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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VYTORIN/ZETIA MARKETING,
SALES PRACTICES AND PRODUCT
LIABILITY LITIGATION

Master Docket No. 08-0285 (DMC)
MDL No. 1938

**ORDER GRANTING PRELIMINARY
APPROVAL OF SETTLEMENT,
PRELIMINARILY CERTIFYING
SETTLEMENT CLASS AND
APPROVING CLASS NOTICE**

THIS MATTER having been opened to the Court by Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, and Seeger Weiss, Co-Liaison Counsel for the Plaintiffs, and Dechert LLP, attorneys for Defendants by way of Joint Motion for preliminary approval of the proposed Settlement in the above matter; and

WHEREAS, the Court finds that it has jurisdiction over this action and each of the parties under 28 U.S.C. § 1331 and that venue is proper in this district; and

WHEREAS the Court finds as follows: The Settlement Agreement was entered into at arms length by experienced counsel and only after extensive arms length negotiations lasting several months. The Settlement Agreement is not the result of collusion. The Settlement bears a reasonable relationship to the claims alleged by plaintiffs and the Settlement is sufficiently within the range of reasonableness so that notice of the Settlement should be given to the members of the proposed class for their consideration as provided by this Order; and

WHEREAS, this Court has fully considered the record of these proceedings, the representations, argument, and recommendation of counsel for the moving parties, and the requirements of law; and good cause appearing,

IT IS THIS 17th day of September, 2009

ORDERED as follows:

1. The terms of the Class Settlement Agreement and Release between Class Plaintiffs and Merck & Co., Inc., Schering-Plough Corp., and Merck/Schering-Plough Pharmaceuticals (“Defendants”), dated August 4, 2009, including all exhibits thereto (the “Settlement Agreement,” attached to the Declaration of James Cecchi (“Cecchi Decl.”) as Exhibit 1) is preliminarily approved, subject to further consideration thereof prior to or at the Final Approval Hearing provided for below.¹

2. The proposed Plan of Allocation dated August 4, 2009, together with all exhibits there to (“Plan of Allocation”), attached as Exhibit 2 to the Cecchi Declaration, also appears to be appropriate and is preliminarily approved, subject to further consideration at the Final Approval Hearing provided for below.

3. The Court further finds, on a preliminary basis and for settlement purposes only, that all requirements of Fed.R.Civ.P. 23(a) and (b)(3) have been satisfied. The court conditionally certifies a Master Class (the “Class”) and two subclasses (the “Subclasses”) as follows:

Master Class: All individuals and entities in the United States and its territories who, for purposes other than resale, purchased, reimbursed, used, and/or paid for VYTORIN or ZETIA during the period from November 1, 2002 through the date the Court enters a Preliminary Approval Order preliminarily approving the Settlement. For purposes of the Class definition, individuals and entities

¹ Unless otherwise provided herein, the terms defined in the Settlement Agreement shall have the same meaning in this Order.

“purchased” VYTORIN or ZETIA if they paid or made a co-payment for some or all of the purchase amount.

Consumer Subclass: All individual persons in the United States and its territories who, for purposes other than resale, purchased, used and/or paid for VYTORIN or ZETIA during the period from November 1, 2002 through the date the Court enters a Preliminary Approval Order preliminarily approving the Settlement. For purposes of the Subclass definition, individuals “purchased” VYTORIN or ZETIA if they paid or made a co-payment pursuant to the terms of a health insurance plan, for some or all of the purchase amount.

Third-Party Payor Subclass: All entities in the United States and its territories that, for purposes other than resale, purchased, reimbursed and/or paid for all or part of the cost of VYTORIN or ZETIA from November 1, 2002 through the date the Court enters a Preliminary Approval Order preliminarily approving this Settlement. Such entities include, but are not limited to, all self-funded employer plans, private insurance providers, managed care organization, insurance companies, employee benefit plans, health and welfare funds, union plans, workers compensation entities, HMOs, PPOs, entities with self-funded plans, and any other entity who is a party to a contract, issuer of a policy, or sponsor of a plan, and is at risk, under such contract, policy, or plan, to pay or reimburse all or part of the cost of prescription drugs dispensed to covered natural persons.

