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| 15 | IN RE XYREM (SODIUM OXYBATE) ANTITRUST LITIGATION | CASE NO. 3:20-md-02966-RS | | | |
| 16 | | CLASS REPRESENTATIVE PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR | | | |
| 17 18 | This Document Relates to: | FINAL APPROVAL OF CLASS ACTION | | | |
| 19 | All Class Actions | SETTLEMENT AND CERTIFICATION OF SETTLEMENT CLASS | | | |
| 20 | | MOTION HEARING | | | |
| 21 | | DATE: January 11, 2024 | | | |
| 22 | | TIME: 1:30 PM LOCATION: Courtroom 3 | | | |
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NOTICE OF MOTION AND MOTION FOR FINAL APPROVAL

PLEASE TAKE NOTICE THAT on January 11, 2024 at 1:30 PM, in Courtroom 3 of the United States District Court for the Northern District of California, San Francisco Division, located at 450 Golden Gate Avenue, San Francisco, CA 94102, Class Representative Plaintiffs, on behalf of a proposed Settlement Class of all persons and entities in the United States that, for the 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 February 28, 2023 (the "Execution Date"), will and hereby do move the Court for an order and judgment granting final approval of the Amneal/Lupin Settlement, certifying the proposed Settlement Class for settlement purposes, appointing Class Counsel and Class Representative Plaintiffs to represent the Settlement Class, and approving settlement administration costs.

A copy of Class Representative Plaintiffs' [Proposed] Order Granting Motion for Final Approval of Amneal/Lupin Settlement and Judgment is separately submitted with this Motion. Because the opt-out and objection deadlines are not until November 27, 2023, the [Proposed] Order attached to this motion has placeholders related to the number of opt-outs and objections. Class Representative Plaintiffs will submit an updated [Proposed] Order with their reply brief.

Class Representative Plaintiffs' Motion is based on Federal Rule of Civil Procedure 23, the Northern District's Procedural Guidance for Class Action Settlement ("District Guidelines"), this Notice of Motion, the supporting Memorandum of Points and Authorities, the joint Declaration of Dena Sharp and Michael Buchman ("Joint Decl."), the pleadings and papers on file in this Action, and any other matter this Court may take notice of. Although the schedule for settlement-related proceedings (ECF 526) also contemplates the potential filing of a motion for the payment of attorneys' fees and expenses, because Class Representative Plaintiffs are requesting that the settlement proceeds be used to pay for ongoing litigation expenses, co-lead class counsel and the members of the Plaintiffs' Steering Committee ("Class Counsel") are not seeking payment of attorneys' fees or past expenses from the settlement.

INTRODUCTION

MEMORANDUM OF POINTS AND AUTHORITIES

I.

Class Representative Plaintiffs move for final approval of a proposed class action settlement (the "Amneal/Lupin Settlement") with Defendants Amneal Pharmaceuticals LLC ("Amneal") and Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin," and together with "Amneal," the "Settling Defendants"). The Settlement Agreement provides for a cash settlement fund of \$3,400,000² and evidentiary and other cooperation by each Settling Defendant, in exchange for a release of the class claims against the Settling Defendants. *See* Settlement Agreement, ECF 423-2 at 6.³ This settlement does not include the other Defendants in the litigation: Jazz Pharmaceuticals Plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz"), and Hikma Labs, Inc. (formerly known as Roxane Laboratories, Inc.), Hikma Pharmaceuticals USA Inc. (formerly known as West-Ward Pharmaceuticals Corp.), Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc. (collectively, "Hikma") (together, with Jazz, the "Remaining Defendants"). No class or individual claims against the Remaining Defendants will be released in connection with the Amneal/Lupin Settlement.

The Court previously granted preliminarily approval of the proposed Amneal/Lupin Settlement and directed notice to the proposed Settlement Class. ECF 500 ("Preliminary Approval Order") and ECF 509 ("Notice Order"). That notice has been viewed millions of times. *See* ECF 547.

The Amneal/Lupin Settlement provides a tangible benefit to Settlement Class members. It is the product of extensive arm's-length negotiations among experienced lawyers familiar with the legal and factual issues in this case, including an acute awareness of the risks of summary judgment, trial, and an

¹ The capitalized terms are intended to have the same meaning as defined in the Settlement Agreement except as otherwise noted.

² Under the terms of the Settlement Agreement, Amneal has deposited into an escrow account \$1,900,000 and Lupin has deposited \$1,500,000. Each Settling Defendant also agreed to provide certain evidentiary and other cooperation. ECF 423-1 at 6.

³ Unless otherwise noted, docket citations are to the MDL docket.

⁴ Par Pharmaceuticals, Inc. is also named as a Defendant in the Consolidated Class Action Complaint, but claims against Par have been stayed pursuant to bankruptcy proceedings initiated by its parent company, Endo International plc. *See* ECF 311 (Notice of Suggestion of Bankruptcy and Automatic Stay of Proceedings).

appeal. The terms of the Amneal/Lupin Settlement treat class members equitably relative to each other. Class Representative Plaintiffs and Class Counsel believe this settlement is fair, reasonable, adequate, in the best interests of the Settlement Class, and respectfully request that the Court grant final approval and certify the Settlement Class.

