

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Miami-Dade Division
Case No.: 13-CV-21158-LENARD/GOODMAN**

MONICA BARBA, JONATHAN REISMAN,)
KAREN DEREUS, RAYNA DEREUS, JODI)
LEIT, MINDI LEIT, AND BARRIE AND)
BRIAN SHANAHAN, on behalf of themselves)
and all others similarly situated,)

Plaintiffs,)

v.)

SHIRE U.S., INC., SHIRE LLC, and)
DOES 1-100,)

Defendants.)

PRELIMINARY APPROVAL ORDER

Upon review and consideration of the Class Action Settlement Agreement dated April 7, 2016 and the exhibits thereto (collectively, “the Settlement Agreement”), and Plaintiffs’ Motion for Preliminary Approval of the Settlement with Shire U.S. Inc. and Shire LLC (collectively “Shire”), and attachments thereto, filed on behalf of Monica Barba, Jonathan Reisman, Karen DeReus, Rayna DeReus, Jodi Leit, Mindi Leit, and Barrie Shanahan and Brian Shanahan on behalf of their minor child B.S., (collectively, “Plaintiffs”), individually and on behalf of a putative class of indirect purchasers of Adderall XR[®], as defined herein, which Plaintiffs asked the Court to certify for settlement purposes only (“the Settlement Class”)

IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

1. Upon review and consideration of the Settlement Agreement, the Court finds that the Settlement between the Settlement Class and Shire was arrived at by arms’ length

negotiations by highly experienced counsel, is fair, is in the best interests of the members of the Settlement Class, and is hereby **PRELIMINARILY APPROVED**, subject to further consideration at the Fairness Hearing provided for below.

2. All defined terms contained herein shall have the same meaning set forth in the Settlement Agreement.

3. Pursuant to Federal Rule of Civil Procedure Rule 23, and for settlement purposes only, the Court hereby certifies this Action as a class action on behalf of the following Settlement Class:

All persons who, for personal or household use, purchased or paid for some or all of the purchase price for branded Adderall XR[®] from January 1, 2007 through the date the Court enters an order granting Preliminary Approval of the Settlement in the District of Columbia and the following states (collectively “the Territory”):

Alabama, Arizona, California, Delaware, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, New Jersey, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin.

Excluded from the Settlement Class are:

- (i) third party payors;
- (ii) persons and entities who purchased directly from Shire;
- (iii) persons and entities who purchased only for resale purposes;
- (iv) “Flat co-pay” or “Cadillac Plan” customers who only made fixed dollar-amount co-payments that do not vary between Adderall XR[®] and its generic equivalents;
- (v) patients with insurance coverage that provided for a flat-rate co-pay provision;
- (vi) governmental entities;

(vii) Shire, its officers, directors, affiliates, legal representatives, employees, predecessors, successors, subsidiaries and assigns, and entities in which Shire has a controlling interest; and

(viii) the judges, justices, magistrates, or judicial officers presiding over this matter.

The persons or entities described in this paragraph 2 shall be herein referred to as the “Settlement Class.”

4. With respect to the Settlement Class, the Court preliminarily finds the prerequisites for a class action under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure have been met, in that:

a. Pursuant to Fed. R. Civ. P. 23(c)(1)(B), the Settlement Class presents the following claims and issues:

- i. Whether Shire unlawfully delayed entry of a generic version of Adderall XR[®] in violation of the federal or state antitrust, unfair competition, consumer protection, or unjust enrichment laws of the states identified in the Territory defined above in paragraph 2;
- ii. Whether Shire’s alleged unlawful activity caused actual injury to members of the Settlement Class; and
- iii. The amount of damages, if any, owed to the members of the Settlement Class under the federal or state antitrust, unfair competition, consumer protection, or unjust enrichment laws of the states identified in the Territory defined above in paragraph 2.

b. Pursuant to Fed. R. Civ. P. 23(a)(1), the Settlement Class is so numerous that joinder of all members is impracticable.

