

# SUNOVION PHARMACEUTICALS INC. CORPORATE POLICY

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<b>External Communications</b>	s Policy		
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### SECTION 1 INTRODUCTION

### 1.1 Purpose and Scope

- 1.1.1 This Policy is intended to be consistent with the Company's Code of Conduct and Ethics and to ensure that Sunovion Inc. and its U.S. subsidiaries ("Sunovion" or the "Company") communicate with external parties about its products and itself at all times and in all places in a manner that is truthful, accurate and fully compliant with relevant laws and regulations.
- 1.1.2 This Policy applies to all external Company communications and materials, wherever they may take place, such as, communications which:
  - promote Company products;
  - are directed to Health Professionals, the media or consumers;
  - are directed to the Investment Community, where appropriate, and the Media; or
  - are training materials related to educational and promotional activities.
- 1.1.3 This Policy is intended to be consistent with the PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, rev. July 10, 2008); the Anti-Kickback Statute (42 U.S.C. § 1320a-76(b)); the Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731, May 5, 2003); DHHS regulations; the federal Food, Drug, and Cosmetic Act; and Food and Drug Administration ("FDA") regulations; relevant FDA guidance; Company policies and guidances; and other statutes and regulations as applicable.
- 1.1.4 This Policy applies to all Employees of the Company and any persons acting on behalf of the Company, including consultants, speakers, agents, or third party vendors, who shall be obligated to follow this Policy, as appropriate, in contractual arrangements or otherwise. Any Employee who violates this Policy and any manager who knowingly permits or directs a subordinate to do so, will be disciplined accordingly, up to and including termination of employment. If a person acting on behalf of the Company violates this Policy, or if such person's manager knowingly permits or directs such person to do so, the Company shall take whatever corrective action may be necessary up to and including termination of the engagement.
- 1.1.5 All Employees and persons acting on behalf of the Company, as described above, under this Policy, shall participate in periodic training on its requirements.

### 1.2 Definitions

1.2.1 "CCO" means the Chief Compliance Officer.

- 1.2.2 "Detail" or "Detailing" refers to the time spent by a Company Employee, agent or co-promotion partner with a Health Professional during which a promotional communication about a Company product(s) occurs.
- 1.2.3 "Employee" means any person employed by the Company on a full-time, part-time, temporary or on a contract basis.
- 1.2.4 "Health Professional" refers to: (a) physicians, nurses, nurse practitioners, pharmacists, medical assistants and other medical professionals involved in patient care, and (b) scientists or others who, because of then professional reputations, may have an influence on clinical opinions even though they would not be prescribing pharmaceutical products.
- 1.2.5 "Investment Community" means any persons or entities that own, are considering purchase, or recommend purchase or sale of shares. This includes media or publications reporting on the Company, its activities, activities of Company officers, or the Company's products.
- 1.2.6 "Material" or "materials" means any communication or material described in Section 1.1.2.
  - 1.2.7 "MSRC" means the Medical and Scientific Review Committee.
- 1.2.8 "Media" means all forms of mass communication through which financial or other information is transmitted, including but not limited to newspapers, magazines, internet, blogging, investor teleconferences, radio, television and presentations at industry-conferences.
  - 1.2.9 "PMRC" means the Promotional Materials Review Committee.
  - 1.2.10 "Policy" means this External Communications Policy.
- 1.2.11 "Promote" or "Promotion" means engaging in any communication that makes a claim concerning the safety or effectiveness of a Company Product, or that otherwise seeks to encourage the use, purchase, sale or recommendation of a Company product.
- 1.2.12 "Sponsor" means the Company Employee who is responsible for the creation of Material and who is responsible for managing the Material through the appropriate review process.
- 1.2.13 "Unapproved Use" refers to the use of a Company product that is not consistent with the uses that are approved and described in the full prescribing information, especially the Indication and Usage, Clinical Studies, or Dosage and Administration sections for a Company product. All of the following examples would be considered information on an Unapproved Use if not specified on a Product label or on the Product's full prescribing information:
  - New indication
  - New treatment schedule/dosing regimen (timing of use)
  - · Different duration of use
  - Different patient population (e.g. different age group; different type of diagnosis)

1.2.14 "Unapproved Drug" refers to a drug that is not the subject of an approved new drug application ("NDA"), abbreviated NDA ("ANDA"), over-the-counter drug monograph, or some other lawful marketing authority.