II. BACKGROUND AND PROCEDURAL HISTORY

Class Representative Plaintiffs and the Settling Defendants seek to resolve the antitrust and consumer protection claims asserted against the Settling Defendants involving alleged restrictions of competition in the market for Xyrem and generic Xyrem. Class Representative Plaintiffs allege that Defendants entered into anticompetitive agreements that delayed full competition from generic Xyrem. The settlement of Class Representative Plaintiffs' claims against the Settling Defendants came after years of hard-fought litigation and provides substantial benefit to settlement class members.

A. The Litigation

As detailed in Class Representative Plaintiffs' Motion for Preliminary Approval (ECF 423) and as summarized below, the Amneal/Lupin Settlement was reached after years of active litigation.

In 2020, Class Representative Plaintiffs filed several class actions against Amneal and Lupin, as well as Jazz, Hikma, and Par. On March 8, 2021, Class Representative Plaintiffs filed a Consolidated Class Action Complaint ("CCAC"), which contains seventeen counts asserting various antitrust and consumer protection claims under federal and state law. *See* ECF 62 at 88-121. In the CCAC, Class Representative Plaintiffs sought damages on behalf of classes consisting of all purchasers in the United States and a subset of 36 states, and nationwide injunctive relief.

To streamline this litigation, the Honorable Lucy H. Koh directed the parties to identify ten causes of action that would proceed through initial resolution, with litigation of the remaining causes of action to be discussed with the Court thereafter. ECF 66 at 2. After the parties made a submission pursuant to the Court's directive, Judge Koh entered an Order on March 30, 2021, identifying those causes of action. ECF 83. Judge Koh subsequently largely denied Defendants' motion to dismiss Class Representative Plaintiffs' seven state law claims, but granted the motion as to the three federal Sherman Act damages claims. ECF 138 at 80-81.

Discovery began before motions to dismiss were filed and concluded on January 30, 2023.

Defendants have produced millions of pages of documents, provided written discovery and information, and the parties have conducted twenty-nine depositions of Defendants' employees and third parties.

Class Representative Plaintiffs have produced relevant documents, searched their files using the parties' agreed-upon search terms, responded to multiple sets of interrogatories, and appeared for depositions.

On November 16, 2022, Class Representative Plaintiffs moved to certify two classes of purchasers of Xyrem and Xywav, seeking damages under Fed. R. Civ. P. 23(b)(3) and injunctive relief under Fed. R. Civ. P. 23(b)(2). ECFs 351–53. Defendants opposed and the issue was fully briefed. Defendants also moved to exclude the testimony of each of Class Representative Plaintiffs' experts involved in the motion for class certification. ECF 473. Class Representative Plaintiffs opposed the *Daubert* motions. ECF. No. 479.

Both issues were heard on April 19, 2023. ECF 494. And, on May 12, 2023, the Court denied the *Daubert* motions and granted Class Representative Plaintiffs' motion for both classes, both of which consisted of all purchasers of Xyrem, but not Xywav. ECF 500 at 28-29. Under Federal Rule of Civil Procedure 23(a) and 23(b)(3), the Court certified the following Classes:

• The Damages Class: 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, 2023.⁵

⁵ 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.

• 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 during the time from January 17, 2017, through and until May 12, 2023.⁶

B. Terms of the Settlement

The parties reached the proposed Settlement now before the Court as a result of hard-fought and adversarial litigation. The Amneal/Lupin Settlement provides for a \$3,400,000 cash payment, no portion of which is eligible to revert to the Settling Defendants after final approval. In exchange, class members agree to release claims against the Settling Defendants only. ECF 423-2 at 6-7, 10-11. As described in Class Representative Plaintiffs' Motion for Preliminary Approval, the Settlement Fund will be used for the payment of common expenses in connection with the continued prosecution of this litigation. ECF 423 at 26-27.

In short, the Settlement Agreement provides for a substantial benefit to settlement class members and does not encumber other, separate claims that class members might have.

C. Preliminary Approval and Notice to the Class

In separate Orders dated May 12, 2023, and June 28, 2023, the Court preliminarily approved the Amneal/Lupin Settlement and appointed A.B. Data as the Settlement Administrator. EFC 500 at 27-28; ECF 524. Following the Court's order, A.B. Data established a settlement website at inrexyremantitrustlitigation.com, which includes: the long-form notice (explaining the procedures to object or exclude themselves); a contact information page that includes an address, email address, and telephone numbers for the Class Settlement Administrator; the Consolidated Class Action Complaint;

⁶ 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 copay" 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.

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the Amneal/Lupin Settlement Agreement; the Order Granting Class Certification and Preliminary Approval of the Amneal/Lupin Settlement; and the order approving the form and manner of Notice. See ECF 547. In addition, the Settlement Administrator also operated a toll-free number for Settlement Class Member inquiries. *Id*.

Notice of the Amneal/Lupin Settlement was provided by: (1) direct notice via USPS First-Class Mail to entities in A.B. Data's TPP Database; (2) direct notice to the Consumers identified in the pharmacy dispensing data for Xyrem via email and, for those whose email was not available, via mail; (3) publication notice of the Amneal/Lupin Settlement, which comprised approximately 12 million impressions and targeted likely settlement class members, on relevant websites and social media platforms; and (4) publication on the settlement website. *Id.* at 2-3.

