly discussed in prior orders and

need not be recounted at length here. *See, e.g.*, Dkt. 138. To recap, Plaintiffs, a mix of insurers and individual consumers, aver violations of federal and state antitrust laws by Defendants, a group of pharmaceutical manufacturers, surrounding the alleged delay of a generic version of Xyrem, a narcolepsy drug. The current phase of litigation involves seven claims for relief. Claims 7–11 of the Consolidated Amended Class Action Complaint ("CAC") each aver conspiracy and combination in restraint of trade under state law; Claim 12 avers monopolization and monopolistic scheme under state law; and Claim 17 seeks declaratory and injunctive relief for violations of the Sherman Act, 15 U.S.C. § 2.[1]

For Claims 7–12, Plaintiffs (except Ruth Hollman) seek certification of the following class under Rule 23(b)(3) ("the Damages Class"):

> All entities in the Class States[2] that, for consumption by their members, employees, insureds, participants, or beneficiaries, and other than for resale, paid and/or provided reimbursement for some or all the purchase price for Xyrem and/or Xywav during the time from January 17, 2017, through and until the date of class certification.

Dkt. 353 ("Mot."), at 1. The Class is composed of insurers, i.e., third-party payors ("TPPs"), rather than individual consumers. For Claim 17, Plaintiffs seek certification of the following class under Rule 23(b)(2) ("the Injunctive Relief Class"):

> All individuals and entities in the United States that, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, and other than for resale, paid and/or provided reimbursement for some or all the purchase price for Xyrem and/or Xywav during the time from January 17, 2017, through and until the date of class certification.

Mot., at 2. Both Classes also exclude certain entities and individuals, including Defendants,

[1] The parties were initially directed to select ten of the original seventeen claims for relief included in the CAC to proceed through initial litigation. Of these ten, three have been dismissed.

[2] "The Class States are Arizona, California, Connecticut, District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin." Mot., at 1 n.2.

federal and state governmental entities, and certain other insurers. *See id.* at 1–2. Plaintiffs also seek appointment as class representatives and for the appointment of Class Counsel under Rule 23.

In support of class certification, Plaintiffs offer expert reports from Dr. Rena Conti and Laura Craft. Dr. Conti's opening report primarily focuses on projecting a "generic conversion rate" for Xyrem — that is, the rate at which generic Xyrem would have supplanted brand Xyrem once generic competition began. From this, Dr. Conti calculates damages stemming from the alleged delayed entry of generic Xyrem, using the narcolepsy drug Provigil as a "yardstick" to "estimate what would have happened absent the alleged anticompetitive conduct." Dkt. 352-24 ("Conti Rpt.") ¶ 106. Ms. Craft's opening report, meanwhile, discusses the various data sources available to analyze Xyrem sales and prescriptions. For his part, Defendants' expert, Dr. James Hughes, critiques Dr. Conti's methodology and conclusions, and in general suggests that various unique features of Xyrem indicate there are potentially many uninjured class members. The reply reports from Dr. Conti and Ms. Craft respond to Dr. Hughes's critiques and, in turn, provide their own critiques of his analysis. Defendants have moved to exclude certain portions of Dr. Conti's and Ms. Craft's testimony under Rule 702 of the Federal Rules of Evidence.

On March 3, 2023, Plaintiffs, along with Defendants Amneal and Lupin, filed a motion for preliminary approval of class settlement. The settlement agreement generally releases all claims against Amneal and Lupin, in exchange for a settlement fund in the amount of $3.4 million to be used to support continued litigation against the remaining Defendants (namely, Jazz and Hikma). The Settlement Class definition largely overlaps with the Damages Class definition, though it contains both individual consumers and TPPs.

III. LEGAL STANDARD

A. Class Certification

Class actions are governed by Rule 23 of the Federal Rules of Civil Procedure. To obtain class certification, plaintiffs bear the burden of showing they have met each of the four requirements of Rule 23(a) and at least one subsection of Rule 23(b). *Zinser v. Accufix Rsch. Inst., Inc.*, 253 F.3d 1180, 1186 (9th Cir.), *amended by* 273 F.3d 1266 (9th Cir. 2001). "A party seeking

class certification must affirmatively demonstrate" compliance with Rule 23. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). Plaintiffs have the burden to establish the Rule 23 requirements by a preponderance of the evidence. *Olean Wholesale Grocery Cooperative, Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 665 (9th Cir. 2022) (en banc).

Rule 23(a) permits a court to certify a class only if it is satisfied the following requirements are met: "(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a). These requirements are commonly referred to as numerosity, commonality, typicality, and adequacy of representation, respectively. *Mazza v. Am. Honda Motor Co., Inc.*, 666 F.3d 581, 588 (9th Cir. 2012).

If all four Rule 23(a) prerequisites are satisfied, plaintiffs must also "satisfy through evidentiary proof" at least one of the three subsections of Rule 23(b). *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013). Certification is appropriate under Rule 23(b)(2) "when a single injunction or declaratory judgment would provide relief to each member of the class," rather than in a circumstance where each class member would be entitled to a unique injunction. *Wal-Mart*, 564 U.S. at 360. Under Rule 23(b)(3), plaintiffs must show that "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." Fed. R. Civ. P. 23(b)(3). Such common questions need only be *capable* of class-wide resolution; plaintiffs are not required to show that "the evidence in fact establishes [they] would win at trial." *Olean*, 31 F.4th at 667. Further, a court may not "decline to certify a class that will require determination of some individualized questions at trial, so long as such questions do not predominate over the common questions." *Id.* at 668. If these showings have been made and the class is thus certified, the court must appoint class counsel, taking into account the counsel's experience, knowledge, resources, and familiarity with the case. Fed. R. Civ. P. 23(g).

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B. Exclusion of Expert Testimony

Rule 702 of the Federal Rules of Evidence requires that a witness proffered as an expert by a party be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Under the test laid out in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), expert opinion testimony is reliable if it has a "basis in the knowledge and experience of [the relevant] discipline." *Id.* at 592. The following factors, among others, are to be considered when evaluating whether an expert's proposed testimony is reliable: (1) "whether a theory or technique . . . can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) the known or potential error rate of the particular scientific theory or technique, and (4) the degree to which the scientific technique or theory is accepted in a relevant scientific community. *Id.* at 593–94; *see Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999) (*Daubert* factors are not exhaustive).

Courts reviewing *Daubert* motions focus on the principles and methodology employed by the expert, not the conclusions the expert ultimately reaches. *See Daubert*, 509 U.S. at 595. As such, expert testimony may not be excluded simply because it is impeachable. *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013). Instead, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

C. Preliminary Approval of Class Settlement

Rule 23(e) provides a process for the approval of classes "proposed to be certified for the purposes of settlement." Fed. R. Civ. P. 23(e). Under the Rule, courts must determine whether the settlement agreement is "fair, adequate, and reasonable to all concerned." *Uschold v. NSMG Shared Servs., LLC*, 333 F.R.D. 157, 169 (N.D. Cal. 2019). This, in turn, requires assessing the following factors:

> (1) the strength of the plaintiff's case; (2) the risk, expense, complexity, and likely duration of further litigation; (3) the risk of maintaining class action status throughout the trial; (4) the amount offered in settlement; (5) the extent of discovery completed and the

> stage of the proceedings; (6) the experience and views of counsel; (7) the presence of a governmental participant; and (8) the reaction of the class members of the proposed settlement.