- c. Pursuant to Fed. R. Civ. P. 23(a)(2), there are questions of law and fact common to the Settlement Class, including:
- i. Whether Shire filed sham patent litigations against generic competitors of Adderall XR[®] including Barr Laboratories, Inc. (“Barr”) and Impax Laboratories, Inc. (“Impax”);
 - ii. Whether Shire’s Citizen Petition submitted to the Food and Drug Administration (“FDA”) during FDA’s review of Abbreviated New Drug Applications (“ANDAs”) for generic Adderall XR[®] was a “sham” within the meaning of *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993), or whether the petition was genuinely aimed at procuring favorable governmental action and therefore deserving of protection under the First Amendment of the U.S. Constitution;
 - iii. Whether the settlement agreements resolving Shire’s patent litigations against Barr and Impax provided them with “reverse payments” in violation of *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013);
 - iv. Whether Shire breached supply agreements pursuant to which Shire agreed to supply Barr and Impax with authorized generic (“AG”) versions of Adderall XR[®];
 - v. Whether Shire executed new contracts with managed care organizations (“MCOs”) whereby Shire agreed to pay higher than usual rebates to the MCOs and in return the MCOs agreed to provide preferred placement of Adderall XR[®] as compared to the AGs; and

vi. Whether, and to what extent, Shire's conduct caused injury to Plaintiffs and the individual members of the Settlement Class (and, if so, the appropriate measure of damages) or whether, and to what extent, Settlement Class members were uninjured by Shire's conduct.

d. Pursuant to Rule 23(a)(4), the Court determines, in connection with and for purposes of settlement, that the Class Representatives will fairly and adequately protect the interests of the Settlement Class. All of the Settlement Class members share a common interest in proving Shire's alleged anticompetitive conduct and in recovering damages.

e. Counsel for the Settlement Class ("Class Counsel") is also adequate, and is well-qualified to represent the Settlement Class in this case given their experience in prior cases and the vigor with which they have prosecuted the above-captioned action ("the Action") thus far.

f. Pursuant to Rule 23(b)(3), the Court determines that, in connection with and for purposes of this Settlement, common questions of law and fact predominate over questions affecting only individual class members.

g. Pursuant to Rule 23(b)(3), the Court determines that, in connection with and for purposes of this settlement, a class action is superior to other available methods for the fair and efficient adjudication of this Action.

h. Settlement Class Members' self-identification as members of the Settlement Class is administratively feasible.

5. Pursuant to Fed. R. Civ. P. Rule 23, the Court hereby appoints Monica Barba, Jonathan Reisman, Karen DeReus, Rayna DeReus, Jodi Leit, Mindi Leit, and Barrie Shanahan

and Brian Shanahan on behalf of their minor child B.S. as representatives of the Settlement Class.

6. Pursuant to Fed. R. Civ. P. 23(c)(1)(B) and 23(g), the Court, having considered the factors provided in Rule 23(g)(1)(A), hereby appoints the following counsel as Class Counsel, who are directed to ensure that any remaining work in the Action is performed efficiently and without duplication of effort:

Conlee Whiteley, Esq. (*Pro Hac Vice*)
c.whiteley@kanner-law.com
Allan Kanner (*Pro Hac Vice*)
a.kanner@kanner-law.com
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, Louisiana 70130
Tel: (504) 524-5777
Fax: (504) 524-5763

-and-

Ruben Honik, Esq. (*Pro Hac Vice*)
RHonik@GolombHonik.com
Richard M. Golomb, Esq. (*Pro Hac Vice*)
RGolomb@GolombHonik.com
Kenneth J. Grunfeld, Esq. (*Pro Hac Vice*)
KGrunfeld@GolombHonik.com
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: (215) 985-9177
Fax: (215) 985-4169

-and-

Gillian L. Wade, Esq. (*Pro Hac Vice*)
Gwade@majfw.com
Sara D. Avila, Esq. (*Pro Hac Vice*)
Savila@majfw.com
MILSTEIN ADELMAN JACKSON FAIRCHILD & WADE, LLP
10250 Constellation Boulevard
14th Floor
Los Angeles, CA 90067

Tel.: (310) 396-9600
Fax: (310) 396-9635

-and-

Brian T. Ku, Esq. (Fla. # 610461)
brian@kumussman.com
Louis Mussman, Esq. (Fla # 597155)
Louis@kumussman.com
M. Ryan Casey, Esq. (*Pro Hac Vice*)
ryan@kumussman.com
KU & MUSSMAN, P.A.
6001 NW 153rd Street, Ste. 100
Miami, Florida 33041
Tel: (305) 891-1322
Fax: (305) 891-4512