D. **Class Response**

Although the deadline for opt-out requests and objections is not until November 27, the response from the class thus far has been positive. As of November 10, 2023, out of the many thousands of class members, A.B. Data has received sixteen opt out requests from TTPs⁷ and none from consumers. ECF 547 at 4; Joint Decl. at ¶ 11. Furthermore, A.B. Data has received no objection as of November 10, 2023. Id. The low number of opt-outs and the absence of objections reflects positively on the Amneal/Lupin Settlement.

III. **ARGUMENT**

Final approval is a multi-step inquiry: first, the Court must determine that the settlement proposal is "fair, reasonable, and adequate;" second, it must determine whether notice has been provided in a manner consistent with Rule 23 and due process; and third, it must certify the proposed

⁷ United HealthCare Services, Inc. ("UHS"), which has been pursuing its individual claims alongside the class plaintiffs, submitted a single opt out request on behalf of itself and eighty-three subsidiaries and affiliates (such as state-specific United health plans). UHS represented in its complaint that it is the payor entity for drugs dispensed to all United members, and it obtained assignments from its affiliated plan entities solely out of an abundance of caution. See UHS Compl. ¶¶ 7-10.

settlement class. *See* Fed. R. Civ. P. 23(e)(2); *Adoma v. Univ. of Phoenix Inc.*, 913 F. Supp. 2d 964, 972 (E.D. Cal. 2012). The Amneal/Lupin Settlement satisfies each of these requirements.

A. The Amneal/Lupin Settlement is Fair, Adequate, and Reasonable

A court may approve a proposed class action settlement "only after a hearing and on finding that it is fair, reasonable, and adequate after considering whether: (A) the class representatives and class counsel have adequately represented the class; (B) the proposal was negotiated at arm's length; (C) the relief provided for the class is adequate, taking into account: (i) the costs, risks, and delay of trial and appeal; (ii) the effectiveness of any proposed method of distributing relief to the class, including the method of processing class-member claims; (iii) the terms of any proposed award of attorney's fees, including timing of payment; and (iv) any agreement required to be identified under Rule 23(e)(3); and (D) the proposal treats class members equitably relative to each other." Fed. R. Civ. P. 23(e)(2).9

As explained more fully below, the proposed Amneal/Lupin Settlement is fair, reasonable, and adequate. Class Counsel are highly experienced in complex pharmaceutical and other class litigation, have actively litigated this case for nearly three years, and negotiated a settlement at arms-length. The Amneal/Lupin Settlement provides significant benefits for settlement class members. And, with respect to the continued litigation against the Remaining Defendants, the Amneal/Lupin Settlement streamlines Class Representative Plaintiffs' case, eases discovery burdens, and facilitates the preparation for a

⁸ The effectiveness of distribution factor is not applicable here as Class Representative Plaintiffs propose to reserve the settlement proceed to fund the ongoing litigation against the Remaining Defendants.

⁹ Before Rule 23 was amended in December 2018, the Ninth Circuit had enumerated a similar list of factors to consider in evaluating a proposed class settlement. *See Churchill Village, L.L.C. v. Gen. Elec.*, 361 F.3d 566, 575 (9th Cir. 2004) (enumerating the following factors: "(1) the strength of the plaintiffs' 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 to the proposed settlement"). In the notes accompanying the Rule 23 amendments, the Advisory Committee explained that the amendments were not designed "to displace any factor, but rather to focus the court and the lawyers on the core concerns of procedure and substance that should guide the decision whether to approve the proposal." Accordingly, courts apply the framework of Rule 23 while "continuing to draw guidance from the Ninth Circuit's factors and relevant precedent." *Hefler v. Wells Fargo & Co.*, No. 16-cv-05479-JST, 2018 WL 6619983, at *4 (N.D. Cal. Dec. 17, 2018), *aff'd sub nom. Hefler v. Pekoc*, 802 F. App'x 285 (9th Cir. 2020).

focused trial.

1. Rule 23(e)(2)(A): Class Representative Plaintiffs and Class Counsel Have Adequately Represented the Settlement Class

Class Representative Plaintiffs and Class Counsel have vigorously prosecuted this case through discovery, motion practice, and preparations for trial. Class Counsel thus "possessed sufficient information to make an informed decision about settlement." *Hefler*, 2018 WL 6619983 *6. Against this backdrop, in its Preliminary Approval Order the Court found that Class Representative Plaintiffs and Class Counsel adequately represented the interests of the Settlement Class. ECF 500 at 7. The ongoing notice program and Class Counsel's other work to advance the proposed settlement further confirm the Court's previous finding and support a finding that this element is satisfied. Fed. R. Civ. P. 23(e)(2)(A).

2. Rule 23(e)(2)(B): The Amneal/Lupin Settlement Was Negotiated at Arm's Length

The Amneal/Lupin Settlement is the product of serious, non-collusive, arm's length negotiations by experienced counsel with the benefit of a full fact discovery record. Class Counsel acted in the best interests of the Settlement Class, and there is no evidence to the contrary—for example, by compromising the claims of the Settlement Class in exchange for higher fees—and there has been no agreement concerning attorneys' fees or otherwise disadvantaging the Settlement Class.

