SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Publications Policy		POLICY NO: 1.3-01	
Supersedes:	**Approval:** **Corporate Policy Review Committee (CPRC)**	**Date Issued:** **May 1, 2014**	**Page: 1 of 8**

SECTION 1. SCOPE AND PURPOSE:

This policy outlines the principles and responsibilities governing the external publication of scientific and medical information about products or disease states of interest to Sunovion Pharmaceuticals Inc. ("Sunovion" or the "Company").

The policy covers all publications in the United States and/or international journals (e.g., publications that concern Sunovion marketed products, drugs in clinical development, therapeutic areas of interest to Sunovion), and discovery research, as well as publications presented at international forums (e.g., scientific or medical congresses). It also covers publications resulting from independent studies that receive financial support from Sunovion through Investigator-Initiated Studies.

SECTION 2. DEFINITIONS:

2.1 **Investigator-Initiated Study** (or "IIS") is a clinical study that is proposed by an investigator who acts as the sponsor of the trial and takes responsibility for the appropriate conduct of the study in accordance with applicable laws.

2.2 **Policy** refers to this Publications Policy.

2.3 **Publication** is any original research article, secondary research article, abstract, poster or review article, as well as any presentation at a scientific or medical congress regardless of the format of the publication (oral, electronic, paper, or other media).

2.4 **Sunovion Study** means any study of a Sunovion drug product conducted by or on behalf of Sunovion where Sunovion or its affiliate is the Investigational New Drug Application (or foreign equivalent) holder.

SECTION 3. APPLICABILITY AND RESPONSIBILITIES:

This Policy applies to Sunovion employees in the United States and third parties acting on behalf of Sunovion involved in authoring Publications or planning or managing Publication-related activities.

The Head of Scientific Communications is responsible for the periodic review and effective communication of this Policy, including training as appropriate. All Sunovion departments are

responsible for compliance with this Policy, including Clinical Development, Medical Affairs, and Drug Discovery Research.

SECTION 4. GENERAL:

4.1 POLICY DETAILS

Communicating the outcomes of research studies undertaken by Sunovion to the scientific and medical community through Publication-related communications is an essential activity of the Company.

Sunovion is committed to publishing clinical data in a timely, objective, accurate, and balanced manner regardless of a study's outcome, in accordance with accepted ethical standards. Furthermore, Sunovion Publications will conform to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" ("Uniform Requirements") of the International Committee of Medical Journal Editors ("ICMJE") as a Company standard for Publications, including but not limited to authorship criteria and disclosure requirements.

It is Sunovion Policy to:

- Adhere to the ICMJE criteria and guidance, including the Uniform Requirements;
- Develop a Publications plan for a product or therapeutic area that is aligned with Sunovion strategies;
- Communicate factual information on Sunovion products and clinical research activities to the international medical and scientific community;
- Ensure that information about the efficacy, tolerability, and safety of a Sunovion product is communicated clearly, accurately, and in a timely manner;
- Maintain high standards of medical and scientific integrity by presenting research results in an accurate, objective, and balanced fashion;
- Disseminate the results of clinical studies, regardless of outcome;
- Allow investigators from individual study sites to publish the results arising from their participation in a multicenter study, in accordance with the Clinical Study Agreement and only after the overall data from the multicenter study have been published, provided that such Publication does not disclose any confidential information of Sunovion;
- Disclose authors'/presenters' academic and commercial relationships, financial interests and any other potential conflicts of interest as appropriate; is close the role of Sunovion as a sponsor of the clinical studies or, in the case of independent Publications, whether Sunovion provided any financial funding;
- Identify authors based on specific and accepted criteria as set forth below;
- Not pay individual authors for participation in Publications; ensure that authors have final approval of the content of the Publications;
- Provide accuracy review with respect to information relating to Sunovion product(s), upon receipt of an unsolicited request from a publisher or author regarding a Publication for which Sunovion has provided no support.

4.2 CRITERIA FOR AUTHORSHIP

Authorship will be based on substantial contributions to **each** of the following:

- A study's conception and design, acquisition of data, or analysis and interpretation of the data;
- Drafting the article or providing critical revision for important intellectual content; *and*
- Final approval of the version to be published.

All three conditions must be met to fulfill criteria for authorship. These conditions apply equally to external investigators/clinical researchers and to Sunovion employees. Participation solely in the collection of data or drafting of the manuscript does not constitute authorship. Each author must give his or her approval to be included in the list of authors.

In large multicenter studies, investigators who do not qualify as authors will be acknowledged in the Publication. In addition, for primary research articles, those individuals from a contract research organization who do not qualify as authors will be acknowledged in the Publication.

Authorship on a Publication resulting from a Sunovion-sponsored clinical study is not intended to impose, nor shall it be construed as imposing, any obligation on an author/investigator to purchase or prescribe (or recommend or arrange for the purchase or prescription of) any Sunovion product.