In re Bluetooth Headset Prods. Liab. Litig., 654 F.3d 935, 946 (9th Cir. 2011) (quoting *Churchill Vill. v. Gen. Elec.*, 361 F.3d 566, 575 (9th Cir. 2004)). The Northern District of California has also adopted additional procedural guidance for such settlements.

IV. MOTION FOR CLASS CERTIFICATION

Defendants do not contest that both proposed classes meet the Rule 23(a) requirements of numerosity, commonality, and typicality. Instead, their opposition focuses on a few select areas. With respect to the Damages Class, Defendants argue the Rule 23(b)(3) predominance and superiority requirements are not met because of the existence of uninjured class members, namely those that are "brand loyal" and those that may be uninjured because they have received some form of reimbursement. They further contend that the Class's claims relating to Xywav prescriptions must be dropped, along with claims from several of the Class States. For the Injunctive Relief Class, Defendants argue that (1) there are no adequate representatives for the Class among the Class Plaintiffs; (2) Plaintiffs have insufficiently described the injunctive relief they seek; and (3) the Class cannot be certified because Class Plaintiffs are primarily seeking monetary relief in this case. With respect to both Classes, Defendants argue Plaintiffs have impermissibly expanded the class definitions beyond what was included in the CAC. Finally, Defendants move to exclude portions of Dr. Conti's and Ms. Craft's expert testimony.

A. Rule 23(a) Requirements

1. Numerosity

First, Plaintiffs state there are "tens of thousands of prescriptions for Xyrem and/or Xywav per month," making joinder of all members impracticable. Mot., at 13. Defendants do not contest this. Looking at either the number of prescriptions or the number of purchasers, both Classes easily satisfy the numerosity requirement.[3]

[3] Courts reviewing similar class actions have determined numerosity by examining the number of prescriptions, *see In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 698 (E.D. Pa. 2020); the

2. Commonality

Second, Plaintiffs raise multiple questions of law common to the Classes. These include, among others:

- Whether Jazz unlawfully maintained and continues to maintain monopoly power through all or part of their overall anticompetitive scheme;
- Whether Defendants conspired to delay generic competition for Xyrem; and
- Whether Defendants' conduct was a substantial contributing factor in causing some amount of delay of the entry of generic Xyrem.

Id. at 14. Defendants do not contest this requirement either. The commonality requirement is often met in antitrust cases such as this, *e.g.*, *Zetia*, 2020 WL 5778756, at *6 (collecting cases), and it is easily satisfied here as well.

3. Typicality

Third, Plaintiffs argue their claims are typical of the rest of the class members' claims, as those claims "arise from the same course of conduct, namely, Defendants' anticompetitive scheme to prevent or delay the availability of less expensive generic Xyrem." Mot., at 15. Defendants again do not argue otherwise. Given that the source of the alleged harm is common to the class members, the typicality requirement is met.

4. Adequacy

Finally, Plaintiffs argue they have demonstrated adequacy, given the absence of conflicts of interest between the Class Plaintiffs and the remainder of each Class, as well as the experience of the proposed Class Counsel. Defendants do not contest that adequacy has been shown with

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total number of drug purchasers (individual consumers and/or TPPs), *see In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 397 (D.R.I. 2019); or both, *see In re Zetia (Ezetimibe) Antitrust Litig.*, No. 18-md-2836, 2020 WL 5778756, at *4–5 (E.D. Va. Aug. 14, 2020). Gauging numerosity based on the number of purchasers, rather than the number of prescriptions, would seem most appropriate in this case: purchasers are the relevant "members" of each class for whom joinder would otherwise be impracticable. Fed. R. Civ. P. 23(a)(1). Here, it is unclear how from Plaintiffs' briefing how many total purchasers are in the Classes. However, the number of TPPs alone appears to be somewhere north of 700, a number that counsel for both parties repeated during oral argument. In any event, then, numerosity is satisfied.

respect to the Damages Class, but they argue that Plaintiffs have failed to establish this criterion for the Injunctive Relief Class. This argument is addressed *infra* section IV.C. For the Damages Class, however, Plaintiffs have satisfied the adequacy requirement.

B. Rule 23(b)(3) Damages Class

Plaintiffs assert that the proposed Damages Class satisfies the Rule 23(b)(3) requirements because common questions relating to antitrust liability, injury, and damages predominate over questions affecting individual class members. Namely, Plaintiffs' conspiracy and monopolization theories, as well as the allegation that Jazz has maintained market power, turn on "Defendants' conduct and the effect on the market, which are common to all class members." Mot., at 17. This, they argue, can all be proven using evidence common to the Class.

While Defendants do not contest that there are common questions with respect to antitrust conduct, they assert that individual questions will predominate with respect to antitrust injury. They argue Plaintiffs have failed to account for factors unique to Xyrem that increase the likelihood of brand loyalty among patients and, by extension, many of the TPPs that pay for those patients' prescriptions. These unaddressed factors create the potential that many class members are uninjured, and Plaintiffs have failed to provide a mechanism to separate them out. Similarly, Defendants claim Plaintiffs have failed to provide "a viable methodology for proving classwide injury for Xywav." Dkt. 409 ("Opp."), at 19. These, together, defeat predominance and show why a class action is not the superior vehicle to resolve these claims. While Xywav prescriptions should be excluded from the Class, Defendants' remaining arguments fail to persuade.

1. Predominance & Brand Loyalty

Defendants' opposition focuses largely on the contention that Plaintiffs have failed to account for factors increasing the potential for brand loyalty among Xyrem consumers — that is, the likelihood that patients taking brand Xyrem would have stuck with the brand instead of switching to generic Xyrem once it became available. First, Xyrem treats a rare disorder, and many TPPs only have a handful of insureds (many with only one insured) who have been prescribed Xyrem. As a result, "unlike nearly all other medicines, the choices of a few insureds

often drive all of a given [TPP's] Xyrem reimbursements." *Id.* at 10. Second, individual patients would have had little to no financial incentive to switch to generic Xyrem; in fact, many would have been disincentivized because the generic would have been more expensive. Third, prescribers and patients may have simply preferred to stay on brand Xyrem rather than switch to a generic, for one reason or another; this, Defendants claim, is supported by trends in prescription data. These factors suggest that many TPPs are effectively proxies for individual consumers; and thus, because many individual consumers would have remained brand loyal, so too would many TPPs. Defendants criticize Plaintiffs and Dr. Conti for failing to account for these factors and for relying on selected forecasts that, Defendants claim, overstate the extent to which generic Xyrem would have taken over the sodium oxybate market. This makes it likely that Plaintiffs have understated the number of uninjured class members — i.e., "brand-loyal TPPs" — and thus minimized the need for individualized injury inquiries.