Before agreeing on the terms of the Amneal/Lupin Settlement, the parties engaged in extensive factual investigation, which included dozens of depositions, the production and review of millions of pages of documents, extensive written discovery, robust motion practice, and expert discovery. Joint Decl. at ¶ 5. The record was thus sufficiently developed to fully inform the parties and enable them to adequately evaluate the strengths and weaknesses of their respective positions and risks to both sides if the case did not settle. *See Nat'l Rural Telecomm. Coop. v. DIRECTV*, 221 F.R.D. 523, 528 (C.D. Cal. 2004); 4 A. Conte & H. Newberg on Class Actions at § 11.24 (4th ed. 2002) ("A court is more likely to approve a settlement if most of the discovery is completed because it suggests that the parties arrived at a compromise based on a full understanding of the legal and factual issues surrounding the case.").

3. Rule 23(e)(2)(C): The Relief Provides Adequate Recovery to the Class

In the Rule 23(e) analysis, "[t]he relief that the settlement is expected to provide to class members is a central concern." Fed. R. Civ. P. 23(e)(2)(C)-(D) advisory committee's note to 2018 amendment. "The Court therefore examines 'the amount offered in settlement." *Hefler*, 2018 WL 6619983 *8 (quoting *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1026 (9th Cir. 1998)). As detailed below, the Amneal/Lupin Settlement provides adequate relief to the class, particularly when weighed against the risks of continued litigation.

a) The Settlement Terms Provide Adequate Relief to the Settlement Class

The proposed Settlement provides substantial consideration for the benefit of the Settlement Class. The Settlement Fund of \$3,400,000, together with any accrued interest or earnings after deposit, will be held in escrow. See ECF 423-2 at 6. The funds will be used to pay ongoing litigation costs and expenses incurred in Class Representative Plaintiffs' continued litigation against the remaining Defendants. See id. at 6-8. Class Counsel recommends these terms, as they are in the best interest of the Settlement Class. See Joint Decl. at ¶ 7. See Giusti-Bravo v. U.S. Veterans Admin., 853 F. Supp. 34, 40 (D.P.R. 1993) ("In view of the fact that competent and experienced counsel have been able to conduct ample discovery which allowed them to properly assess the probability of success on the merits of the putative class claim . . . their recommendation should be entitled to substantial weight"). And the proposed use of the Amneal/Lupin Settlement funds will help, rather than hinder, Class Representative Plaintiffs' efforts to recover the full measure of the anticompetitive overcharge damages from Jazz and Hikma. Thus, while the fund is significant standing alone, the amount of relief provided to the class is particularly reasonable relative to the risk of continued litigation, and in light of the fact that it furthers the Class's potential for a substantial recovery from the Remaining Defendants.

Reserving the entirety of the \$3.4 million for ongoing litigation expenses is also reasonable in light of the costly nature of pharmaceutical antitrust class actions. Class Representative Plaintiffs have retained experts covering a wide range of topics including patent issues, classwide impact and damages, the economics of the challenged settlement agreements, market power, and Jazz's REMS-related conduct. Expert costs incurred during pretrial proceedings and trial will, therefore, be significant and

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taking a complex case to trial is a costly endeavor. Even in cases in which there were two classes of purchasers (direct purchasers, and indirect purchasers) splitting the litigation expenses, plaintiffs have easily spent as much, or more, than \$3.4 million. E.g., In re Restasis Antitrust Litig., Case No. 1:18-md-2819, ECF 741 (E.D.N.Y. Aug. 2, 2022) (allowing end-payer plaintiffs \$4,635,684 in expenses, despite separate cost award to direct purchaser plaintiffs).

b) The Risks of Continued Litigation Against the Settling Defendants

Continued litigation against the Settling Defendants involves substantial risks and would complicate the litigation against the Remaining Defendants. Though Class Representative Plaintiffs and their counsel have confidence in their claims, a favorable outcome at trial was not assured. Class Representative Plaintiffs would need to prevail at summary judgement, overcome numerous defenses at trial, and possibly succeed on appeal. Furthermore, Defendants and their experts would surely contest every theory of liability and measure of damages, including, among other things: (i) whether the Settling Defendants' agreements with Jazz were anticompetitive or had procompetitive justifications, (ii) whether the challenged conduct resulted in overcharges to Class Representative Plaintiffs, and (iii) whether the lawsuit is blocked by the statute of limitations and/or laches.

There were also substantial questions as to whether Class Representative Plaintiffs would be able to prove at trial that Amneal and Lupin's conduct, as later-filing generics, caused the anticompetitive overcharges that the Class has paid. Trial would have involved a clash of expert analysis as to whether the Settling Defendants' agreements with Jazz were anticompetitive; how damages or restitution should be calculated; and what damages and/or restitution, if any, should be awarded.