4.3 SUNOVION STUDIES

4.3.1 Number of Authors

The number of authors of each Publication will be determined based on their contribution and fulfillment of ICMJE criteria for authorship and will conform to the requirements of the relevant journal or congress. Each author must meet the criteria outlined in the Uniform Requirements. While it is important that authorship be based on the Uniform Requirements consideration should also be given to ensure an appropriate balance of internal and external authors.

4.3.2 Sunovion Authors

Sunovion staff will be included as authors on Publications of Sunovion Studies to reflect their involvement in those studies; authorship is based solely on fulfillment of all the authorship requirements described in the Uniform Requirements and should not be offered simply as a matter of recognition and contribution to the project. There may be exceptional circumstances, for example, when a new product is acquired, under which Sunovion staff may not meet all authorship criteria; in those instances, the extent of the review by Sunovion medical staff will be acknowledged in the Publication.

Presentation of data at medical congresses should be given by one of the authors, preferably an external clinical expert. An internal author may also present data at medical congresses as agreed at the outset of the Publication. In most instances the internal authors will be the clinicians or researchers involved with the conduct of the study and its analysis and clinical interpretation.

If a Sunovion employee leaves the Company, his/her authorship on a Publication will be determined on a case-by-case basis. Once this has been determined, he/she may be asked to sign a confidentiality agreement.

4.3.3 Sunovion Internal Review

Publications for peer-reviewed journals or peer-to-peer presentation at medical or scientific congresses are subject to review by a peer-review mechanism of journals and congresses and are distinct from promotional materials. Such Publications, however, still require internal review by Sunovion prior to submission.

The functional role of each reviewer in the internal review process for Publications is as follows:

- Clinical Development and Medical Affairs – Has responsibility to ensure medical and scientific accuracy, including consistency with protocol, disease background, data accuracy, data review and interpretation regarding efficacy, safety and tolerability, and context of known medical literature.

- Lead Biostatistician – Ensures most appropriate data sets and statistical analyses are utilized. Responsible for the statistical interpretation and verification of the study data.

- Scientific Communications – Responsible for initial contact with external authors, briefing communications agencies, reviewing drafts from communications agencies, and circulating manuscripts for review. Scientific Communications is also responsible for the collation of comments and discussions with external authors and internal teams during the development process for Publications.

- Legal Affairs – Responsible for legal review of all Publications including, but not limited to, ensuring that patent and intellectual property rights are protected.

- Regulatory Affairs – Responsible for ensuring adherence with FDA requirements.

Marketing Representatives for each therapeutic area may be invited to the annual Publications plan review and *ad hoc* Publications plan reviews. In addition, Marketing may also request and receive, as a courtesy (at the discretion of Medical Affairs) a copy of the manuscript prior to submission for publication. However, Marketing shall not participate in the formal internal review process or have any editorial rights.

Only authors approve the content of Publications.

4.3.4 Disclosure

Upon submission of a manuscript, authors should provide details of all potential conflicts of interest for consideration by the journal publishers. Sponsorship of the study by Sunovion will also be disclosed.

4.3.5 Acknowledgments

External agencies hired by Sunovion may facilitate the development of a manuscript with input and direction from the authors. The role of the agency will be acknowledged in the Publication. Other contributors to the study and the Publication will also be acknowledged, as appropriate. Funding by Sunovion, if any, for writing support will also be acknowledged.

Written permission should be obtained from all those who qualify for and who are named/listed in the acknowledgment.

4.3.6 Access to Data

There is an important distinction between accountability for the content of a Publication and

ownership of the data to create it. While accountability for the content of a Publication can be shared with non-company researchers, the data arising from Sunovion Studies are the property of the Company.

External authors (both investigators and other experts directly involved in the study) will have access to the appropriate study protocol, CRFs, the statistical analysis plan, results of statistical analyses and the clinical study report. Investigators may request additional tables, or graphs regarding the study.

4.3.7 Copyright

Copyrighted information in a Publication (for example, tables and figures) cannot be used by Sunovion in a Publication intended for external dissemination without prior approval from the publisher.

The right of Sunovion to disseminate copies of a Publication or make copies for its own internal use is governed by copyright laws and any agreements entered into with the publishers. Consequently, it is important that any external documents referring to assignment of copyright be reviewed and approved by the Legal Affairs Intellectual Property Department before they are signed by an authorized Vice President or his/her designee on behalf of Sunovion.

4.4 Publications Other Than Those Derived From Sunovion Studies

4.4.1 Investigator-Initiated Studies ("IIS")

An employee of Sunovion must not be an author on any Publication related to a study conducted independently of Sunovion. Sunovion may provide financial support for independent studies in accordance with its Investigator-Initiated Studies Policy 1.14. Sunovion shall have no involvement in the development of Publications that are the result of the IIS program, and Company employees may not be authors on an IIS Publication. Sunovion may provide financial assistance to investigators for the development of Publications but this should be identified in the IIS agreement.

Notwithstanding the foregoing, if during a publication review (for information relating to patentable items) pursuant to a clinical research grant agreement, Sunovion identifies an inaccuracy with respect to Sunovion data, safety information or FDA approved label information relating to Sunovion products, Sunovion shall provide written notification to the author(s) regarding any such inaccuracies.