7. In Plaintiffs' Motion for Preliminary Approval of the Settlement (D.E. 423), Plaintiffs sought the Court's approval of a Notice Plan, which the Court hereby **APPROVES**, as to form and content (or as may be amended by the Court). In accordance with the Notice Plan, Plaintiffs shall use: (i) print publication notice; (ii) digital notice; and (iii) a long form notice with more detail than the print or digital notices (substantially in the form of Exhibits E, F, and G attached to the Settlement Agreement (D.E. 423-1)). Plaintiffs will make the notices available on a website (i.e., www.AdderallXRSettlement.com or something similar) ("the Settlement Website") and via e-mail and mail upon request. All forms of notice to the Class will include, among other information: a description of the Settlement, a date by which Class members may make a claim, exclude themselves from the Settlement Class, or object to the Settlement; the address of the Settlement Website; and the toll-free telephone line. Plaintiffs' shall notify Settlement Class members by at least the following: (i) publication in *Better Homes and Gardens*, *National Geographic*, and *People* magazines; (ii) targeted website and portal banner advertisements with embedded links to the long form notice and the Settlement Website on general Run of Network (RON) sites, which may includes sites such as *USA Today's* website and

drugstore.com; and (iii) e-newsletter placements with *ADDitude*, a magazine dedicated to helping children and adults with attention deficit disorder and learning disabilities lead successful lives. Plaintiffs must also include at least the following on the Settlement Website: an electronic and printable copy of the long form notice, information about the Action and the Settlement, important Court documents, and an electronic and printable Claim Form, which may be submitted online or printed and mailed. The Court finds that the proposed methods for giving notice of the Settlement to members of the Settlement Class, as set forth in this Order and in the Settlement Agreement, meet the requirements of Federal Rule of Civil Procedure Rule 23 and requirements of state and federal due process, is the best notice practicable under the circumstances, and shall constitute due and sufficient notice to all persons entitled thereto. The Court authorizes the parties to make minor revisions to the Class Notice as they may deem necessary or appropriate, without the necessity of further Court action or approval.

8. The Court appoints Kurtzman Carson Consultants LLC (“KCC”) as claims administrator (“the Settlement Administrator”) to assist in providing notice to the Settlement Class regarding the Settlement. The Settlement Administrator shall: (i) establish and maintain a Post Office box for requests for exclusion from the Settlement Class; (ii) establish and maintain a toll-free telephone line for answering Settlement-related inquiries; (iii) establish and maintain the Settlement Website; (iv) respond to any mailed Class member inquiries; (v) process requests for exclusion; (vi) track and process Claim Forms and investigate any suspected fraudulent claims; (vii) calculate and distribute appropriate funds to the Settlement Class; and take all other steps the parties deem appropriate to effectuate the Settlement. All expenses incurred by the Settlement Administrator must be reasonable, are subject to Court approval as well as the provisions of the Escrow Agreement, and shall be payable solely from the Settlement Fund.

9. The Court directs the Settlement Administrator to establish the Settlement Website, making available copies of this Order, the long form Class Notice, the Claim Form that may be downloaded and submitted online or by mail, the Settlement Agreement and all Exhibits thereto, frequently asked questions, a free toll-free telephone line and such other information as may be of assistance to Settlement Class Members or required under the Settlement Agreement.

10. The Claim Form and long form Notice shall be made available to Settlement Class Members through the Settlement Website and on the websites of Class Counsel (at their election) no later than **May 2, 2016**.

11. Internet and print publication notice shall commence no later than **June 27, 2016**.

12. The Court appoints Huntington National Bank to serve as Escrow Agent for the purpose of administering the Escrow Account holding the Settlement Fund.

13. On or before **September 16, 2016**, Plaintiffs shall submit a Motion for Final Approval of the Settlement by the Court, seeking entry of final judgment and order.

14. All Settlement Class members shall be bound by all determinations and judgments in the Action concerning the Settlement, whether favorable or unfavorable to the Settlement Class.

15. The Court approves the Parties' proposed form and content of the Claim Form (attached as Exhibit H to the Settlement Agreement). Any Settlement Class member who wishes to receive money from the Settlement shall complete the Claim Form in accordance with the instructions contained therein, and the Claim Form shall be postmarked or submitted online to the Class Action Settlement Administrator no later than **October 7, 2016**. Such deadline may be further extended without notice to the Settlement Class by Court Order.

16. The Settlement Administrator shall have the authority to accept or reject claims in accordance with the Settlement Agreement and the Notice Plan.

17. Any Settlement Class member may enter an appearance in the Action, at his or her own expense, individually and through counsel. All Settlement Class members who do not enter an appearance will be represented by Class Counsel.