Excluded from the Class and Subclasses are Defendants and their affiliates, assignees, and successors-in-interest, and their officers, directors, and employees; any Judge who presides or has presided over this litigation and/or its constituent actions, together with his/her immediate family members and any other individual residing in the Judge’s household; Plaintiffs’ counsel and their employees, together with their immediate family members and any other individual residing in the household of such individuals; Defendants’ counsel and their employees, together with their immediate family members and any other individual residing in the household of such individuals; individuals and entities that opt-out of the Settlement in accordance with the procedures approved by this Court; IRHPs that have entered into a separate IRHP Settlement Agreement with Defendants; individuals and entities that own or operate businesses commonly known as pharmacy benefit managers (“PBMs”), third party administrators (“TPAs”) and/or administrative service organizations (“ASOs”) to the extent that, as part of their business

operations, they contract with Third-Party Payors to perform administrative and/or management services in connection with the Third-Party Payor's purchase of prescription drugs; and the United States and/or State governments and their agencies and departments.

The Court finds that the requirements of Rule 23(a) are satisfied for settlement purposes only, as follows:

- (a) Pursuant to Fed.R.Civ.P. 23(a)(1), the members of the Class are so numerous that joinder of all members is impracticable.
- (b) Pursuant to Fed.R.Civ.P. 23(a)(2) and 23(c)(1)(B), the Court determines that, in the context of settlement, there are common issues of law and fact as follows:
 - (i) Whether Defendants concealed material information from Plaintiff, members of the Class and Subclasses, physicians, and the general public concerning the efficacy and safety of Zetia and Vytorin, including without limitation the results of the ENHANCE study;
 - (ii) Whether Defendants concealed material information from Plaintiff, members of the Class and Subclasses, physicians, and the general public as part of a centrally orchestrated scheme of deception; and
 - (iii) Whether Defendants engaged in a fraudulent and/or deceptive scheme of marketing and selling Zetia and Vytorin for treating high cholesterol and associated risk factors for heart attacks, such as atherosclerosis; and
- (c) Pursuant to Fed. R. Civ. P. 23(a)(3), the claims of the Representative Plaintiffs (as defined below) are typical of the claims of the Class and

Subclasses in that the Representative Plaintiffs allege that they have purchased and/or paid for Vytorin or Zetia during the Class Period.

- (d) Pursuant to Fed. R. Civ. P. 23(a)(4), in the context of settlement, the Representative Plaintiffs will fairly and adequately protect and represent the interests of all members of the Class and Subclasses, and the interest of the Representative Plaintiffs are not antagonistic to those of the Class or Subclasses. The Representative Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action litigation.

The Court further finds that the requirements of Rule 23(b)(3) are satisfied for settlement purposes only, as follows:

- (a) Questions of law and fact common to the members of the Class, as described above predominate over questions that may affect only individual members; and
- (b) A class action is superior to all other available methods for the fair and efficient adjudication of this controversy.

II. Class Representatives

The Court preliminarily appoints the following as class representatives of the Consumer Subclass: Helen Aronis, Kenneth Bever, Glenda Morgan, Roy Cosgrove, Charles Miller, Anna Iannuzzi, Robery Mastrondrea, Robert Love, Donald Varino, Frances Weiland, and Daniel Tollefson. The Court preliminarily appoints the following as class representatives of the TPP Subclass: IBEW Local 164 Welfare Fund, Fire & Police Retiree Health Care Fund of San Antonio, Pipefitters Local 537 Trust Fund, Teamsters Healthcare, Midwestern Teamsters Health

& Welfare Fund, UFCW & Employers Arizona Health & Welfare Trust, County of Suffolk, and Louisiana Health Insurance Indemnity Company.

III. Approval of Settlement Notices and Notice Program

The Court finds that the Settlement Notices attached as Exhibits 3 and 5 to the Declaration of Katherine Kinsella (“Kinsella Declaration”) and Claim Forms attached as Exhibits 6 and 7 to the Declaration of James E. Cecchi (“Cecchi Declaration”) satisfy the requirements of Rule 23(c)(2) and due process and accordingly approves those Settlement Notices. The Court further approves the Notice Program.

