

CAHILL GORDON & REINDEL LLP
EIGHTY PINE STREET
NEW YORK, NY 10005-1702

FLOYD ABRAMS
L. HOWARD ADAMS
ROBERT A. ALESSI
HELENE R. BANKS
ANIRUDH BANSAL
LANDIS C. BEST
BRADLEY J. BONDI
SUSAN BUCKLEY
KEVIN J. BURKE
JAMES J. CLARK
BENJAMIN J. COHEN
SEAN M. DAVIS
STUART G. DOWNING
ADAM M. DWORKIN
ANASTASIA EFIMOVA
JENNIFER B. EZRING
JOAN MURTAGH FRANKEL
JONATHAN J. FRANKEL

BART FRIEDMAN
CIRO A. GAMBONI
PIERRE M. GENTIN
CHARLES A. GILMAN
JASON M. HALL
WILLIAM M. HARTNETT
CRAIG M. HOROWITZ
DOUGLAS S. HOROWITZ
TIMOTHY B. HOWELL
DAVID G. JANUSZEWSKI
ELAI KATZ
THOMAS J. KAVALER
BRIAN S. KELLEHER
DAVID N. KELLEY
RICHARD KELLY
CHÉRIE R. KISER*
EDWARD P. KRUGMAN
JOEL KURTZBERG

TELEPHONE: (212) 701-3000
WWW.CAHILL.COM
1990 K STREET, N.W.
WASHINGTON, DC 20006-1181
(202) 862-8900
CAHILL GORDON & REINDEL (UK) LLP
24 MONUMENT STREET
LONDON EC3R 8AJ
+44 (0)20 7920 9800
WRITER'S DIRECT NUMBER

212-701-3621

MARC R. LASHBROOK
ALIZA R. LEVINE
JOEL H. LEVITIN
GEOFFREY E. LIEBMANN
ANN S. MAKICH
JONATHAN I. MARK
BRIAN T. MARKLEY
WILLIAM J. MILLER
NOAH B. NEWITZ
MICHAEL J. OHLER
ATHY A. O'KEEFFE
DAVID R. OWEN
JOHN PAPACHRISTOS
LUIS R. PENALVER
KIMBERLY PETILLO-DÉCOSSARD
MICHAEL W. REDDY
JAMES ROBINSON
THORN ROSENTHAL
TAMMY L. ROY

JONATHAN A. SCHAFFZIN
JOHN SCHUSTER
MICHAEL A. SHERMAN
DARREN SILVER
HOWARD G. SLOANE
JOSIAH M. SLOTNICK
RICHARD A. STIEGLITZ JR.
SUSANNA M. SUH
ANTHONY K. TAMA
JONATHAN D. THIER
JOHN A. TRIPODORO
GLENN J. WALDRIP, JR.
HERBERT S. WASHER
MICHAEL B. WEISS
S. PENNY WINDLE
DAVID WISHENGRAD
COREY WRIGHT
JOSHUA M. ZELIG
DANIEL J. ZUBKOFF

* ADMITTED IN DC ONLY

March 8, 2016

Re: *Amarin Pharma, Inc., et al. v. United States Food & Drug
Admin., et al.*, 15 Civ. 3588 (PAE)

Dear Judge Engelmayer:

I write to advise the Court that the parties have reached agreement on the resolution of this matter, subject to Your Honor's approval. Pursuant to Local ECF Rule 18.3, our proposed order of settlement has been emailed to the Clerk of the Court today. I have also enclosed a signed copy for your reference and convenience.

Respectfully,



Floyd Abrams

The Honorable Paul A. Engelmayer
United States District Judge
Thurgood Marshall United States Courthouse
40 Foley Square
New York, NY 10007

Enclosure

VIA ECF

cc: Ellen Melissa London, Esq.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AMARIN PHARMA, INC.,
DR. JONATHAN HERBST,
DR. ERIC RISHE,
DR. PETER GOTTESFELD, and
DR. RALPH YUNG,

Plaintiffs,

v.

UNITED STATES FOOD & DRUG
ADMINISTRATION, UNITED STATES OF
AMERICA, ROBERT M. CALIFF, M.D., in
his official capacity as Commissioner of Food
and Drugs, and SYLVIA MATHEWS
BURWELL, in her official capacity as
Secretary of the Department of Health &
Human Services,

Defendants.

