

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: **PROGRAF ANTITRUST
LITIGATION**

MDL No. 2242

Master File No. 1:11-cv-02242 RWZ

THIS DOCUMENT RELATES TO:

ALL INDIRECT PURCHASER ACTIONS:

*Louisiana Health Service Indemnity Company
d/b/a Bluecross/Blueshield of Louisiana v.
Astellas Pharma US, Inc., No. 11-cv-12326*

*Janet M. Paone v. Astellas Pharma US, Inc.,
No. 11-cv-11647*

***RWZ* ~~PROPOSED~~ PRELIMINARY APPROVAL ORDER**

Upon review and consideration of the Settlement Agreement dated February 3, 2016 and the exhibits thereto (collectively, the "Settlement Documents"), and Plaintiffs' Motion for Preliminary Approval of the Settlement with Astellas Pharma, Inc. ("Astellas"), and attachments thereto, filed on behalf of Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana ("BCBSLA"), and Janet M. Paone ("Paone") (collectively, "Plaintiffs"), individually and on behalf of a putative class of Indirect Purchasers of Prograf, as defined herein, which Plaintiffs have asked the Court to certify for settlement purposes only (the "Settlement Class"), IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

1. Upon review of the record, the Court finds that the Settlement between the Settlement Class and Astellas was arrived at by arms'-length negotiations by highly experienced counsel, is within the range of fairness, 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. The proposed settlement is on behalf of:

All persons (“Consumers”) or entities (“Third Party Payors”) in the United States and its territories who purchased and/or paid for some or all of the purchase price for branded Prograf capsules and/or any of its AB-rated generic equivalents in any form in the states of Arizona, California, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin, for consumption by themselves, members of their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, at any time during the period from April 15, 2008 until December 31, 2010 (the “Class Period”). For purposes of the Settlement Class definition, persons and entities “purchased” or “paid for” Prograf and/or any of its AB-rated generic equivalents if they paid, or reimbursed someone who paid, some or all of the dispensing pharmacy’s price for such drug.

Excluded from the Settlement Class are:

- a) Astellas and its officers, directors, management, employees, parents, subsidiaries, and affiliates;
- b) All federal governmental entities (except for government-funded employee benefit plans);
- c) All persons or entities who purchased Prograf and/or any of its AB-rated generic equivalents for purposes of resale or directly from Astellas or its affiliates;
- d) All fully insured health plans (i.e., plans that purchased insurance from another entity covering 100% of the plan’s reimbursement obligations to its members);
- e) All “flat co-pay” consumers whose purchases were paid in part by a third-party payor and whose co-payment share of the dispensing pharmacy’s price did not vary between brand-name and generic drug purchases; and
- f) The judges in this case and any members of their immediate families.

The persons or entities described in this paragraph 2 shall be herein referred to as the

“Settlement Class.”

3. Based upon a rigorous analysis of the prerequisites for the certification of a settlement class as required by *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 623-624, 117 S. Ct. 2231, 138 L. Ed. 2d 689 (1997), the Court makes the following determinations with respect to Rule 23(e)(3) of the Federal Rules of Civil Procedure, solely for purposes of settlement, pursuant to Fed. R. Civ. P. 23(b)(3):

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

- i. Whether Astellas unlawfully delayed entry of a generic version of Prograf in violation of the state antitrust, unfair competition, consumer protection, or unjust enrichment laws of the states identified in the Class definition set forth in paragraph 2 (the “Class States”);
- ii. Whether the alleged unlawful activity of Astellas 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 state antitrust, unfair competition consumer protection, or unjust enrichment law of each Class State.

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 fact common to the Settlement Class, including:

- i. Whether Astellas’s citizen petition submitted to FDA during FDA’s review of ANDAs for generic tacrolimus 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 Constitution of the United States;

- ii. Whether the FDA delayed its approval of an Abbreviated New Drug Application (“ANDA”) for a generic version of Prograf until it responded to Astellas’s citizen petition or whether the FDA delayed responding to Astellas’s citizen petition until such an ANDA was ready for approval;
- iii. Whether Astellas unlawfully maintained monopoly power by delaying generic entry or whether Astellas’s citizen petition caused no delay; and
- iv. Whether, and to what extent, Astellas’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 Astellas’s conduct.

d. The Plaintiffs are hereby appointed as representatives of the Settlement Class, for the following reasons:

- i. The Plaintiffs allege on behalf of the Settlement Class the same manner of injury from the same course of conduct that they complain of themselves, and the Plaintiffs assert on their own behalf

substantially the same legal theories that they assert for the Settlement Class as a whole. The Court finds these claims are typical of the claims of the proposed Settlement Class members within the meaning of Rule 23(a)(3).

- ii. Pursuant to Rule 23(a)(4), the Court determines, in connection with and for purposes of settlement, that the Plaintiffs will fairly and adequately protect the interests of the Settlement Class. All of the Settlement Class members share a common interest in proving Defendant's alleged anti-competitive conduct and in recovering damages.
- iii. Counsel for the 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 this action thus far.

e. 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. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997); *see also Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1196 (2013).

f. 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.

g. The Court finds that membership in the Settlement Class can be

determined by administratively feasible means through the use of objective proofs.

h. The Court appoints the above-identified Plaintiffs as representatives of the Settlement Class. Further, 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 this litigation that is performed by any counsel of record in this Action is performed efficiently and without duplication of effort:

J. Gerard Stranch, IV
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David Franco
DUGAN LAW FIRM
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4. The Court approves and appoints as Allocation Counsel Christopher M. Burke to represent the interests of Third Party Payor members of the Settlement Class, and Kenneth A. Wexler to represent the interests of Consumer members of the Settlement Class, respectively, for the purpose of negotiating, at arms' length, an agreement regarding the allocation of the Net Settlement Fund (as defined in the Settlement Agreement) between these two groups (the "Allocation Agreement"), informed by the expert reports, affidavits, declarations and depositions of Dr. Meredith Rosenthal and Dr. Pierre Cremieux. The Court finds that Allocation Counsel

have the experience and qualifications necessary to reach an Allocation Agreement through an arms' length negotiation that allocates the Net Settlement Fund between Third Party Payor and Consumer members of the Settlement Class fairly, adequately, and in a manner consistent with due process.