The Court further directs that Kinsella Communications, Ltd., be appointed the Class Notice Consultant and, consistent with the Notice Program, directs the Class Notice Consultant to provide notice to the Settlement Class in the following manner:

- (a) Publication of Notice Forms substantially in the forms contained in Exhibits 5 of the Kinsella Declaration on dates and in publications substantially as set forth in the Notice Program;
- (b) Distribution by direct mail of Notice Forms substantially in the forms contained in Exhibit 3 of the Kinsella Declaration to all members of the Class that can be identified by reasonable means, including through receipt of information submitted by TPPs and IRHPs for this purpose, or who have requested a copy, which mailing shall be placed in the mail no later than November 1, 2009;
- (c) Development and management of a toll free telephone number with an automated system providing information about the Settlement Agreement, with the ability to request copies of the Settlement Notices or Settlement Agreement, during the period from October 1, 2009, until entry of Final Judgment; and
- (d) Development and management of a website to provide information and permit the review and downloading of the Settlement Notices, Settlement Agreement, and exhibits to the Settlement Agreement, during the period from October 1, 2009, until Final Judgment.

IV. Appointment of Class Counsel

The Court preliminarily finds that the following counsel fairly and adequately represent the interests of the putative Class and hereby appoints Seeger Weiss LLP and James E. Cecchi as

Co-Lead Class Counsel pursuant to Rule 23(g). The Court also acknowledges that the Settlement Agreement identifies Hagens Berman Sobol Shapiro LLP as Counsel for the Nationwide Third-Party Payor Subclass and Wolf Haldenstein Adler Freeman & Herz LLC and Quinn Emanuel Urquhart Oliver & Hedges LLP as Counsel for Nationwide Consumer Subclass.

V. Qualified Settlement Fund

The Court finds that the settlement fund escrow established pursuant to the Settlement Agreement (the “Settlement Fund”) is a “qualified settlement fund” as defined by Section 1.468B-1(a) of the Treasury Regulations in that it satisfies each of the following requirements:

- (a) The Settlement Fund is established pursuant to an order of this Court and is subject to the continuing jurisdiction of this Court;
- (b) The Settlement Fund is established to resolve or satisfy one or more claims that have resulted or may result from an event that has occurred and that has given rise to at least one claim asserting liabilities; and
- (c) The assets of the Settlement Fund are segregated from other assets of the Defendants, the transferor or payments to the Settlement Fund.

Under the “relation-back” rule provided under section 1.468B-1(j)(2)(i) of the Treasury Regulations, the Court finds that:

- (a) the Settlement Fund met the requirements of paragraphs 15(b) and (c) of this Order approving the establishment of the Settlement Fund subject to the continued jurisdiction of this Court; and
- (b) Defendants and Claims Administrator may jointly elect to treat the Settlement Fund as coming into existence as a “qualified settlement fund” on the later of the date the Settlement Fund met the requirements of

paragraphs 15(b) and (c) of this Order or January 1, of the calendar year in which all requirements of paragraph 15 of this Order are met. If such a relation-back election is made, the assets held by the Settlement Fund on such date shall be treated as having been transferred to the Settlement Fund on that date.

VI. Final Approval Hearing

The Court directs that pursuant to Fed.R.Civ.P. 23(e)(2) a hearing will be held on February 8, 2010, to consider final approval of the Settlement (the "Final Approval Hearing" or "Fairness Hearing") including, but not limited to, the following issues: (a) whether the Master Class, Consumer Subclass, and TPP Subclass should be certified, for settlement purposes only; (b) the fairness, reasonableness, and adequacy of the Settlement and of the Proposed Plan of Allocation; and (c) Class Counsel's application for an award of attorneys' fees and costs. The Final approval Hearing may be adjourned by the Court without further notice to the Class other than which may be posted at the Court and on the Court's and Claims Administrator's websites.