Attorneys' Fees and Expenses c)

The payment of attorneys' fees, expenses, and service awards, if any, is subject to approval of the Court based on a finding that such amounts are fair and reasonable. If the Court approves Class Representative Plaintiffs' request to use the Settlement Fund for costs and expenses incurred in the ongoing litigation, Class Representative Plaintiffs do not intend to move for an award of attorneys' fees or service awards from the Settlement. See Joint Decl. at ¶ 8. Instead, the entire Settlement Fund (less any administrative expenses) would be used for the payment of common expenses (i.e. expert fees, database hosting, depositions, etc.) in connection with the continued prosecution of this litigation on

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27 28 behalf of the Xyrem and Xywav purchasers. Thus, there is thus no aspect of the Amneal/Lupin Settlement regarding the payment of attorneys' fees and expenses that raises any concern about the reasonableness, fairness, or adequacy of the Amneal/Lupin Settlement. 10

d) **Other Agreements**

The Court is required to consider "any agreements required to be identified under Rule 23(e)(3)." The Court has been provided with the Amneal/Lupin Settlement Agreement and relevant accompanying materials. See ECF 423-2. There are no other agreements made in connection with the settlement.

4. Rule 23(e)(2)(D): The Proposal Treats Class Members Equitably Relative to **Each Other**

As previously discussed, the Settlement Fund of \$3,400,000 and any accrued interest or earnings after deposit, will be held in escrow, see ECF 423-2 at 6, and used to pay litigation costs and expenses incurred in Class Representative Plaintiffs' continued litigation against the remaining Defendants. See id. at 6-8. The relief thus treats class members equitably relative to each other because the class will benefit from the continued litigation against the Remaining Defendants.

5. The Amneal/Lupin Settlement Satisfies the Remaining Ninth Circuit **Approval Factors**

In addition to the framework of Rule 23 as amended in 2018, courts "continu[e] to draw guidance from the Ninth Circuit's factors and relevant precedent" in evaluating a proposed class settlement. Hefler, 2018 WL 6619983, at *4; Churchill, 361 F.3d at 575 (courts should consider "(1) the strength of the plaintiffs' 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 to the proposed settlement").

¹⁰ In any event, the parties have reached no agreements regarding the amounts of attorneys' fees, expenses, and service wards that would be paid. Joint Decl. at ¶ 9; see, e.g., In re Hyundai & Kia Fuel Econ. Litig., 926 F.3d 539, 569-70 (9th Cir. 2019) (en banc) (rejecting objection because counsel "did not reach an agreement with the automakers regarding the amount of attorney's fees to which they were entitled," which "[p]rovid[es] further assurance that the agreement was not the product of collusion").

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Many of these factors, such as the strength of plaintiffs' case, the risk and duration of further litigation, and the amount offered, overlap with the Rule 23(e)(2)(C) factors and are addressed above. The remainder favor final approval as well, as described below.

a) The Response of Class Members Has Been Positive

As of November 10, 2023, out of the thousands of notices delivered and the millions of impressions from banner and social media ads, there were 16 opt-outs and no objections. Joint Decl. at ¶ 11. These figures represent a positive response from the class. *See Churchill*, 361 F.3d at 577 (noting a court may infer appropriately that a class action settlement is fair, adequate, and reasonable when few class members object to it); *Zepeda v. PayPal, Inc.*, 2017 WL 1113293, at *16 (N.D. Cal. Mar. 24, 2017) ("[T]he indisputably low number of objections and opt-outs, standing alone, presents a sufficient basis upon which a court may conclude that the reaction to settlement by the class has been favorable); *Cruz v. Sky Chefs, Inc.*, 2014 WL 7247065, at *5 (N.D. Cal. Dec. 19, 2014) ("A court may appropriately infer that a class action settlement is fair, adequate, and reasonable when few class members object to it."). Consistent with the Court-ordered schedule, Class Representative Plaintiffs will submit updated opt-out and objections statistics on December 1, 2023, and respond to any objections that may be submitted on December 11, 2023. ECF 526.

b) Class Counsel Endorses the Settlement

In considering whether to grant final approval, courts afford significant weight to the opinions of experienced class counsel who are familiar with the litigation. *Ontiveros v. Zamora*, 303 F.R.D. 356, 371 (E.D. Cal. 2014) (citing *Hanlon*, 150 F.3d at 1026); *see also In re Volkswagen "Clean Diesel"*Mkt'g, Sales Pracs., and Prods. Liab. Litig., 2016 WL 6248426, at *14 (N.D. Cal. Oct. 25, 2016)

("Courts afford 'great weight to the recommendation of counsel, who are most closely acquainted with the facts of the underlying litigation.") (quoting Nat'l Rural Telecomms. Coop. v. DIRECTV, Inc., 221 F.R.D. 523, 528 (C.D. Cal. 2004)). This is because "[p]arties represented by competent counsel are better positioned than courts to produce a settlement that fairly reflects each party's expected outcome in litigation." In re Pac. Enters. Sec. Litig., 47 F.3d 373, 378 (9th Cir. 1995).

Class Counsel is experienced in complex pharmaceutical and other class litigation and settlement, including in antitrust cases like this one. Joint Decl. at ¶ 7. Based on this experience, Class

Counsel firmly believe that the Amneal/Lupin Settlement provides a positive outcome for class members and, in light of the uncertainties and risks in continued litigation, strongly recommends its approval.