5. No later than June 1, 2016, Plaintiffs shall file a Motion for Preliminary Approval of Allocation Agreement and Notice Plan, which seeks (i) preliminary approval of the Allocation Agreement, (ii) approval of long- and short-form notices to the members of the Settlement Class, and (iii) approval of a plan to give notice of the Settlement, the terms of the Settlement Agreement, and the terms of the Allocation Agreement to members of the Settlement Class. The Motion shall inform the Court why the proposed notice plan and forms of notice satisfy the requirements of Rule 23(e) of the Federal Rules of Civil Procedure and due process, are otherwise fair and reasonable, and thus should be approved for dissemination to the Settlement Class.

6. The Court appoints Garden City Group, Inc. as claims administrator (the "Claims Administrator") to assist in providing notice to the Class regarding the Settlement, communicating with Class members, collecting opt-out forms from Settlement Class members, and collecting and determining claims from Settlement Class members. All expenses incurred by the Claims Administrator must be reasonable, are subject to Court approval, are subject to the provisions of the Escrow Agreement, and shall be payable solely from the Settlement Fund.

7. The Court appoints Pinnacle Financial Partners to serve as Escrow Agent for the purpose of administering the Escrow Account holding the Settlement Fund.

8. Within six (6) months after the date of this Order, after appropriate notice to the Settlement Class, and no less than thirty (30) days before the Fairness Hearing (defined below),

Plaintiff shall submit a Motion for Final Approval of the Settlement by the Court, seeking entry of final judgment and order.

9. A hearing regarding the final approval of the Settlement (the “Fairness Hearing”) shall be held before this Court on November 2, 2016 at 2:00 p.m. Eastern Time, in the courtroom assigned to the Honorable Rya Zobel, U.S.D.J., at the United States District Court for the District of Massachusetts, John Joseph Moakley U.S. Courthouse, 1 Courthouse Way, Courtroom 12, Boston, Massachusetts 02210. At the Fairness Hearing, the Court will consider, *inter alia*: (a) the fairness, reasonableness and adequacy of the Settlement; (b) whether the Court should finally approve the Allocation Agreement for the distribution of Net Settlement Funds as between Third Party Payor members of the Settlement Class and Consumer members of the Settlement Class; (c) whether the Court should approve the proposed plan of final allocation for the Settlement Fund, including the method proposed by Class Counsel for distributing the Net Settlement Fund among Consumer members of the Settlement Class and among Third Party Payor members of the Settlement Class (the “Allocation Plan”), which Plaintiffs will submit to the Court at least thirty (30) days prior to the Fairness Hearing as provided in paragraph 9 of the Settlement Agreement; (d) whether the Court should approve and award the attorneys’ fees and expenses requested by Class Counsel; (e) whether the incentive awards requested by Class Counsel should be made to those Plaintiffs that served as class representatives; and (f) whether entry of a Final Judgment and Order terminating this litigation, in the form submitted by the parties to the Settlement Agreement, should be entered. The Fairness Hearing may be rescheduled or continued; in this event, the Court will furnish all counsel with appropriate notice. 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 Claims

Administrator and by notifying any Settlement Class member or counsel for a Settlement Class member that has filed a Notice of Appearance pursuant to paragraph 11 below. The Court may approve the Settlement with only such modifications (if any) as may be agreed to in a writing signed by all of the parties to the Settlement, if appropriate, without further notice to the Settlement Class.

10. All briefs, exhibits, and other materials in support of final approval of the Settlement, entry of the final judgment proposed by the parties to the Settlement Agreement, the fee petition by Class Counsel, and any application for incentive awards, shall be filed with the Court and served on the following counsel by no later than 30 days prior to the Fairness Hearing:

On behalf of Class Counsel, Plaintiffs and the Settlement Class:

J. Gerard Stranch, IV
Joe P. Leniski, Jr.
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On behalf of Astellas:

John W. Treece
Jana D. Wozniak
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One South Dearborn
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11. 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 District of Massachusetts, John Joseph Moakley U.S. Courthouse, 1 Courthouse Way, Suite 2300, Boston, Massachusetts 02210, with copies to the following counsel:

On behalf of Class Counsel, Plaintiffs and the Settlement Class:

J. Gerard Stranch, IV
Joe P. Leniski, Jr.
BRANSTETTER, STRANCH & JENNINGS, PLLC
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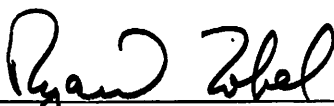
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To be valid, any such Notice of Appearance must be postmarked no later than ten (10) days prior to the Fairness Hearing. Except as herein provided, no person or entity shall be entitled to object to the terms of the proposed Settlement. All persons and entities who fail to file a Notice of Appearance as provided above shall be deemed to have waived any such objection by appeal, collateral attack or otherwise and will not be heard in person at the Fairness Hearing.

13. Neither this Order, nor the Settlement Agreement, nor any other Settlement-related document, nor anything contained therein or contemplated hereby, nor any proceedings 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 Astellas as to the validity of any claim that has been or could have been asserted against it or any of its 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.

IT IS SO ORDERED.

Dated: April 29, 2016



The Honorable Rya W. Zobel
United States District Court Judge
U.S. District Court for the District of Massachusetts