VI. Objection to the Settlement

Persons wishing to object to the proposed settlement and/or be heard at the Fairness Hearing shall follow the following procedures:

- (a) To object, a Class member, individually or through counsel, must file a written objection with the Clerk, and must also mail a copy thereof to the following:

Lead Class Counsel

Christopher A. Seeger
Stephen A. Weiss
SEEGER WEISS LLP
One William Street
New York, New York 10004

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sweiss@seegerweiss.com

James E. Cecchi
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Counsel for Nationwide Third-Party Pavor Subclass

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Counsel for Nationwide Consumer Subclass

Adam J. Levitt
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Stephen Neuwirth
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Counsel for Defendants

Theodore V.H. Mayer
HUGHES HUBBARD & REED LLP
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mayer@hugheshubbard.com

Ezra D. Rosenberg
DECHERT LLP
Suite 500
902 Carnegie Center
Princeton, New Jersey 08540
ezra.rosenberg@dechert.com

- (b) Any Class member who files and serves a written objection by the deadline may also appear at the Fairness Hearing, either in person or through an attorney hired at the Class Member's expense, to object to the fairness, reasonableness or adequacy of the proposed settlement. Any attorney representing a Class member for the purpose of making objections must also file a Notice of Appearance with the Clerk, and must also serve copies by mail to the counsel listed above.
- (c) Class members or their attorneys intending to appear at the Fairness Hearing must serve on Class counsel and counsel for Defendants, and file with the Clerk, a notice of Intent to Object, which includes: (i) the name, address and telephone number of the Class member and, if applicable, the name, address and telephone number of the Class member's attorney (who must file a Notice of Appearance); (ii) the objection, including any papers in support thereof; and (iii) the name and address of any witnesses to be presented at the Fairness Hearing, together with a statement as to the matters on which they wish to testify and a summary of the proposed testimony.
- (d) Any Class member who does not timely file and serve a Notice of Intent to Object, and any witness not identified in the Notice of Intent to Object, shall not be permitted to appear at the Fairness hearing, except for good cause shown.

VII. Appointment of Co-Claims Administrators

The Court hereby appoints Rust Consulting, Inc. ("Rust," formerly Complete Claims Solutions, Inc.) and Class Action Settlement Services, LLC ("CASS") as Joint Claims Administrators. Rust shall provide claims administration services, including the administration of the settlement claims process for both consumers and TPPs (and IRHPs as set forth in the Plan of Allocation), the review of claims, the disbursement of funds, the preparation of tax filings and payment of any taxes due as a result of interest earned by the Escrow Account, and the preparation of a Final Accounting. CASS shall process information provided by insurance companies, self-insured employers, Taft Hartley plans, and other third-party payors concerning Vytorin/Zetia copayments made by insured consumer class members (as further delineated in Section VIII, *infra*).

TPP Class members and IRHPs are ordered to provide data concerning payments by insured co-payers directly to CASS in order to increase the participation of consumers in the Settlement. TPPs are only required to make reasonable good-faith efforts to provide the requested data, and Consumers are encouraged to submit their own claim forms. TPPs are not required to warrant that their data is complete or error-free, and neither they nor the Co-Claims Administrators shall be held liable to Class members or anyone else as a result of any errors or omissions in the data.

Data provided in compliance with this order falls within the HIPAA safe haven for information provided pursuant to a court order.²

² See Qualified Protective Order Regarding Protection of Health Information, filed herewith.

IX. Procedures and Deadlines for Opt-Outs, Opt-Ins, and Claimants

(A) Opt-Out Rights

Class Members who elect not to participate in the Settlement (i.e., “opt-out”) must submit a written request for exclusion that is postmarked no later than January 15, 2010. Rust shall compile a list of all TPP and Consumer Opt Outs to be filed with the Court no later than February 3, 2010.

As part of the written request for exclusion submitted by any TPP, such TPP shall be requested to include (a) a statement of the actual dollar amount that TPP paid to purchase or reimburse purchases of Vytarin and/or Zetia during the Class Period, using the same criteria requested of TPPs submitting a claim for reimbursement from the Settlement, and (b) the total enrollment of that TPP, stated in terms of covered lives in the United States. Any TPP providing the information requested by this Paragraph shall be bound by the information included in the written request for exclusion. To the extent a TPP submitting a written request for exclusion fails to comply with this Paragraph (a “non-Compliant TPP”), Lead Class Counsel shall subpoena the non-compliant TPP if necessary to effectuate the terms of this Paragraph.