Brand loyalty is a commonly raised objection to class certification in generic delay antitrust cases. Indeed, federal courts have recognized that brand loyalty can be a significant obstacle, because failing to sort out potentially uninjured class members raises the chances that their claims will inappropriately be included in an aggregate damages award. *See Niaspan*, 464 F. Supp. 3d at 715. This has frequently been a dispositive issue when plaintiffs seek certification of classes that include individual consumers. *See, e.g.*, *id.* at 717 ("[T]he Court concludes that identification of consumer brand loyalists would require extensive individualized inquiries and defeat predominance."); *In re Intuniv Antitrust Litig.*, 16-cv-12396-ADB, 2019 WL 3947262, at *8 (D. Mass. Aug. 21, 2019); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. 04-5898, 2010 WL 3855552, at *25 (E.D. Pa. Sept. 30, 2010); *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *12 (D.N.J. Oct. 30, 2018) (unpublished).

However, courts have typically rejected this argument where plaintiffs seek certification of classes composed *only* of TPPs. This stems largely from the very low bar a TPP must overcome to establish antitrust injury: if even a single one of a TPP's enrollees would have bought the generic

drug even one time, that TPP has been injured. *In re HIV Antitrust Litig.*, No. 19-cv-02573-EMC, ECF No. 1388, at 37 (N.D. Cal. Sept. 27, 2022). As a simple matter of mathematics, the more prescriptions a TPP fills, the less likely it becomes that *none* of those prescriptions would have been filled by the generic. *Niaspan*, 464 F. Supp. 3d at 717 (crediting expert's calculation that the odds a TPP with ten claims for a given drug "had no generic claims [was] approximately 1 in 1 billion"). For this reason, "courts facing the issue of brand-loyal TPPs have universally concluded that it is 'highly unlikely' that 'institutional payors were uninjured even if some of their members are brand-loyal.'" *Zetia*, 2020 WL 5778756 at *19 (quoting *Loestrin*, 410 F. Supp. 3d at 402)); *see In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 WL 4621777, at *18 (D. Mass. Oct. 16, 2017); *Niaspan*, 464 F. Supp. 3d at 717; *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 562–63 (S.D.N.Y. 2021); *In re Celexa & Lexapro Mkt. & Sales Practices Litig.*, 915 F.3d 1, 13 (1st Cir. 2019); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 306 (D. Mass. 2021). *But see In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 231–32 (E.D. Pa. 2012).

Defendants do not meaningfully distinguish these cases, nor do they cite more favorable authority. Rather, they argue that reliance on mathematics does not suffice here: Xyrem is a meaningfully different drug that would have been subject to greater brand loyalty. However, none of their arguments on this point are persuasive.

a. Rare Disorder and Low Numbers of Patients

First, Defendants argue the fact that Xyrem treats a rare disorder means that enrollees' "idiosyncratic choices" are of greater significance here than in the average prescription drug antitrust case. Opp., at 11. The main import of this point is that the relatively small number of Xyrem consumers means that any given TPP likely has a small number of insureds that take it. Many have just a single insured taking Xyrem. This argument is flawed for a number of reasons, as reflected in how courts have found the same argument to be "not well supported." *HIV*, 19-cv-02573-EMC, No. 1388, at 42 (similar numbers of TPPs with low numbers of insureds). For one thing, as Dr. Conti demonstrates, the data upon which Dr. Hughes relied to calculate the number

of unique TPPs with Xyrem claims is flawed. The data appears to have erroneously listed numerous TPPs as separate entities when they really should be listed as one entity. This has the effect of increasing the number of TPPs with low reported numbers of insureds who take Xyrem.

Perhaps the biggest flaw with Defendants' argument is that it assumes a brand-loyal consumer would *always* have ordered brand Xyrem. This defies basic logic. Even if a given consumer would have had some particular reason to prefer brand Xyrem when ordering in a given instance, this does not mean they would have chosen brand Xyrem in every other purchase. Rather, that consumer could have switched from a brand to a generic at any time, for many different reasons, or even tried the generic once before switching back to the brand for every other purchase. Again, as long as that consumer would have tried the generic once, the TPP would been injured. Dr. Conti explains this concept in her reply report:

> If a consumer purchased many prescriptions of Xyrem, then if generic Xyrem had launched absent the alleged anticompetitive conduct, that patient would have had many opportunities to switch to the generic, and their health plan would have had a long time to apply pressure to effect that switch. As a result, a consumer who purchased 50 prescriptions of Xyrem would have had a *vanishingly small chance* of never purchasing generic Xyrem absent the alleged anticompetitive conduct.

Dkt. 449-2 ("Conti Reply Rpt.") ¶ 12 (emphasis added). Once this possibility is accounted for, along with the flaws in the data noted above, the likelihood that a given TPP would be uninjured drops substantially. *Id.* ¶ 16. Defendants thus fail to persuade that the number of TPPs with few insureds meaningfully undercuts predominance. Even conceding that some TPPs would be "brand loyal" and, thus, uninjured, there is next to no support that there would be more than a *de minimis* number of brand-loyal TPPs. *See Olean*, 31 F.4th at 669.

b. Financial Considerations

Second, Defendants argue many individual consumers (and thus TPPs) would have remained brand loyal because there would have been no financial incentives to switch to generic Xyrem. This theory does not withstand scrutiny. The fact that Jazz acted to reduce the cost of Xyrem (sometimes to $0) has little bearing on what would have occurred in Plaintiffs' but-for

world, because it assumes that generic manufacturers would *not* have acted aggressively to reduce their costs. To the contrary, Dr. Conti explains why and how TPPs would have acted to encourage their insureds to switch to generic Xyrem, which almost undoubtedly would have had a lower sticker price than the brand version. TPPs have multiple tools to accomplish this, including "step-therapy, which could require a patient to try and fail with generic Xyrem before filling a prescription with brand Xyrem; prior authorization, which could require the patient to get specific authorization from their doctor before filling a prescription for brand Xyrem; or formulary exclusion, which could remove brand Xyrem completely from the plan's formulary." Conti Reply Rpt. ¶ 32. Some could have adopted coupons similar to Jazz; indeed, since the release of generic Xyrem in January 2023, Hikma has done exactly this. This is in addition to the fact that many states *require* generic drugs to be substituted when available. *Id.* ¶ 47. Thus, there is little evidence that with Xyrem, unlike with other generic market entries, patients would have lacked financial incentives to switch to the generic, or that TPPs would have been unable to compel them to do so.

c. Patient and Prescriber Preferences

Defendants' third argument is somewhat more amorphous, claiming that patients and prescribers "have non-financial reasons not to switch to a generic version of Xyrem," though these reasons are not stated clearly. Opp., at 13. Defendants suggest the rareness of narcolepsy and effective treatments for it may make patients more likely to stick with brand Xyrem once finding it helps manage their disorder. *See id.* at 3, 13. This theory is rooted more in inference than in evidence. Regardless of the exact reasons, Defendants argue they weigh heavily on brand loyalty here, as reflected in data showing the number of Xyrem prescriptions that have been designated as "dispensed as written" ("DAW"). A DAW designation indicates that a prescription should be filled with the brand drug, rather than substituted with the generic. This designation can either be requested by the patient or by the prescriber. Examining the DAW data from August 2022 to January 2023 (the month when generic Xyrem first entered the market), Dr. Hughes concludes that the above-average rate of DAW designations demonstrates that both physicians and patients strongly prefer brand Xyrem.