6. The Court-Approved Notice Plan Satisfied Due Process and Adequately Provided Notice to Class Members

Rule 23 requires that prior to final approval, "[t]he court must direct notice in a reasonable manner to all class members who would be bound by the proposal." Fed. R. Civ. P. 23(e)(1). For classes certified under Rule 23(b)(3), "the court must direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B). The Rule provides that "notice may be by one or more of the following: United States mail, electronic means, or other appropriate means." *Id*.

A.B. Data has carried out a thorough notice campaign. A.B. Data provided individual notice to TPP class members. ECF 547. The over 62,000 direct notices sent by A.B. Data included 42,006 mail notices to TPPs and intermediaries employed by TPPs,¹¹ 19,789 emails to consumer class members, and 1,816 mail notices to consumer class members¹² (where an email address was not available or whose email notices were returned as undeliverable). *Id.* at 1-3.

In addition to direct notice, A.B. Data also carried out a robust publication notice campaign. The program includes targeted banner advertising on selected advertising networks and social media, which are targeted to class members. *Id.* at 2. The Digital Notices link directly to the Settlement website. *Id.* The Digital Notices served at least 12 million impressions. *Id.* The Digital Notices began running on July 28, 2023, and ran for 30 days. *Id.*

The Settlement Notice represents the best notice practicable. Copies of the final versions of all the notice documents are attached as exhibits to the Miller Declaration (ECF 547 Exs. A-E); they are clear and concise, and directly apprise class members of all the information they need to know to opt out

¹¹ 161 of the notices to TPP class members were returned as undeliverable. A.B. Data located updated addresses and remailed 119 of these notices. ECF 547 at 3.

¹² Of the 1,816 notices mailed to consumer class members, 30 notices were returned as undeliverable. A.B. Data located updated addresses and remailed 14 of these notices. ECF 547 at 3.

1 or object. See Fed. R. Civ. P. 23(c)(2)(B). The Notice Plan is consistent with other similar court-2 approved notice plans, the requirements of Federal Rule of Civil Procedure 23(c)(2)(B), and the Federal Judicial Center ("FJC") guidelines for adequate notice. See In re Lidoderm Antitrust Litig., No. 14-md-3 02521 (N.D. Cal June 13, 2017), ECF 751 (approving similar notice plan); In re Zetia (Ezetimibe) 4 5 Antitrust Litig., 18-md-02836 (E.D. Va. 2022), ECF 1497 (same); In re Aggrenox Antitrust Litig., No. 6 14-md-02516 (D. Conn. Mar. 6, 2018), ECF 766 (same); In re Solodyn (Minocycline Hydrochloride) 7 Antitrust Litig., No. 14-md-2503 (D. Mass. Dec. 4, 2017), ECF 828 (same).

As there is no alternative method of notice that would be practicable here or more likely to notify class members, the Notice Plan constitutes the best practicable notice to class members and complies with the requirements of Due Process.

В. The Court Should Certify the Settlement Class

In the Preliminary Approval Order, the Court found that the differences between the certified classes¹³ and the Settlement Class did not substantively alter the Court's Rule 23 analysis or provide any basis for declining to certify the Settlement Class, which is defined as:

All 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. 14

ECF 500 at 27. The factors that supported the Court's prior conclusions remain true, and the Settlement Class should be certified.

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¹³ These were the **Damages Class** (All individuals, in the certain states, who paid for Xyrem between January 17, 2017 and May 12, 2023) and an **Injunctive Relief Class** (All individuals and entities in the United States, who paid for Xyrem between January 17, 2017 and May 12, 2023).

¹⁴ Excluded from the Settlement Class are: (a) Defendants and their counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates; (b) Express Scripts Specialty Distribution Services, Inc. and any of its counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates; (c) federal and state governmental entities, not including cities, towns, municipalities, counties or carriers for Federal Employee Health Benefit plans; (d) 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 (e) all judges assigned to this case and any members of their immediate families. The execution date is February 28, 2023. See ECF 423-2.

Because the Court already certified similar classes in this matter under Rule 23(b)(3), "the only information ordinarily necessary is whether the proposed settlement calls for any change in the class certified, or of the claims, defenses, or issues regarding which certification was granted." Fed. R. Civ. P. 23, 2018 committee notes subdivision(e)(1). The Court must then determine whether the proposed modification alters the reasoning underlying its earlier decision to grant class certification pursuant to Rule 23(b)(3). See, e.g., Allen v. Similasan Corp., 2017 WL 1346404, at *3 (S.D. Cal. Apr. 12, 2017) (approving expansion of settlement class where the expansion did not change the court's previous class certification analysis of whether Rule 23(a) and 23(b) had been met). If it does not, the Court need not revisit the Rule 23(b) analysis and instead must only "consider[] whether the Settlement is fair, adequate, and reasonable." De La Torre v. CashCall, Inc., 2017 WL 2670699, at *6 (N.D. Cal. June 21, 2017). Plaintiffs must identify and explain any differences between the certified class and the Settlement Class and between the claims in the operative complaint and the Released Claims. See District Guidelines ¶ 1(a), (b), (d).