Other than as set forth in this Article, any Consumer or TPP failing to properly and timely mail such a written notice of exclusion shall be automatically included in the Master Class and the Consumer Subclass (if a natural person) or the TPP Subclass (if an entity) and shall be bound by all the terms and provisions of the Settlement Agreement and the Settlement and Order of Final Judgment, whether or not such member of the Consumer Subclass or TPP Subclass shall have objected to the Settlement and whether or not such member of the Consumer Subclass or TPP Subclass makes a claim under or participates in the Settlement.

The Court shall resolve any disputes concerning the Opt-Out provisions of the Settlement Agreement.

(B) Claims Deadline

In order to participate in the Settlement and receive a distribution from the Settlement Fund, TPP and Consumer Subclass Members must mail to the Rust a properly executed Proof of Claim and Release Form in substantially the form contained in Exhibits 6 and 7 to the Cecchi Declaration, as applicable. To be effective, any such Proof of Claim and Release Form must be postmarked no later than April 1, 2010, and must otherwise comply with the procedures and instructions set forth in the Proof of Claim and Release Form.

X. Deadlines

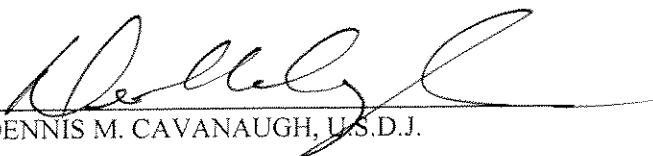
<u>EVENT</u>	<u>DATE</u>
Notice of Class Action Settlement and Claim Forms To be Mailed to TPPs and Posted on Internet	October 8, 2009
Notice of Class Action Settlement to be Published in National Media	December 15, 2009
Postmark/Filing Deadline for Requests for Exclusions, and Objections	January 15, 2010
Service/Filing Notice of Appearance at Fairness Hearing	January 15, 2010
Affidavit of Compliance with Notice Requirements and Report of Exclusions and Objections	February 3, 2010
Filing Motion for Final Approval, Attorney Fees, Reimbursement of Expenses, and Incentive Awards To be Filed by Class Counsel	February 3, 2010
Fairness Hearing	February <u>8</u> , 2010

In the event that the Settlement Agreement is terminated in accordance with the applicable provisions thereof, the Settlement Agreement, the proposed settlement, and all related

proceedings shall, except as expressly provided to the contrary in the Settlement Agreement, become null and void, shall have no further force and effect, and Class members shall retain all of their current rights to assert any and all claims against Defendants and any other released party, and the Defendants and any other released parties shall retain any and all of their current defenses and arguments thereto (including but not limited to arguments that the requirements of Fed. R. Civ. P. 23(a) and (b)(3) are not satisfied for purposes of continued litigation). These actions shall thereupon revert forthwith to their respective procedural and substantive status prior to the date of execution of the Settlement Agreement and shall proceed as if the Settlement Agreement and all other related orders and papers had not been executed.

Neither this Order nor the Settlement Agreement nor any other settlement-related document nor anything contained herein or therein or contemplated hereby or thereby nor any proceedings undertaken in accordance with the terms set forth in the Settlement Agreement or herein or in any other settlement-related document, shall constitute, be construed as or be deemed to be evidence, of or an admission or concession by Defendants as to, the validity of any claim that has been or could have been asserted against any or all of them or as to any liability by any or all of them as to any matter set forth in this Order, or as to the propriety of class certification for any purposes other than for purposes of the current proposed settlement.

All other proceedings in these actions are hereby stayed until such time as the Court renders a final decision regarding approval of the proposed settlement. Neither this Order nor the Settlement Agreement shall constitute any evidence or admission of liability by any Defendant.


DENNIS M. CAVANAUGH, U.S.D.J.