This argument, too, has little merit. The DAW data presented by Defendants covers only the six months prior to the entry of generic Xyrem; during this time, a DAW designation would have been of no practical consequence since brand Xyrem was the only option available. Looking at the data from before August 2022 further undercuts Defendants' argument because the rate of DAW designations remains largely constant between February 2022 and January 2023. *See* Dkt. 448-3 ("Craft Reply Rpt.") ¶ 8. A more likely explanation for this trend would appear to be prescribers' personal habits in filling Xyrem prescriptions, given the layout of the forms themselves. *Id.* ¶¶ 12–15. Finally, while the percentage of *patients* requesting brand Xyrem clearly (if only slightly) increased in the months leading up to generic entry, this is hardly a pattern from which any meaningful conclusions could be drawn. Indeed, the data set is so small that it is hard to discern any patterns at all. The only other evidence Defendants rely on to support the argument that prescribers prefer brand Xyrem is a single survey indicating a significant number of doctors would continue prescribing the brand even after generic entry. However, as both Dr. Conti and Ms. Craft convincingly show, this survey is riddled with flaws, including its small sample size, its potential for bias among the sample, and its vague and leading language. *See* Conti Reply Rpt. ¶¶ 47, 71; Craft Reply Rpt. ¶¶ 19–20. There is thus little reason to conclude that patients and prescribers are significantly more wedded to brand Xyrem than to the generic, at least insofar as it bears on the predominance analysis.

d. Dr. Conti's Yardstick Methodology

Defendants assert that "Dr. Conti's failure to consider these characteristics of Xyrem infects her analysis," such that the generic erosion curves she uses are much too aggressive.[4] As described in the preceding sections, Defendants have offered no compelling reasons why Xyrem has any such characteristics, rendering this argument largely moot. Moreover, Defendants fail to

[4] A generic erosion curve models the rate at which generics take over the market for a given drug over time. As one might expect, the amount of generics increases over time: for example, a generic may constitute 60% of a drug's market after only one month on sale, but could constitute 90% after a year. The erosion curve thus shows how "aggressively" this process occurs.

show Dr. Conti's analysis relies on such unrealistically high rates of generic conversion that it "paper[s] over" many uninjured class members. Opp., at 17.

To model what would have happened when generic Xyrem entered the market, Dr. Conti chose Provigil, a narcolepsy drug that has already experienced generic entry, as a "yardstick" or analogue. As explained in Dr. Conti's report, Provigil has many similarities to Xyrem: both generated substantial revenue, both treat narcolepsy, and both are taken orally. Defendants suggest that Dr. Conti arbitrarily chose a flawed analogue in order to base her analysis on an unrealistically aggressive generic erosion curve. Had she used what they argue is a more realistic generic erosion curve, her analysis would reflect a significantly higher number of brand-loyal (and thus uninjured) class members.

For the purposes of the predominance analysis, the question is not whether Dr. Conti's projection is correct. The question is only whether individualized inquiries will predominate over common ones. Defendants repeatedly caution that, after correcting for Dr. Conti's use of Provigil and using a more realistic generic erosion curve, "nearly a third of the putative class could be uninjured." Opp., at 17 (emphasis omitted). Yet here, virtually all the erosion curves cited by both Dr. Conti and Dr. Hughes indicate that, at most, a small minority of class members would have remained brand loyal. The only ones that indicate the high portion of uninjured class members are both outliers; one of these is from the survey discussed in the previous section, which carries very little persuasive weight. While Provigil certainly falls on the high end of the range of cited erosion curves, it is nonetheless a plausible projection.[5] Thus, while the particular generic erosion curve applicable to generic Xyrem is a question for the jury to decide, Plaintiffs have clearly not relied on such extreme data that the Class must fail for lack of predominance.

e. Summary

Plaintiffs have shown that issues common to the Damages Class predominate over any

[5] Indeed, it is more or less on par with various projections Defendants themselves conducted previously.

issues affecting individual class members. Courts have generally rejected arguments that the presence of brand-loyal TPPs would destroy predominance, and Defendants have offered no reason to depart from this trend. On the record Plaintiffs present, there would appear to be, at most, a *de minimis* number of completely uninjured TPPs. This does not defeat certification of a Rule 23(b)(3) class.

2. Superiority

Defendants argue that because of the likelihood of brand loyalty among consumers, "the class device is not superior here." Opp., at 24. This is because TPPs would have "skewed incentives to attest to whatever (unspecified) information Plaintiffs propose to ask them" regarding their insureds' brand loyalty, "without any cross-examination by Defendants." *Id.* at 25. For the reasons explained in the previous section, none of Defendants' arguments concerning brand loyalty are persuasive; at most, a *de minimis* number of patients would have remained brand loyal, and this does not negate the benefits of the class device. Any aggregate damages award would, under Dr. Conti's methodology, necessarily account for brand loyalty by calculating damages based only on the number of purchases that would have been for generic Xyrem rather than brand Xyrem. *See* Conti Rpt. ¶¶ 112–13; Dkt. 450 ("Reply"), at 17. Thus, even if the jury were to accept a less aggressive generic erosion curve than the one Dr. Conti adopted, any generic erosion curve would still account for brand loyalty as to the Class as a whole.

With respect to individualized inquiries and defenses, Defendants' concern is unfounded. Any claims administration process can be designed to ensure Defendants are offered a mechanism to challenge individual class members' claims to ensure they are not compensated unjustifiably. Defendants offer no convincing reason to think affidavits would be insufficient here, nor is there reason to believe the class members would not answer truthfully. Given the number of claims and class members here, and the complexity of the common questions, Plaintiffs have more than satisfied their burden to show why the class device is superior with respect to the Damages Class.

3. Xywav Prescriptions

Defendants also object to the inclusion of Xywav prescriptions in the Damages Class.

Xywav, another sodium oxybate drug launched by Jazz in 2020, has unique clinical advantages over Xyrem, including its much lower quantity of sodium. This is important for patients with high blood pressure, for example. Xywav also treats some conditions Xyrem does not. Defendants argue Plaintiffs have "not include[d] any evidence to substantiate the idea that patients would *not* have taken [Xywav] once it became available." Opp., at 19. Plaintiffs respond that this is essentially a merits question common to the Class — "whether class members were injured with respect to at least one Xyrem or Xywav purchase" — and Dr. Conti's damages model accounts for either answer. Reply, at 11.