The Settlement Class is co-extensive with the certified class, except that the claims for the proposed Settlement Class have a different end date, have an earlier start date, include purchasers nationwide, and include purchases of Xywav in addition to Xyrem. The addition of an end date reflects when the parties settled and is appropriate and necessary for administration purposes. *See Foster v. Adams & Assocs.*, 2021 WL 4924849, at *3 (N.D. Cal. Oct. 21, 2021) (granting modification to the previously certified class to specify end date). And the start date of January 1, 2015, is similarly justifiable. As the Court stated in its Order Granting Preliminary Approval, ECF 500 at 28, "2015 was the year included in the class definition in the CAC, and as such, this date was the date Plaintiff had in mind when they began settlement negotiations[.]" Furthermore, the release of damages for two years prior to 2017 is likely a small concession "given the small settlements that individual consumers could have expected." *Id.* Finally, there is good reason to settle claims of nationwide purchasers in light of the nationwide injunctive relief class and other nationwide claims. *See* ECF 500 at 29. And including nationwide purchasers and Xywav purchasers in the Settlement Class definition likewise does not change the overall common nature of the claims at issue, or the benefits derived from the Settlement.

The Settlement Class is also appropriately certified under a traditional application of the Rule 23

factors. The slight differences between the litigation classes and the proposed Settlement Class do not alter the Court's prior certification analysis, except that the predominance analysis operates differently, but is less stringently applied in the settlement context. *See Hyundai*, 926 F.3d at 558.

Rule 23(a)(1): Numerosity. The Settlement Class includes both individual consumers and third-

Rule 23(a)(1): Numerosity. The Settlement Class includes both individual consumers and third-party payors who purchased, paid and/or provided reimbursement for some or all of the cost of Xyrem and/or Xywav prescriptions. Data from Express Scripts Specialty Distribution Services ("ESSDS"), the sole distributor of Xyrem and Xywav, confirms that tens of thousands of prescriptions for Xyrem and/or Xywav are filled each month. *See* ECF 353 at 20. Courts in the Ninth Circuit generally agree that numerosity is satisfied if the class includes forty or more members. *See* ECF 500 at 6. The Settlement Class easily meets that threshold.

Rule 23(a)(2): Commonality. As in other end-payor pharmaceutical antitrust cases, the Settlement Class satisfies Rule 23(a)(2). This case presents numerous common questions of fact and law that relate to the Settling Defendants' anticompetitive conduct, including whether the Defendants entered into unlawful agreements in restraint of trade to prevent or delay entry of generic competition. See ECF 500 at 7 (listing common questions of law and fact). "Antitrust liability alone constitutes a common question that 'will resolve an issue that is central to the validity' of each class member's claim 'in one stroke'" because proof of the violation "will focus on defendants' conduct and not on the conduct of individual class members." In re High-Tech Employee Antitrust Litig., 985 F. Supp. 2d 1167, 1180 (N.D. Cal. 2013) (citing Dukes, 564 U.S. at 349). The Settlement Class, therefore, satisfies this requirement.

Rule 23(a)(3): Typicality. As before, Class Representative Plaintiffs' claims are typical of the claims of the Settlement Class because: (i) their injury (supracompetitive prices) arises from the same course of conduct (Defendants' anticompetitive conduct); (ii) their claims rely on the same legal theories (unlawful restraint of trade and monopolization); and (iii) their claims allege damages in the form of overcharges. Accordingly, Class Representative Plaintiffs' and the Settlement Class' claims stem from the same practice or course of conduct and "seek to recover pursuant to the same legal theories." Wolin v. Jaguar Land Rover N. Am., LLC, 617 F.3d 1168, 1175 (9th Cir. 2010); see also Just Film v. Buono,

847 F.3d 1108, 1116 (9th Cir. 2017) (class representative's "claim is typical of the class because it shares 'some common question of law and fact with class members' claims'") (quoting Newberg on Class Actions § 3:31 (5th ed.)). Thus, Class Representative Plaintiffs' claims are typical of the Settlement Class.

Rule 23(a)(4): Adequacy. Adequacy is also presumed where, as here, a fair settlement was negotiated at arm's length. 2 Newberg on Class Actions, § 11.28, 11-59. There is no conflict of interest between Class Representative Plaintiffs and settlement class members. *Staton v. Boeing Co.*, 327 F.3d 938, 957 (9th Cir. 2003). Class Representative Plaintiffs have fairly and adequately protected the interests of the Settlement Class.

Rule 23(b)(3): Predominance. Questions common to the Settlement Class predominate over questions affecting only individual class members. Predominance is met when plaintiffs' claims "depend upon a common contention . . . of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). "Even if just one common question predominates, 'the action may be considered proper under Rule 23(b)(3) even though other important matters will have to be tried separately." *Hyundai*, 926 F.3d at 557 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442 (2016)); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (predominance "is a test readily met in certain cases alleging consumer or securities fraud or violations of the antitrust laws.").