4.4.2 Review Articles and Journal Supplements

4.4.2.1 Review Articles

Types of review articles covered by this policy include, but are not limited to, the following:

- *Systematic Reviews* – Publications that offer a critical assessment of literature and data sources pertaining to clinical topics, including factors such as etiology, diagnosis, prognosis, therapy, HEOR articles or prevention of disease.*Clinical Reviews* – Publications that address a specific question or issue that is relevant to clinical practice and provide an evidence-based, balanced review focused on improving patient care.

4.4.2.2 Origin of Review Articles and Journal Supplements

A proposal for a review article may be received from an author, academic institution, or clinical research institute. A review article may also be conceived as a result of a Sunovion activity. For example, Sunovion may identify gaps in the current literature that warrant the development of a review article; this may occur following a comprehensive literature search relevant to patient care and therapeutic treatment decisions; development of a strategic Publications plan; inquiries made by healthcare professionals; advisory boards; or information obtained from investigators or through guidance from the FDA. In cases in which Sunovion identifies the need or concept for a review article, that article may be developed by an external expert in the following manner: Sunovion will contact an external communications agency and convey the concept for the article; he communications agency will independently select external experts who, in turn, will independently develop, write and submit the article without additional input or discussion with Sunovion.

Sunovion may also determine that a journal supplement is necessary for a given area of interest. A journal supplement may be deemed appropriate following a comprehensive review by Sunovion of the current literature relevant to patient care and therapeutic treatment decisions, or as a result of inquiries made by healthcare professionals, the outcome of advisory boards, or information obtained from investigators or through guidance from other external sources. A journal supplement may be developed only if prepared independently by external experts.

4.4.2.3 Authorship of Review Articles and Journal Supplements

Sunovion employees or agents may not be authors on a review article or journal supplement.

4.3.2.4 Support from Sunovion and Required Disclosures

Sunovion may provide financial support for a review article and/or journal supplement proposed by an external author, academic institution, or clinical research institute. The rationale for approval or rejection of support will be based on the scientific and medical merit of the proposal following review and agreement by the Medical Affairs therapeutic team in consultation with the Head of Scientific Communications.

As discussed above, in the case of review articles conceived by Sunovion, the Company may select and provide financial support to an independent agency/medical writer who independently selects an external expert who, in turn, will independently develop and write the review article. The communication agency can assist such an author in preparing the review article.

When Sunovion provides financial support for review articles or journal supplements, full disclosure of the support must accompany the Publications. In cases in which Sunovion originates the concept or identifies the need for the review article/journal supplement, as described above, that fact must also be disclosed in the Publication.

4.4.2.5 Accuracy Review of Sunovion Information

Sunovion recognizes that the conclusions drawn by authors remain expressions of their scientific viewpoint, and neither Sunovion employees nor its agents will attempt to influence or edit the conclusions or analyses of review articles or journal supplements.

In response to an unsolicited request from a publisher or author, Sunovion may provide a review of a proposed article or journal supplement (for which Sunovion is not providing any funding),

provided such feedback is focused solely on the article's accuracy of any Sunovion data, safety information and FDA approved label information relating to Sunovion products.

If Sunovion provides feedback to the author(s) in the context of such an accuracy review, including comments, the communications back to the author must specifically indicate that the author has the ultimate decision in considering the comments for incorporation into the final Publication. Authors, however, should ensure disclosure of Sunovion's accuracy review in the Publication whenever such review is provided.

These same standards apply to a Publication involving an independent study for which Sunovion did not provide any support.

4.5 CASE REPORTS/SERIES

Sunovion will not provide financial and/or writing/editorial support for the development of case reports or series for publication. Individual investigators/physicians may report/publish case reports or series independently of any involvement of Sunovion. However, investigators/physicians may not disclose any confidential information/data acquired in the conduct of a Sunovion Study.

SECTION 5. OTHER MATTERS:

5.1 AMENDMENT

Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sunovion Corporate Policy 1.0, **"Corporate Policy Review Committee"**.

5.2 FAILURE TO COMPLY

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES MAY BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.

5.3 REPORTING CONCERNS

Reports concerning wrongful behavior, violations or suspected violations of this or any other policy, the Code of Conduct and Ethics, law or regulation may be submitted on a confidential basis or may be submitted anonymously through Sunovion's Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior will be maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Reporting Hotline Options:

A. Toll free telephone number. 866-886-1348
B. Via the internet at: www.ethicspoint.com

5.4 AUDIT

Scientific Communications shall perform periodic reviews of the implementation of this Policy, under the oversight and guidance of the Chief Compliance and Ethics Officer.

5.5 RELATED CORPORATE POLICIES

Clinical Studies Policy 9.0

Investigator-Initiated Studies Policy 1.14

Code of Conduct and Ethics

External Communications Policy 1.3

Conflicts of Interest Policy 1.06

Aggregate Spend Policy 1.17