Plaintiffs' justification for looking at Xywav prescriptions has been inconsistent up to this point in the case. Even now, for instance, though a prior order confirmed Plaintiffs could not allege a viable "product hop" theory by Jazz, *see* Dkt. 138, at 64, and Plaintiffs claim not to be pursuing this theory, *see* Reply, at 12, Dr. Conti expressly describes the launch of Xywav in this way, *see* Conti Rpt. ¶¶ 21–22. Plaintiffs have delicately attempted to argue around this by stating that Xywav prescriptions are relevant to the calculation of aggregate damages: Xywav prescriptions and Xyrem prescriptions, together, form the overall sodium oxybate market, which as a whole would have been impacted by the entry of generic Xyrem. Thus, "[h]ad generic Xyrem launched earlier in a competitive market, either Xywav would have been available (in which case Class Plaintiffs are not claiming damages related to it), or Xywav would not have been available (and patients would have purchased generic Xyrem instead)." Reply, at 12.

This proposition really contains two questions: (1) whether Jazz would have launched Xywav absent the alleged anticompetitive conduct; and if so (2) whether patients would have purchased generic Xyrem instead. The former is clearly a common question subject to common evidence: Plaintiffs would have to prove, as they suggest, that it would have been uneconomical for Jazz to launch Xywav absent the anticompetitive conduct alleged. The latter question, however, would not generate such uniform, classwide answers. While there may well be significant overlap in the two patient pools, Plaintiffs do not propose a methodology for determining on a classwide basis which Xywav patients would or could have been prescribed

Xyrem instead. For instance, they do not provide a way to identify which patients were prescribed Xywav because of their concerns about Xyrem's high sodium content, or what portion of patients take Xywav to treat conditions Xyrem does not treat. Without such a methodology, individualized inquiries regarding Xywav prescriptions would not only arise but would necessarily predominate over common questions. Certification of the Damages Class is therefore unwarranted with respect to Xywav prescriptions.

4. Maximizer Programs, Medicare Part D, and Rebates

Defendants further claim that Plaintiffs fail to provide a method for identifying TPPs that are potentially uninjured because their purchases were either subsidized or reimbursed in some way — namely through "maximizer programs,"[6] Medicare Part D payments, and manufacturer rebates. Plaintiffs respond that these arguments are speculative and irrelevant, and they argue Dr. Hughes in some instances mischaracterizes the nature of these payment programs.[7] They also point out that other courts facing similar challenges have typically rejected them. *See, e.g.*, *Lidoderm*, 2017 WL 679367, at *25; *HIV*, 19-cv-02573-EMC, ECF No. 1388, at 47; *Ranbaxy*, 338 F.R.D. at 294.

While these programs may be relevant to a given class member's damages recovery, they are simply irrelevant to the question of antitrust *injury*. This is because "antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015); *see Hawaii v. Standard Oil Co. of Cal.*,

[6] Many drug manufacturers provide coupons to help patients cover the cost of their coinsurance payment for a given drug. The coupons are worth up to a certain amount a year, but they are often not used in full because, once the patient hits their annual out-of-pocket maximum, the patient no longer needs to make any coinsurance payments; the TPP covers the rest. With a "maximizer program," the TPP essentially alters which payments count toward patients' out-of-pocket maximums, which allows the TPP "to receive the full value of the . . . coupon, reducing the [TPP's] net payment on the price of the drug." Opp., at 20.

[7] Dr. Hughes also claims TPPs may be uninjured because they passed along the alleged overcharges to consumers by raising premiums. Defendants do not advance this argument in their opposition, but it should be noted that a previous order has rejected this argument in the context of a discovery dispute. *See* Dkt. 392, at 2.

405 U.S. 251 (1972). Here, it may be the case that a TPP's maximizer program helped mitigate its damages due to the alleged anticompetitive conduct; or Medicare Part D may have covered a large part of the allegedly inflated prices of brand Xyrem. In either case, though, the alleged overcharge would still have occurred — and that is all that need be shown on a classwide basis. Dr. Conti has further demonstrated that mitigation from maximizer programs is already factored into her damages calculations, and she provides a method for the jury to remove rebate payments from the aggregate damages award. Reply Rpt. ¶¶ 78, 92. While further individualized questions may arise in the course of determining individual class members' damages, this often arises in class actions. *Olean*, 31 F.4th at 668, 679. It is therefore no obstacle to class certification.

5. Class States and Standing

a. Montana, Missouri, California, Kansas, New York, and Tennessee Claims

Finally, Defendants argue the removal of individual consumers from the proposed Damages Class forecloses, as a matter of law, bringing claims in six of the Class States (Montana, Missouri, California, Kansas, New York, and Tennessee). The parties have presented only limited briefing on these issues. At least with respect to Montana and Missouri law, Defendants' position does not appear well supported. *See In re Lithium Ion Batteries Antitrust Litig.*, No. 13-MD-2420 YGR, 2014 WL 4955377, at *19 (N.D. Cal. Oct. 2, 2014) (noting courts have "been uniform in reaching the same conclusion that indirect-purchaser status alone does not bar Missouri consumers from bringing claims under the [Missouri Merchandising Practices Act]"); *In re Dynamic Random Access Memory (Dram) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1113 (N.D. Cal. 2007) (concluding the term "person" under relevant Montana law "includes both individuals and businesses in its definition" and "allows all 'consumers' to bring suit, without distinction as to natural persons or otherwise"); *cf. In re Optical Disk Drive Antitrust Litig.*, No. 10-MD-2143 RS, 2012 WL 1366718, at *8 (N.D. Cal. Apr. 19, 2012) ("[P]laintiffs' claims under South Carolina law are not subject to dismissal notwithstanding a limitation on class actions in the state statute."). The parties submit competing authorities on the propriety of bringing the remaining four state law claims. *Compare In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, No. 2895, 2022 WL

736250, at *18 (D. Del. Mar. 11, 2022) (relevant California, New York, and Tennessee statutes "do not prohibit claims against one co-conspirator who participated in a concerted scheme"), *with In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practice & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1313 (D. Kan. 2018) (dismissing or limiting California, Kansas, New York, and Tennessee claims "because these statutes do not recognize unilateral conduct claims").

As Defendants conceded at oral argument, this question need not be resolved at the class certification stage. Thus, these state law claims will not be excised from the Damages Class at this time but may be reexamined in later motion practice.

b. Article III Standing

Defendants also argue that, because Class Plaintiff Blue Shield Blue Cross Association ("BCBSA") lacks Article III standing due to its lack of injury in fact, the Class cannot be certified as to those Class States where only BCBSA has claims.[8] While the question was not decided when briefing on the present motion was completed, the motion to dismiss is being granted in a contemporaneous order, BCBSA is being dismissed, and BCBSA will not be permitted to participate in the class action under the class definition (and exclusions) included in the motion for class certification. *See* Dkt. 499. Plaintiffs contend this argument should have been brought as a challenge to typicality under Rule 23(a), in accordance with a prior ruling in this case. *See* Dkt. 138, at 80. That Defendants may not have raised this concern as a Rule 23(a) typicality challenge does not mean they have waived the objection. It similarly does not obviate the need to address the Article III question here as it pertains to the claims of class members from states besides those in which the Class Plaintiffs have claims themselves.