The predominance inquiry is more straightforward in the settlement context because, unlike certification for litigation, "manageability is not a concern in certifying a settlement class where, by definition, there will be no trial." *Id.* at 556–57. The central question at this stage will be whether this settlement is fair, reasonable, and adequate. *See Hanlon*, 150 F.3d at 1026-27. Even if the Court examines the disputed questions that would be tried absent settlement, Plaintiffs allege common questions of law and fact, including whether Defendants' conduct violated antitrust and consumer protection laws and delayed the generic entry of Xyrem. *See In re Cipro Cases I & II*, 121 Cal. App. 4th 402, 411 (2004) (collecting cases) ("[C]ommon issues usually predominate in cases where the

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defendants are alleged to have engaged in collusive, anticompetitive conduct resulting in artificially high market-wide prices for a product.").

Though the Court excluded Xywav purchasers from the litigation classes, the settlement does not raise concerns over individual inquiries related to Xyway, such as which "Xyway patients would or could have been prescribed Xyrem instead." ECF 500 at 16 (excluding Xywav purchasers from the litigation class because Plaintiffs did not provide a manageable methodology to identify injured Xywav purchasers); see also In re ZF-TRW Airbag Control Units Prod. Liab. Litig., 2023 WL 6194109, at *12 (C.D. Cal. July 31, 2023) ("A class may be certifiable for settlement even though it may not be certifiable for litigation where the settlement obviates the need to litigate individualized issues that would make a trial unmanageable.") (internal quotations and citations omitted). Here, the settlement obviates the need to conduct individual inquiries into whether Xywav patients would have been prescribed generic Xyrem, as the funds will not be distributed. Furthermore, the inclusion of Xywav purchasers reflects the parties' bargaining and compromises at the time of the settlement, which took place prior to the issuance of the Court's class certification order. *In re Apple Inc. Device Performance* Litig., 50 F.4th 769, 781 (9th Cir. 2022) (analyzing the issues of injury and predominance at the time of settlement). And the Court did not find Xywav purchasers were uninjured, but instead found that Plaintiffs had not supplied a viable methodology for proving classwide injury for Xywav purchasers. Importantly, the inclusion of Xywav in the Settlement Class does not change the common, predominant questions concerning Defendants' conduct.

Rule 23(b)(3): Superiority. Certification of the Settlement Class for settlement purposes will avoid congesting the Court with the need to repeatedly adjudicate such actions; prevent the possibility of inconsistent results; and allow class members an opportunity for redress that might otherwise be denied. And when considering certification for settlement purposes, "a district court need not inquire whether the case, if tried, would present intractable management problems, *see* Fed. Rule Civ. Proc. 23(b)(3)(D), for the proposal is that there be no trial." *Amchem*, 521 U.S. at 620

In sum, the Settlement Class meets all relevant requirements of Rule 23(a) and (b) and should be certified for purposes of settlement. In addition, as noted above, Class Representative Plaintiffs and

Class Counsel have adequately represented the interests of the Settlement Class throughout the course of the litigation and settlement, and the Court should appoint them to represent the Settlement Class.

Costs of Administering the Amneal/Lupin Settlement Are Reasonable

The Settlement Administrator has submitted invoices for its expenses incurred as of October 2023, totaling \$195,926.52. Joint Decl. at ¶ 12. A.B. Data projects that the additional expenses for completing the Court-approved Notice Plan will not exceed \$5,000. *Id.* Accordingly, Class Representative Plaintiffs request that the Court approve payment to A.B. Data of up to \$203,000 for settlement administration costs, which is \$22,000 less than the projected cost in the Long Form Notice. *Id.*; *See also* ECF 511-2. Class Counsel will, of course, only authorize payment from the Settlement Fund for costs that are actually incurred by A.B. Data and reasonably spent. Class Representative Plaintiffs will provide updated information concerning costs incurred and expected future costs in advance of the Fairness Hearing, and are prepared to provide the Court with periodic updates thereafter should that be of assistance to the Court.

IV. CONCLUSION

For the foregoing reasons, Class Representative Plaintiffs and Class Counsel respectfully request that the Court enter the proposed order certifying the Settlement Class, appointing Dena C. Sharp of Girard Sharp LLP and Michael M. Buchman of Motley Rice LLC as Settlement Class Counsel, appointing Class Representative Plaintiffs to represent the Settlement Class, granting final approval of the Amneal/Lupin Settlement, as set forth above and in the accompanying proposed order or such further and additional relief as the Court deems appropriate.

¹⁵ The Settlement Administrator sent a combined notice regarding both the certified class and the Amneal/Lupin Settlement. The manner of notice—and related costs—would have been the same had the Settlement Administrator only sent notice of the Amneal/Lupin Settlement. Thus, no part of the requested payment to the Settlement Administrator reflects costs incurred only for sending notice of the certified class, as opposed to notice of the Amneal/Lupin Settlement.

| 1 | Dated: November 10, 2023 | Respectfully submitted, | |
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| 2 | | | |
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| 16 | | Co-Lead Counsel and Proposed Settlement | |
| 17 | | Class Counsel | |
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| | PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR FINAL APPROVAL OF CLASS | | |

CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2023, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will automatically send notification of the filing to all counsel of record.

By: <u>/s/ Dena C. Sharp</u> Dena C. Sharp