18. Any person falling within the definition of the Settlement Class may, upon his or her request, be excluded from the Class. Any such person must submit a written request for exclusion to the Settlement Administrator postmarked or submitted online no later than **October 7, 2016** (the “Opt-Out Deadline”), as set forth in the Class Notice. Requests for exclusion purportedly filed on behalf of groups of persons are prohibited and will be deemed to be void.

19. Any Settlement Class member who does not send a completed, signed request for exclusion to the Settlement Administrator postmarked or submitted online on or before the Opt-Out Deadline will be deemed to be a Settlement Class member for all purposes and will be bound by all further orders of the Court in this Action and by the terms of the Settlement, if finally approved by the Court. The written request for exclusion must request exclusion from the Class, must be signed by the Settlement Class member and must include a statement indicating that the person is a Settlement Class member. All persons who submit valid and timely requests for exclusion in the manner set forth in the Settlement Agreement shall have no rights under the Settlement Agreement and shall not be bound by the Settlement Agreement or the Final Judgment and Order.

20. A list reflecting all requests for exclusion shall be filed with the Court by Class Counsel at or before the Fairness Hearing.

21. Any Settlement Class member who desires to object to the Settlement, the requested attorneys' fees and costs and/or the Class Representatives' Service Awards must timely file with the Clerk of the Court and timely serve on the Class Counsel and Shire's counsel by hand or first-class mail a written objection, together with all papers that the Settlement Class member desires to submit to the Court no later than **October 7, 2016** (the "Objection Deadline"). The Court will consider such objection(s) and papers only if such papers are received by the Court, Class Counsel and Shire's counsel on or before the Objection Deadline provided in the Class Notice.

22. All objections to the Settlement must contain the following information:

- a. The name of this Action;
- b. The objecting Settlement Class member's full name and address;
- c. All grounds for the objection, accompanied by any legal support known to the objecting Settlement Class member or his or her counsel;
- d. The identity of any and all counsel, including the lawyer's name, address and telephone number, who represent the objecting Settlement Class member, including any former or current counsel who may be entitled to compensation for any reason related to the objection.
- e. A statement confirming whether the objecting Settlement Class member or any counsel representing the objecting Settlement Class member intends to personally appear and/or testify at the Fairness Hearing; and
- f. The signature of the objecting Settlement Class member. A signature by the objector's counsel will not be sufficient.

23. All objections must be filed with the Clerk and served on Class Counsel and Shire's counsel as set forth above no later than the Objection Deadline. Objections received after the Objection Deadline will not be considered at the Fairness Hearing. Any responses to objections must be filed with this Court no later than **October 26, 2016**.

24. Settlement Class members who do not oppose the Settlement and the applications for attorneys' fees and costs and the Class Representatives' Service Awards need not take any action to indicate their approval.

25. A person's failure to submit a written objection in accordance with the Objection Deadline and the procedure set forth in the Class Notice waives any rights the person may have to object to the Settlement and the applications for attorneys' fees and costs and the Settlement Representatives' Service Awards, or to appeal or seek review of the Final Judgment and Order.

26. A hearing regarding the final approval of the Settlement ("the Fairness Hearing") shall be held before this Court on **November 9, 2016 at 2:30 p.m.** Eastern time, in the courtroom assigned to the Honorable Joan A. Lenard, U.S.D.J., at the United States District Court for the Southern District of Florida, Wilkie D. Ferguson, Jr. U.S. Courthouse, 400 North Miami Avenue, Courtroom 12-1, Miami, Florida 33128. At the Fairness Hearing, the Court will consider, *inter alia*: (i) the fairness, reasonableness, and adequacy of the Settlement; (ii) whether the Court should approve and award attorneys' fees, costs, and expenses requested by Class Counsel; (iv) whether the service awards requested by Class Counsel should be made to those Plaintiffs that served as class representatives; and (d) whether entry of a Final Judgment and Order terminating this Action, in the form submitted by the parties to the Settlement Agreement, should be entered. The Fairness Hearing may be rescheduled or continued. Class Counsel shall be responsible for

communicating any such notice promptly to the Settlement Class by posting a conspicuous notice on the Settlement Website established by the Settlement Administrator.