As it stands, Class Plaintiffs (minus now-dismissed BCBSA) have claims in sixteen of the thirty-one Class States. The salient question Defendants raise is whether a "headless" class can be certified — that is, whether Class Plaintiffs can represent class members in the fifteen states where

[8] These states are Arizona, Connecticut, Kansas, Maine, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, South Dakota, and Wisconsin.

none of the Class Plaintiffs themselves have claims. Commentators and courts have concluded that the "application of the Article III standing test in the class context is 'complicated . . . because a named plaintiff seeks to litigate the claims of others.'" *Senne v. Kansas City Royals Baseball Corp.*, No. 14-cv-00608-JCS, 2021 WL 3129460, at *15 (N.D. Cal. July 23, 2021) (quoting 1 NEWBERG & RUBENSTEIN ON CLASS ACTIONS § 2.6 (6th ed. 2022)). That said, several circuits have permitted plaintiffs to represent absent class members in states beyond those in which the named plaintiff has an individual claim, including in antitrust suits. These courts have reasoned that "once a named plaintiff establishes injury and membership in the class, the inquiry should shift" from the Article III standing analysis to the Rule 23 analysis. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 51 (1st Cir. 2018); *see Langan v. Johnson & Johnson Cons. Cos., Inc.*, 897 F.3d 88, 92–96 (2d Cir. 2018); *Mayor of Baltimore v. Actelion Pharma. Ltd.*, 995 F.3d 123, 133–34 (4th Cir. 2021). The Ninth Circuit has not squarely addressed this question with respect to multistate classes, but on the question of standing in class actions generally, it has held that class plaintiffs can represent absent class members whose claims do not "implicate a significantly different set of concerns." *Melendres v. Arpaio*, 784 F.3d 1254, 1263 (9th Cir. 2015) (quoting *Gratz v. Bollinger*, 539 U.S. 244, 265 (2003)).

Since *Melendres*, district courts in the Ninth Circuit have differed over whether a "named plaintiff has individual standing to assert claims under the laws of one state but seeks to represent class members who assert claims under a different state's laws." *Senne*, 2021 WL 3129460, at *15. In the context of a Rule 23(b)(2) class certification motion, for instance the *Senne* Court concluded that this was better addressed as a Rule 23 question, not as a standing question, given that the named plaintiff's wage and hour claims under Florida law did not "implicate a significantly different set of concerns than the claims of the putative class members under Arizona and California law." *Id.* at *17 (citing *In re Chrysler-Dodge-Jeep Ecodiesel Mktg., Sales Pracs., & Prod. Liab. Litig.*, 295 F. Supp. 3d 927 (N.D. Cal. 2018); and *Kutza v. Williams-Sonoma, Inc.*, No. 18-cv-03534-RS, 2018 WL 5886611 (N.D. Cal. Nov. 9, 2018). *But see Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 909 (N.D. Cal. 2019).

This approach is sound in the present case. Here, Class Plaintiffs themselves clearly have Article III standing: they have demonstrated injury at least in the states in which they paid for Xyrem prescriptions. While the Class Plaintiffs may not have their own individual claims in nearly half of the Class States, there is little reason to suspect they would have an insufficient personal stake in the adjudication of the absent class members claims. As the *Asacol* Court recognized:

> [A]ll plaintiffs who were forced to pay a higher price in the absence of generic competition have a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages. And the fact that judgments for some class members will nevertheless enter under the laws of states other than the states under which any of the class representatives' judgments will enter, where those laws are materially the same, has no relevant bearing on the personal stake of the named plaintiffs in litigating the case to secure such judgments.

907 F.3d at 49. Defendants have made no suggestion that the laws of the respective Class States differ so significantly as to prevent Class Plaintiffs from being either typical of the class members in those states or inadequate to represent them. In the absence of such a showing (which Defendants are not precluded from making in the future), there is no Article III standing problem to certifying the Damages Class for each of the Class States proposed.

C. Rule 23(b)(2) Injunctive Relief Class

As noted above, Plaintiffs have demonstrated the Injunctive Relief Class satisfies the first three requirements under Rule 23(a). Defendants argue the Class Plaintiffs are not adequate to represent the Class, and they raise two other objections to certification overall. None of these arguments are persuasive.

First, with respect to adequacy, Defendants argue Plaintiff Ruth Hollman is an inadequate representative because she has not demonstrated that "she suffers, or stands to suffer, from Defendants' conduct." Opp., at 33. This argument ultimately dovetails with several of those targeted toward the Rule 23(b)(3) Class, and it fails for the same reason: even if her payments were capped as the result of a coupon from Jazz, she has alleged an antitrust injury by alleging an overcharge. *Nexium*, 777 F.3d at 9, 27. Furthermore, Plaintiffs have shown that, contrary to

Defendants' assertions, generic Xyrem would have been cheaper than the brand under Ms. Hollman's plan.

While Defendants also argue there are conflicts of interest between the Class Plaintiffs and the other class members, rendering the Class Plaintiffs inadequate, this argument similarly lacks merit. Plaintiffs have presented compelling data showing that generic Xyrem would have been less expensive for all payors, both individual consumers and TPPs alike, meaning their interests are aligned. While Defendants cite to several cases for the proposition that conflicts of interest can preclude finding adequacy as a general matter, courts have rejected this argument in circumstances analogous to those presented here. *See Zetia*, 2020 WL 5778756, at *7 ("[Plaintiffs'] interests are aligned with the putative TPP class members because all their claims depend on the same alleged anticompetitive conduct by Defendants, resulting in the same injury — paying overcharges for ezetimibe."); *Flonase*, 284 F.R.D. at 218; *Solodyn*, 2017 WL 4621777, at *13; *Lidoderm*, 2017 WL 679367, at *14–15. There are thus no fundamental conflicts of interest between the Class Plaintiffs and the class members writ large, and Plaintiffs have established they can adequately represent the Injunctive Relief Class.

Second, Defendants insist that Plaintiffs have not stated their claim for injunctive relief with requisite specificity. To be clear, the CAC itself requests the following form of injunctive relief: "Permanently enjoin Defendants both from continuing the unlawful conduct alleged here, and from engaging in similar or related conduct in the future." CAC ¶ 521. As Plaintiffs elaborated at oral argument, this would consist at least of declaring each of the volume-capped authorized generic agreements to be unlawful and enjoining Defendants from continuing to operate pursuant to them. This suffices to establish with specificity the relief Plaintiffs seek. True, the Federal Rules require an injunction to "describe in reasonable detail . . . the act or acts restrained or required." Fed. R. Civ. P. 65(d). Yet at the end of the day, this is a responsibility that lies with the Court, as guided and bound by the Federal Rules and well-established principles of equity. *See, e.g.*, *Foothill Church v. Watanabe*, No. 15-cv-02165 KJM EFB, 2023 WL 1767748, at *2–3 (E.D. Cal. Feb. 3, 2023). This is not a basis on which to deny certification.

