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: _____

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SO ORDERED:

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HONORABLE PAUL A. ENGELMAYER
UNITED STATES DISTRICT JUDGE