UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AMARIN PHARMA, INC., DR. JONATHAN HERBST, DR. ERIC RISHE, DR. PETER GOTTESFELD, and DR. RALPH YOUNG, Plaintiffs, v. UNITED STATES FOOD & DRUG ADMINISTRATION, UNITED STATES OF AMERICA, STEPHEN OSTROFF, M.D., in his official capacity as Acting 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

DECLARATION OF ELLEN LONDON

I, ELLEN LONDON, pursuant to 28 U.S.C. § 1746, declare the following under penalty of perjury:

1. I am an Assistant United States Attorney for the Southern District of New York, and one of the attorneys assigned to represent the United States Food & Drug Administration ("FDA"), the United States of America, Stephen Ostroff, M.D., in his official capacity as Acting Commissioner of Food and Drugs, and Sylvia Mathews Burwell, in her official capacity as Secretary of the Department of Health and Human Services (together, the "Government") in the above-captioned action. I have been assigned to this matter since the inception of this action and am familiar with the proceedings herein.

2. I make this declaration in support of the Government's opposition to Plaintiffs' motion for preliminary injunction. Exhibits A through V to this declaration were provided to this Office by FDA personnel and are attached in the form provided by FDA.

3. A true and complete copy of the letter from Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research, FDA, to Steven Ketchum, Ph.D., President of Research and Development at Amarin Pharma, Inc. ("Amarin"), dated June 5, 2015, addressing the allegations in the Complaint filed in this matter and docketed on June 8, 2015 (Docket No. 24) (the "June 5 Letter"), is attached as Exhibit A.

4. A true and complete copy of the ANCHOR Trial Special Protocol Assessment ("SPA") Agreement, from Eric Colman, M.D., Deputy Division Director, Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, FDA, to Peggy Berry, Vice President, Regulatory Affairs, Amarin Neurosciences, Ltd. (July 6, 2009), which is cited in footnote 3 of the June 5 Letter, is attached as Exhibit B.

5. A true and complete copy of the ANCHOR Trial SPA agreement was subsequently amended. Letter from Eric Colman, M.D., Deputy Division Director, Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, FDA, to Peggy Berry, Vice President, Regulatory Affairs, Amarin Neurosciences, Ltd. (May 12, 2010), which is cited in footnote 3 of the June 5 Letter, is attached as Exhibit C.

6. A true and complete copy of Minutes to the July 14, 2008, pre-IND Meeting, which is cited in footnote 4 of the June 5 Letter, will be attached as Exhibit D. This exhibit is being submitted to the Court separately due to proposed redactions.

7. A true and complete copy of REDUCE-IT Trial SPA Agreement, from Eric Colman, Deputy Division Director, Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, FDA, to Peggy Berry, Vice President, Regulatory Affairs, Amarin Neurosciences, Ltd. (Aug. 5, 2011), which is cited in footnote 5 of the June 5 Letter, is attached as Exhibit E.

8. A true and complete copy of The REDUCE-IT Trial SPA Agreement was subsequently amended. Letter from Peggy J. Berry, Vice President, Regulatory Affairs and Clinical Quality, Amarin Pharma, Inc., to Mary Parks, Director, Division of Metabolism and Endocrinology Products, Center for Drug Evaluation and Research, FDA re: Request for Amendment to SPA Agreement (Apr. 2, 2013), which is cited in footnote 5 of the June 5 Letter, is attached as Exhibit F.

9. A true and complete copy of Formal Dispute Resolution Appeal Denial Letter I from Curtis Rosebraugh, Office of Drug Evaluation II, Office of New Drugs, Center for Drug Evaluation and Research, FDA, to Steven Ketchum, President of Research and Development, Amarin Pharma, Inc. (Apr. 22, 2014), which is cited in footnotes 6 and 10 of the June 5 Letter, is attached as Exhibit G.

10. A true and complete copy of Letter from Peggy J. Berry, Vice President, Regulatory Affairs and Clinical Quality, Amarin Pharma, Inc., to Mary Parks, Director, Division of Metabolism and Endocrinology Products, Center for Drug Evaluation and Research, FDA re: NDA 202057 S-005 (Feb. 21, 2013), which is cited in footnote 7 of the June 5 Letter, is attached as Exhibit H.

11. A true and complete copy of the Summary Minutes of the Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee (October 16, 2013), which is cited in footnote 8 of the June 5 Letter, is attached as Exhibit I.

12. A true and complete copy of the SPA Agreement Rescission Letter from Eric Colman, Deputy Division Director, Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, to Peggy Berry, Vice President, Affairs and Clinical Quality, Amarin Pharma, Inc. (Oct. 29, 2013), which is cited in footnote 9 of the June 5 Letter, is attached as Exhibit J.

13. A true and complete copy of the Formal Dispute Resolution Appeal Denial II Letter from John Jenkins, Director of Office of New Drugs, Center for Drug Evaluation and Research, FDA, to Steven Ketchum, President of Research and Development, Amarin Pharma, Inc. (Sept. 11, 2014), which is cited in footnote 10 of the June 5 Letter, is attached as Exhibit K.

14. A true and complete copy of the Minutes of the December 16, 2013 Type A Meeting, which is cited in footnote 10 of the June 5 Letter, is attached as Exhibit L.

15. A true and complete copy of Complete Response Letter from James P. Smith, Division of Metabolism and Endocrinology Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, FDA, to Steven Ketchum, President of Research and Development, Amarin Pharma, Inc. (Apr. 27, 2015), which is cited in footnote 11 of the June 5 Letter, is attached as Exhibit M.

16. A true and complete copy of FDA, *Revised Draft Guidance for Industry*, *Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices* (Feb. 2014) ("Revised Good Reprint Practices Draft Guidance"), which is cited in footnote 12 of the June 5 Letter, is attached as Exhibit N.