Finally, Defendants argue Plaintiffs cannot seek injunctive relief because they "primarily seek monetary relief." Opp., at 34. This argument relies on a misguided reading of *Wal-Mart Stores, Inc. v. Dukes*. There, the Supreme Court held that a claim for monetary relief could not be certified under Rule 23(b)(2) unless it was only "incidental to the injunctive or declaratory relief." 564 U.S. at 360. This holding limits only the relief plaintiffs can seek under a Rule 23(b)(2) class, not the relief they can seek in their suit as a whole. Put differently, nothing in *Wal-Mart* prevents a court from certifying both a damages class under Rule 23(b)(3) *and* an injunctive relief class under Rule 23(b)(2).[9] *See Holt v. Noble House Hotels & Resort, LTD*, No. 17cv2246-MMA (BLM), 2018 WL 5004996, at *8 (S.D. Cal. Oct. 16, 2018) (citing *Ellis v. Costco*, 657 F.3d 970, 987 n.10 (9th Cir. 2011)); *HIV*, 19-cv-02573-EMC, ECF No. 1388, at 59–60 (rejecting this argument). The fact that TPPs are members of both Classes is of no moment.

Defendants have voiced no reasoned justification for why certification of the Injunctive Relief Class should be denied here. Plaintiffs having satisfied each of the Rule 23(a) requirements and Rule 23(b)(2), the Injunctive Relief Class will be certified. However, Xywav purchases will be excluded for the same reasons articulated above with respect to the Damages Class.

D. Expansion of the Class Definitions

In addition to their specific objections to each Class, Defendants argue Plaintiffs have impermissibly expanded the class definitions beyond what was originally included in the CAC. Defendants first object to the fact that Plaintiffs have rolled back the start date of the Class Period from July 17, 2017, to January 17, 2017. *Compare* CAC ¶¶ 329, 332, *with* Mot., at 1–2. Yet Defendants can hardly complain of any surprise or prejudice from this shift: in a letter from Plaintiffs' counsel to Defense counsel, Plaintiffs' counsel agreed to shifting the discovery window back to January 1, 2016 — over a year before the start of the Class Period. *See* Dkt. 450-14.[10]

[9] Even if Defendants' position was correct, they provide no way of determining what constitutes Plaintiffs' "primary relief sought." They provide no support for the notion that Plaintiffs here are primarily seeking damages, aside from their assertion that that is the case.

[10] It should be noted that this document post-dates the one Defendants cite. *Compare* Dkt. 409-22

Under these circumstances, the fact that Plaintiffs have modified the class definitions from what was included in the CAC is of little consequence, and it certainly does not foreclose class certification or preclude certification under the revised definitions. *See In re TFT-LCD (Flat Panel) Antitrust Litig.*, 267 F.R.D. 583, 591 (N.D. Cal. 2010). Defendants appear to raise the concern that Plaintiffs may decide arbitrarily to shift the Class Period back even further, but this concern is misplaced: any further modifications would require Plaintiffs to bring a motion to modify the class definition.

Defendants also argue that because Plaintiffs have surrendered any product hop claims they may have had, they cannot now include Xywav prescriptions within the class definitions. This argument is moot in light of the fact that neither Class will be certified to include Xywav prescriptions.

E. *Daubert* Motion

Defendants' *Daubert* motion seeks to exclude certain portions of Plaintiffs' expert testimony: (1) Dr. Conti's opinions related to the generic conversion rate for Xyrem in the but-for world and the use of Provigil as a yardstick drug; (2) Dr. Conti's opinions on "the application and impact of couponing in the but-for world;" (3) both experts' opinions on the rate of DAW prescriptions; and (4) both experts' opinions on the veracity of a particular survey cited by Dr. Hughes. Dkt. 473 ("*Daubert* Mot."), at 1. While these arguments are not without merit, they each at their core go to the weight of the experts' testimony, rather than its admissibility.

1. Use of Provigil as a Yardstick

Defendants first argue that Dr. Conti "cherry-picked" Provigil as a yardstick drug to justify relying on an overly aggressive generic erosion curve. *Id.* at 2. They insist the criteria she used to select a yardstick drug were arbitrary and that she failed to apply them faithfully in selecting Provigil. Her conclusions on this topic are therefore biased and unreliable.

Dr. Conti's report provides not only adequate but ample reasons for selecting Provigil. As

(dated Sept. 20, 2021); *with* Dkt. 450-14 (dated Nov. 17, 2021).

both parties note (and as Jazz employees themselves lamented), it is often very difficult to select a yardstick drug that perfectly tracks that of the drug at issue. While it is true that Provigil followed an aggressive generic erosion curve, Dr. Conti notes that its numerous similarities with Xyrem (including, most importantly, its total sales volume) support using it as a yardstick. On the flip side, she explains why several other drugs would be less useful analogues. That there are differences between Provigil and Xyrem does not fatally undermine her choice. To the extent Defendants believe her analysis was conducted incorrectly and a different drug (or several different drugs) would be more appropriate yardsticks, this can be explored in cross-examination or by proffering an alternative analysis. Defendants' citation to *Muffett v. City of Yakima*, No. CV-10-3092-RMP, 2012 WL 12827492 (E.D. Wash. July 20, 2012), is inapposite: there, the expert witness based his opinions on his own memory of certain numbers, rather than on any reliable data source. *Id.* at *3–4. The motion is therefore denied in this respect.

2. Coupons

Defendants next argue that Dr. Conti provides contradictory and incorrect opinions on the use of coupons by brand and generic drug manufacturers. In her opening report, Dr. Conti noted that generic manufacturers generally do not offer coupons, but, as Dr. Hughes pointed out, she calculated damages based on an assumption that *generic* Xyrem consumers would have continued receiving coupons. Dr. Conti corrected this error in her reply report, which provides revised damages calculations. *See* Conti Reply Rpt. ¶¶ 118–21. This would seem to ameliorate the concern about the reliability of these calculations.

More broadly, though, Defendants suggest that Dr. Conti's "about-face" on the subject of generic coupons undermines her conclusion that Xyrem patients would have had financial incentives to switch from the brand to the generic. *Daubert* Mot., at 18. As discussed above, her opinion is sound for many reasons. Aside from the discrepancy in her damages calculations, Dr. Conti's statements in her opening report and her reply report are entirely consistent: while generic manufacturers may not *generally* provide coupons, *see* Conti Rpt. ¶ 34, the fact that Hikma has started to offer coupons for generic Xyrem simply makes it an exception, which Dr. Conti

acknowledges. *See* Conti Reply Rpt. ¶ 37 (describing Hikma coupon program and stating that "[c]o-pay coupons for generic drugs are not common in general"). What Defendants appear to be trying to do is to assert that, in Dr. Conti's but-for world, generic Xyrem manufacturers would *not* have provided coupons, but Jazz *would* have kept providing coupons, thus making brand Xyrem cheaper. This scenario is unsupported, and nothing in Dr. Conti's reports is to the contrary. *See id.* ¶ 45 n.68. Her opinions on this subject are not unreliable, and the motion is denied in this respect.

3. DAW Opinions

Defendants next object to opinions from both Dr. Conti and Ms. Craft concerning their criticisms of Dr. Hughes's reliance on DAW prescription data. Both experts note in their reports that prescribers may have marked Xyrem prescriptions with a DAW designation because of the allegedly confusing layout of the prescription form. Defendants argue neither expert is qualified to opine on this topic. While neither expert has suggested they have significant background or training in prescription form design, their experience in the medical and pharmaceutical field generally is sufficient to support their opinions about the Xyrem forms. In any event, this is yet another area that could be probed through cross-examination.