### 1.3 Responsibilities

- 1.3.1 The primary responsibility for implementation and oversight of this Policy is with line management. Management oversight may be supplemented by audits.
- 1.3.2 The CCO or her/his designate shall be responsible for developing, operating, monitoring and auditing compliance with this Policy and shall assist management and Employees by providing information and advice on the implementation and continued adherence to the Policy.
- 1.3.3 Management, working with the CCO, is responsible for ensuring that relevant Employees are trained on the Policy. Management is also responsible for ensuring that Employees understand that they are encouraged to ask questions about the Policy, discuss compliance issues, and report possible noncompliance to management and/or the CCO.
- 1.3.4 The Regulatory Affairs Department shall be responsible, through direct operations and/or through the direction of the Promotional Materials Compliance Management ("PMCM") Department, for the organization and functioning of the PMRC. This includes authoring and maintaining SOPs to effectuate the process of such Committees. PMCM will manage the process and daily activities of PMRC.
- 1.3.5 The Medical Affairs Department shall be responsible, through direct operations and through the direction of other departments, for the organization and functioning of the MSRC. This includes authoring and maintaining SOPs to effectuate the process of such Committees.
- 1.3.6 The Communications Department shall be responsible, through direct operations and through the direction of other departments, for the organization and functioning of the Corporate Communications Committee ("CCC"). This includes authoring and maintaining an SOP to effectuate the process of such Committee.
- 1.3.7 Any person acting as a reviewer of Material on any committee, as appropriate, shall not also act as the Sponsor of that Material or have a substantial direct role in the creation of the Material.
- 1.3.8 This Policy shall apply to all communications relating to lobbying or government interactions, however, approval of such communications shall be obtained through policies or SOPs maintained by the Company's Government Affairs group.
- 1.3.9 This Policy shall apply to all company confidential information, however, approval processes may exist for those materials in other Company policies which more specifically cover the use of Company confidential information.

### SECTION 2 GENERAL RULES ON COMMUNICATIONS

### 2.1 Concerning Drugs and Uses Prior to Approval

- 2.1.1 The Company will not engage in the promotion of a drug prior to its approval by the FDA, or the promotion of a product for any use until such use of the drug is approved by the FDA, and the Company shall not otherwise provide information to Health Professionals about unapproved drugs or unapproved uses of drugs except as permitted in this Policy.
- 2.1.2 Communications to the Investment Community and the Media regarding drugs under development or otherwise pre-approval are to be in accordance with Section 6 of this Policy.

### 2.2 Concerning Drugs and Uses Upon Approval

- 2.2.1 After a drug and a specific use of a drug are approved by the FDA, information provided by the Company in promotion must be consistent with its approved full prescribing information, and must be truthful, scientifically robust and not misleading.
- 2.2.2 Communications to the Investment Community and the Media regarding drug approval are to be in accordance with Section 6 of this Policy.

### 2.3 Approved Drugs

### 2.3.1 In General

- 2.3.1.1 For a drug that is approved (that is, where the product and its intended use are covered by an NDA or other marketing authorization), information provided by the Company must be consistent with the approved prescribing information, unless the rules governing information for Unapproved Drugs and Unapproved Uses are followed.
- 2.3.1.2 Promotional activities consist of communications about an approved drug that are consistent with the approved full prescribing information. Promotional activities shall not include communications about Unapproved Drugs or Unapproved Uses.
- 2.3.1.3 Promotional activities shall be truthful, scientifically robust, and not misleading, and shall include a balanced discussion of the benefits, limitations and risks of the drug.