17. A true and complete copy of FDA, *Draft Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011) ("Draft Unsolicited Requests Guidance"), which is cited in footnote 12 of the June 5 Letter, is attached as Exhibit O.

18. A true and complete copy of FDA, *Good Reprint Practices for Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009) ("Good Reprint Practices Guidance"), which is cited in footnote 12 of the June 5 Letter, is attached as Exhibit P.

19. A true and complete copy of the Citizen Petition Response from Leslie Kux, J.D., Assistant Commissioner for Policy, FDA, to Alan R. Bennett, Ropes & Gray, et al., Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079 (June 6, 2014), which is cited in footnote 14 of the June 5 Letter, is attached as Exhibit Q.

20. A true and complete copy of the December 22, 2014 Update to the Citizen Petition Response from Leslie Kux, J.D., Associate Commissioner for Policy, FDA, to Alan R. Bennett, Ropes & Gray, et al., Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079 (June 6, 2014), which is cited in footnote 14 of the June 5 Letter, is attached as Exhibit R.

21. A true and complete copy of the Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401) (Sept. 8, 2004) ("Martek Petition Response"), which is cited in footnote 18 of the June 5 Letter, is attached as Exhibit S.

22. A true and complete copy of the Letter Responding to Health Claim Petition dated June 23, 2003 (Wellness petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart

Disease (Docket No. 2003Q-0401) (Sept. 8, 2004) ("Wellness Petition Response"), which is cited in footnote 18 of the June 5 Letter, is attached as Exhibit T.

23. A true and complete copy of the Letter from Christine J. Lewis, Ph.D., FDA, to Jonathan W. Emord, Esq., Emord & Associates, P.C., "Letter Regarding Dietary Supplement Health Claim for Omega-3 Fatty Acids and Coronary Heart Disease" (Docket No. 91N-0103), October 31, 2000, which is cited in footnote 21 of the June 5 Letter, is attached as Exhibit U.

24. A true and complete copy of *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims* (Jan. 2009), which is cited in footnote 22 of the June 5 Letter, is attached as Exhibit V.

25. Excerpts from Amarin's Form DEF 14A Proxy Statement dated April 30, 2014, are attached as Exhibit W.

26. Excerpts from Amarin's Form DEF 14A Proxy Statement dated April 24, 2015, are attached as Exhibit X.

27. On its website, Amarin provides hyperlinks to clinical manuscripts regarding its drug Vascepa and scientific presentations about results from the ANCHOR trial on its website. Amarin Corporpation plc – Publications, http://investor.amarincorp.com/publications.cfm (last visited June 18, 2015). According to Amarin's website, many of the manuscripts are available at no cost, including the following:

- Ballyntyne CM, et al. Efficacy and safety of eicosapentaenoic acid ethyl ester (AMR101) therapy in statin-treated patients with persistent high triglycerides (from the ANCHOR study). *Am. J. Cardiol.* 2012. 110:984-992. ("the 2012 Ballyntyne publication")

- Ballyntyne CM, et al. Effects of icosapent ethyl on lipoprotein particle concentration and size in statin-treated patients with persistent high triglcyerides (the ANCHOR study). *J Clin Lipidol.* 2014. ("the 2014 Ballyntyne publication")

- Brinton EA, et al. Effects of icosapent ethyl on lipid and inflammatory parameters in patients with diabetes mellitus-2, residual elevated triglycerides (200-500 mg/dL), and on statin therapy at LDL-C goal: the ANCHOR study. *Cardiovasc Diabetol.* 2013;12:100. ("the Brinton publication")

- Bayes HE, et al. Icosapent ethyl, a pure ethyl ester of eicosapentaenoic acid: effects on circulating markers of inflammation from the MARINE and ANCHOR studies. *Am J Cardiovasc Drugs*. 2013;13:37-46

28. Also according to Amarin's website, Amarin has discussed the results of the ANCHOR trial at many scientific conferences, including the American Diabetes Association Abstract about the Brinton publication, several American Heart Association Abstracts about other ANCHOR-related publications, and a European Society of Cardiology Abstract about Brinton EA, et al. Effects of AMR101 on lipid and inflammatory parameters in patients with diabetes mellitus-2 and residual elevated triglycerides (200-500 mg/dL) on statin therapy at LDL-C goal: the ANCHOR study. *Eur Heart J.* 2012; 33(suppl 1):280. In some cases, Amarin posts the presentation and abstract on its website, as it did for the National Lipid Association Abstract and presentation, both of which are entitled "Icosapent Ethyl (eicosapentaenoic acid ethyl ester): Effects of Apolipoprotein C-III in Patients from the MARINE and ANCHOR Studies." There is no mention of the 2012 Ballyntyne publication in Amarin's Complaint filed in this matter. Screenshots of Amarin's website and copies of the posted presentation and abstract are attached as Exhibit Y.

29. A true and complete copy of the Drug Industry Act of 1962: Report of the Senate Committee on the Judiciary of the 87th Congress, 2d Session, Report No. 1744 (July 19, 1962), is attached as Exhibit Z.

30. Excerpts from the Drug Industry Antitrust Act of 1962: Hearings before the Subcommittee on Antitrust and Monopoly of the House Committee on the Judiciary, 87th Congress, 2d Session, on H.R. 6245 (May 17, 18, 23 and 24, 1962), are attached as Exhibit AA.

31. Excerpts from Administered Prices: Drugs: Report of the Senate Committee on the Judiciary, Made by its Subcommittee on Antitrust and Monopoly Pursuant to S. Res. 52, of the 87th Congress, 1st Session, Report No. 1961 (June 27, 1961), is attached as Exhibit BB.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York
June 23, 2015

/s/ Ellen London
ELLEN LONDON
Assistant United States Attorney