15 Civ. 3588 (PAE)

ECF Case

[PROPOSED] STIPULATION AND ORDER OF SETTLEMENT

WHEREAS, Plaintiffs filed a complaint on May 7, 2015;

WHEREAS, Plaintiffs made a motion for a preliminary injunction on May 22, 2015;

WHEREAS, Defendants opposed the motion on June 23, 2015;

WHEREAS, Defendants filed an answer on July 27, 2015;

WHEREAS, the Court entered an Opinion and Order on August 7, 2015 (the "August 7 Order");

WHEREAS, the parties wish to avoid further cost, time, and expense spent in litigation;
and

WHEREAS, the entry of this FINAL ORDER resolves all causes of action raised in
Plaintiffs' complaint;

NOW THEREFORE IT IS HEREBY STIPULATED AND AGREED TO by the Plaintiffs and Defendants, subject to approval and entry by this Court, that:

1. Defendants agree to be bound by the Court's conclusion that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa®, *i.e.*, to treat patients with persistently high triglycerides, and under *Caronia*, such speech may not form the basis of a prosecution for misbranding.
2. Defendants agree to be bound by the Court's conclusion that, based on the information known as of August 7, 2015, the combination of statements and disclosures that Amarin proposes to make to doctors relating to use of Vascepa® to treat persons with persistently high triglycerides, as such communications have been modified in the August 7 Order, is truthful and non-misleading.
3. Amarin bears the responsibility, going forward, of assuring that its communications to doctors regarding off-label use of Vascepa® remain truthful and non-misleading.
4. All terms contained herein are to be interpreted consistently with the August 7 Order, and nothing in this Order shall be construed to limit Amarin's constitutional rights to free speech concerning Vascepa®.
5. In addition to the optional procedures generally available for submitting proposed communications to FDA for comment, Amarin may submit to FDA under the preclearance procedure described in this paragraph up to two proposed communications per calendar year about the off-label use of Vascepa® before communicating them in promotion to doctors to determine if FDA has concerns with Amarin's proposed communications. If FDA has concerns with a proposed communication that Amarin submits to FDA under this paragraph, FDA will contact Amarin with its specific concerns

or objections within 60 calendar days (FDA and Amarin may agree to extend this period). After any such contact, Amarin will provide a specific response to FDA's concerns or objections within 45 calendar days (FDA and Amarin may agree to extend this period). Within 30 calendar days of Amarin's response, FDA will notify and detail to Amarin the specifics of any dispute that remains. Should a dispute then remain, either party may file a motion with this Court requesting judicial resolution of the dispute. Each interchange between Amarin and FDA will be accompanied by supporting data and information reasonably necessary for the parties to assess the proposed communication, concern, or objection. The procedure described in this paragraph applies only to proposed communications about the off-label use of Vascepa® that Amarin has not yet communicated to doctors in promotion and will cease to be in effect as of December 31, 2020.

6. The parties agree to work in good faith to resolve any dispute on matters arising under this Order. In the event of such a dispute other than those arising under paragraph 5, the aggrieved party will provide written notice to the other party of the issue to be resolved. The other party will have 60 calendar days to cure or resolve the issue (this period may be extended by mutual consent). If the aggrieved party is not satisfied after the proposed cure or resolution, it will provide notice thereof to the other party with a specific response within 30 calendar days (this period may be extended by mutual consent). In the event of a dispute covered by this paragraph, unless necessary to protect public health, the parties will take no action against each other related to the dispute until the completion of the above procedure. Should a dispute remain unresolved at the end of the procedure, either party may file a motion with this Court requesting judicial resolution of the dispute.

Nothing in this Order shall be construed to prevent FDA from communicating with doctors through whatever channels FDA deems appropriate (e.g., publications, postings on websites, and press releases) after the identification of a dispute covered by this paragraph.

7. This Order applies to Amarin and its representatives (including each of its affiliates and agents and their respective successors and assigns, directors, officers, employees, and agents).
8. The parties waive all rights to appeal this Order.
9. Each party will bear its own costs and fees.
10. This Court shall retain jurisdiction for the purpose of ensuring compliance with and resolving any dispute arising under this Order.
11. This case is closed pursuant to the terms of this Order.

Dated: New York, New York
March 8, 2016

CAHILL GORDON & REINDEL LLP

By: 

FLOYD ABRAMS
JOEL KURTZBERG
MICHAEL B. WEISS
80 Pine Street
New York, New York 10005
Tel.: (212) 701-3000
Fax: (212) 269-5420
Email: fabrams@cahill.com
jkurtzberg@cahill.com
mweiss@cahill.com

Attorneys for Plaintiffs

Of counsel:

JOSEPH T. KENNEDY
Executive Vice President, General Counsel &
Strategic Initiatives
c/o Amarin Pharma, Inc.
1430 Route 206
Bedminster, NJ 07921
Tel.: (908) 719-1315
Fax: (908) 719-3012

Attorney for Plaintiff Amarin Pharma, Inc.

PREET BHARARA
United States Attorney
Southern District of New York

By:



ELLEN LONDON
Assistant United States Attorney
86 Chambers Street
New York, New York 10007
Tel.: (212) 637-2737
Fax: (212) 637-2702
Email: ellen.london@usdoj.gov

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
Civil Division

JONATHAN F. OLIN
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director
Consumer Protection Branch

ANDREW E. CLARK
Assistant Director

KERALA T. COWART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
Tel.: (202) 353-3881
Email: kerala.t.cowart@usdoj.gov

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Associate General Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

KAREN E. SCHIFTER
Senior Counsel

JULIE DOHM
Associate Counsel
U.S. Dept. of Health & Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Attorneys for Defendants

SO ORDERED:

HONORABLE PAUL A. ENGELMAYER
UNITED STATES DISTRICT JUDGE