27. Settlement Class members who wish to object to, or otherwise be heard with respect to, the proposed Settlement, or to appear in person or through counsel at the Fairness Hearing, must first send a Notice of Intention to Appear and a Summary Statement (“Notice of Appearance”) outlining the position(s) to be asserted and the grounds therefor, together with copies of any supporting papers or briefs, via first-class mail, postage prepaid, to the Clerk of the United States District Court for the Southern District of Florida, Wilkie D. Ferguson, Jr. United States Courthouse, 400 North Miami Avenue, Miami, Florida 33128, with copies to the following counsel:

Class Counsel, Plaintiffs, and the Settlement Class

Conlee Whiteley, Esq.
c.whiteley@kanner-law.com
Allan Kanner, Esq.
a.kanner@kanner-law.com
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, Louisiana 70130
Tel: (504) 524-5777
Fax: (504) 524-5763

-and-

Ruben Honik, Esq.
RHonik@GolombHonik.com
Richard M. Golomb, Esq.
RGolomb@GolombHonik.com
Kenneth J. Grunfeld, Esq.
KGrunfeld@GolombHonik.com
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: (215) 985-9177
Fax: (215) 985-4169

-and-

Gillian L. Wade, Esq.
Gwade@majfw.com
Sara D. Avila, Esq.
Savila@majfw.com
MILSTEIN ADELMAN JACKSON FAIRCHILD & WADE, LLP
10250 Constellation Boulevard
14th Floor
Los Angeles, CA 90067
Tel.: (310) 396-9600
Fax: (310) 396-9635

-and-

Brian T. Ku, Esq. (Fla. # 610461)
brian@kumussman.com
Louis Mussman, Esq. (Fla # 597155)
Louis@kumussman.com
M. Ryan Casey, Esq. (*Pro Hac Vice*)
ryan@kumussman.com
KU & MUSSMAN, P.A.
6001 NW 153rd Street, Ste. 100
Miami, Florida 33041
Tel: (305) 891-1322
Fax: (305) 891-4512

The Shire Defendants

Porter F. Fleming, Esq.
pfleming@flhlaw.com
Michael F. Brockmeyer, Esq.
mbrockmeyer@flhlaw.com
David A. Zwally, Esq.
dzwally@flhlaw.com
Edgar H. Haug, Esq.
ehaug@flhlaw.com
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
Tel: (212) 588-0800
Fax: (212) 588-0500

-and-

Chris Allen, Esq.
callen@shire.com
Head Counsel, US Litigation & Investigations
SHIRE
300 Shire Way
Lexington, MA 02421
Office: 781-482-1446

28. The Parties' Agreed Motion for Leave to File Amended Complaint in Accordance with Class Action Settlement (D.E. 422) is hereby **GRANTED**. The Third Amended Complaint is deemed filed in accordance with paragraph 1.2 of the Settlement Agreement.

29. All proceedings in this Action are hereby stayed until such time as the Court renders a final decision regarding the approval of the Settlement, and, if it approves the Settlement, enters final judgment in the form provided in the Settlement Agreement and dismisses the Action with prejudice.

30. If the Settlement Agreement is finally approved, the Court shall enter a Final Judgment and Order of Dismissal approving the Settlement Agreement. The Final Judgment and Order of Dismissal is attached to the Settlement Agreement as Exhibit I. Said Final Judgment and Order of Dismissal shall be fully binding with respect to all members of the Settlement Class who did not request exclusion by the date set in the Class Notice, in accordance with the terms of the Class Notice and the Settlement Agreement.

31. The Court shall retain continuing jurisdiction over the Action, the Parties and the Settlement Class, the Escrow Agent, and the administration, enforcement and interpretation of the Settlement Agreement.

32. Neither this Order, nor the Settlement Agreement, nor any other Settlement-related document, nor anything contained therein or contemplated hereby, nor any proceeding undertaken in accordance with the terms set forth in the Settlement Agreement shall constitute,

be construed as, or be deemed to be evidence of or an admission or concession by Shire of any violation of any statute or law, of any liability or wrongdoing by Shire (including, without limitation, that Shire has engaged in any conduct or practices that violate any antitrust laws or any other laws), or of the truth of any of the claims or allegations contained in any complaint or any other pleading or document filed in this Action nor as to the validity of any claim that has been or could have been asserted against it or any of its predecessors, successors, affiliates, subsidiaries, officers, directors, employees, or other representatives as to any liability by any or all of them or as to any matter set forth in this Order.

DONE AND ORDERED in Chambers at Miami, Florida this 11th day of April, 2016.


JOAN A. LENARD
UNITED STATES DISTRICT JUDGE