In addition, Defendants argue Ms. Craft made inaccurate statements about missing data in her critique of the use of the DAW data overall. Namely, Ms. Craft stated there were multi-month gaps in the DAW data that undermined its reliability. The data for these periods does appear to exist, and the parties dispute whether Ms. Craft had access to or notice of it when assembling her reply report. This is ultimately of no moment because, even if her opinion on the gaps in the data is given little weight, her remaining opinions on the DAW data pool are well founded. Exclusion is not necessary as to her opinions on DAW data, nor as to Dr. Conti's opinions, and the motion is denied in this respect as well.

4. Survey Data

Finally, Defendants take issue with opinions from both experts critiquing the reliability of a survey cited by Dr. Hughes that indicates only a minority of prescribers would switch their patients from brand to generic Xyrem. Defendants similarly claim that neither expert is qualified

to opine on survey design. This argument can be discarded by reference to both experts' education and experience in the healthcare field generally. Indeed, most of the critiques they level would seem to require at most an introductory level knowledge of research methods and survey design, which both possess. Defendants' critiques go solely to the weight of the experts' testimony, and Defendants are free to bolster the survey's credibility in their own case or to attack Plaintiffs' expert testimony on cross-examination. The motion is therefore denied in this respect.

V. MOTION FOR PRELIMINARY APPROVAL

Plaintiffs have negotiated a settlement agreement with Defendants Amneal and Lupin. They seek preliminary approval of a Settlement Class, which is defined as follows:

> [A]ll persons and entities in the United States that, for consumption by themselves, their families, their members, employees, insureds, participants, or beneficiaries, and other than for resale, paid and/or provided reimbursement for some or all the purchase price for Xyrem and/or Xywav during the time from January 1, 2015, through the Execution Date.

Dkt. 423-2 ¶ 1. Like with the Damages Class and the Injunctive Relief Class, the Settlement Class also excludes certain individuals and entities. The agreement establishes a $3.4 million settlement fund, with Amneal contributing $1.9 million and Lupin contributing the remaining $1.5 million. *Id.* ¶ 6. Instead of distributing the fund to the Settlement Class members, the fund is to be used to support continued litigation against the remaining Defendants. *See id.* ¶ 10. In turn, the agreement releases all claims against Amneal and Lupin in connection with this action.

After reviewing the agreement and the motion, the Settlement Class meets the Rule 23(e) requirements and the Northern District's procedural guidance for class action settlements. It appears to be the product of "arm's length, non-collusive, negotiated resolution," *Rodriguez v. West Publ'g Corp.*, 563 F.3d 948, 965 (9th Cir. 2009), and Plaintiffs' counsel has more than enough experience to determine that such a settlement is advisable and beneficial for the class members in the context of the overall case. Plaintiffs acknowledge there are differences between the Settlement Class and the two Classes for which Plaintiffs have sought certification. For one, the Settlement Class covers claims that extend to two years before those of the two certified

Classes (i.e., 2015 versus 2017); and the Settlement Class includes individual consumers and TPPs, while the Damages Classes includes only TPPs. These differences are justifiable. With respect to the time discrepancy, Plaintiffs explain that 2015 was the year included in the class definition in the CAC, and as such, this was the date Plaintiffs had in mind when they began settlement negotiations with Amneal and Lupin. Further, the release of Plaintiffs' damages claims for this period (which, again, otherwise would not be covered by the Damages Class) appears ultimately to amount only to a minor concession given the small settlements that individual consumers could have expected. The same is true in justifying use of the settlement fund for continued litigation rather than distribution: as Class Plaintiffs argue, these class members have a greater interest in seeing the remaining litigation carried through to resolution.

As such, the motion for preliminary approval will be granted. Further steps toward finalization of the settlement, including distributing class notice, are detailed below.

VI. CONCLUSION

1. The motion for class certification is granted, except insofar as the Classes attempt to include Xywav prescriptions.
2. The following Damages Class is certified pursuant to Rules 23(a) and 23(b)(3):

> All entities in Arizona, California, Connecticut, District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin that, for consumption by their members, employees, insureds, participants, or beneficiaries, and other than for resale, paid and/or provided reimbursement for some or all the purchase price for Xyrem during the time from January 17, 2017, through and until May 12, 2023.
>
> Excluded from the Health Benefit Plan Payor Class are: (1) Defendants and their counsel, parents, subsidiaries, and affiliates; (2) Express Scripts Specialty Distribution Services, Inc. and any of its counsel, parents, subsidiaries, and affiliates; and (3) federal and state governmental entities. This exclusion does not include cities, towns, municipalities, or counties or carriers for Federal Employee Health Benefit plans.

3. Class Plaintiffs (with the exception of BCBSA, which has been dismissed, and Ruth Hollman,

who is not a member of the Class) are appointed as the Damages Class representatives.

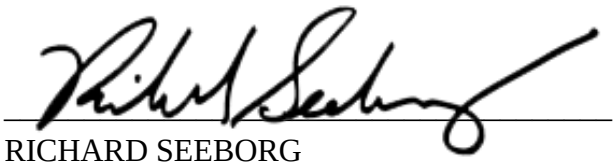
4. The following Injunctive Relief Class is certified pursuant to Rules 23(a) and 23(b)(2):

> All individuals and entities in the United States that, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, and other than for resale, paid and/or provided reimbursement for some or all the purchase price for Xyrem during the time from January 17, 2017, through and until May 12, 2023.
>
> Excluded from the Injunctive Relief Class are (1) Defendants and their counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates, (2) Express Scripts Specialty Distribution Services, Inc. and any of its counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates, (3) federal and state governmental entities. This exclusion does not include cities, towns, municipalities, counties or carriers for Federal Employee Health Benefit plans, (4) any "single flat co-pay" consumers whose benefit plan requires a co-payment that does not vary based on the drug's status as a brand or generic, and (5) all judges assigned to this case and any members of their immediate families.

5. Class Plaintiffs (with the exception of BCBSA) are appointed as the Injunctive Class representatives.
6. Pursuant to Rule 23(g), Co-lead Counsel and the Plaintiffs' Steering Committee, as listed in the motion for class certification, are appointed as Class Counsel for both certified Classes.
7. Defendants' motion to exclude Plaintiffs' expert opinion testimony is denied.
8. The motion for preliminary approval of class settlement is granted as to the Settlement Class, under the definition stated in the motion. Claims against Amneal and Lupin are stayed pending final approval of the settlement. Citibank is appointed as the Escrow Agent for the settlement; Class Plaintiffs (with the exception of BCBSA, which has been dismissed) are appointed as Settlement Class representatives; and Girard Sharp LLP and Motley Rice LLC are appointed as Class Counsel.
9. Within 21 days of the entry of this order, Plaintiffs shall file a motion for approval of a notice plan regarding the two certified Classes as well as the Settlement Class.
10. A separate order will enter regarding the related administrative motions to file under seal.

IT IS SO ORDERED.

Dated: May 12, 2023



RICHARD SEEBORG
Chief United States District Judge

United States District Court
Northern District of California