### 2.4 Unapproved Drugs or Unapproved Uses

- 2.4.1 The Company shall not engage in promotional activities for Unapproved Drugs or Unapproved Uses.
- 2.4.2 No Company Employees shall promote Unapproved Drugs or Unapproved Uses with a Health Professional or related target audience, even if the discussion was initiated by the Health Professional. If Company personnel serving in a promotional capacity receive a request from a Health Professional for information relating to Unapproved Drugs or Unapproved Uses, the individual receiving such request must:

- (i) Reference the approved indication or appropriate information from the labeling and note that the use referenced by the Health Professional is not approved, and
- (ii) Refer the Health Professional to Medical Information through an approved Company process.
- 2.4.3 Communications to Health Professionals about Unapproved Drugs or Unapproved Uses shall be limited to the following:
  - (i) Scientific and Educational Settings: Participation at third-party scientific and educational meetings where communications about Unapproved Drugs or Unapproved Uses are limited to posters, oral presentations, articles or other limited scientific communications, are scientifically rigorous and balanced, do not contain claims concerning the safety or efficacy of unapproved drugs or uses and are clearly separate from any promotional activity. (See Section 5.1, below)
  - (ii) Publications: Publication of scientific articles in peer-reviewed, independent, medical and scientific journals.
  - (iii) Medical Information: Responses to unsolicited requests for information including study results, copies of published information or other medical information. (See Section 5.4, below)
  - (iv) Responses at Speaker's Programs: Responses by a Speaker to unsolicited questions from Health Professionals attending an approved Company Speakers Program. (See Section 4.9, below)
  - (v) Press Releases: Appropriately qualified press releases and other communications to stockholders or the public regarding new scientific findings or other newsworthy Company developments that are part of the normal course of business. This covers only the initial issuance of the press release or other communication, and not the subsequent distribution of a press release or other communication to a targeted Health Professional or other audience. (See Section 6.2, below)
  - (vi) Communications to *bona fide* consultants, investigators and other service providers of the Company or potential consultants, investigators or service providers, where such communications are necessary or appropriate for the consultants', investigators' or other service providers' rendering of services to the Company, or to the identification and recruitment of individuals to provide such services to the Company. (See Section 2.5, below)
  - (vii) The dissemination of peer-reviewed reprints containing information on approved Company products, where the dissemination is clearly separate from any promotional activity. (See Section 2.6, below)

(viii) The publication of information on clinical trial registries and clinical trial results databases, including clinicaltrials.gov. and ClinicalStudyResults.org.

### 2.5 Obtaining Services from Health Professionals (Consultants and Speakers)

- 2.5.1 The Company may retain Health Professionals and others as consultants, speakers, or other forms of service providers to the Company. When retaining a Health Professional as a Consultant, Speaker or other service provider, the Company shall assure that the relationship is one of a bona-fide Consultant that is, the Consultant, Speaker or other service provider must perform needed and valuable services to the Company under a written contract consistent with relevant Company policies, and be compensated at a fair market value for those services.
- 2.5.2 All communications to Consultants, Speakers or other service providers concerning Company products must also be relevant to the services being performed. For example, where information concerning a Company product is provided to a Consultant, the information must be related to the feedback being sought from the Consultant.

### 2.6 Reprints and Textbooks

- 2.6.1 Reprints and textbooks discussing an approved Company product may contain information regarding that product that has not been approved by the FDA ("Emerging Information"). In no event shall any Company representatives use these materials to promote the use of Company products for an Unapproved Use.
- 2.6.2 In the interest of advancing medical and scientific education, the Company may engage in an exchange of scientific information and provide certain materials containing Emerging Information to certain Health Professionals ("Restricted Materials") if the following conditions are met:
  - (i) Reprints. Reprints may be provided to Health Professionals in the following circumstances:
    - (a) during a Detail in line with the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications SOP:
    - (b) by Medical Affairs in line with this Policy;
    - (c) by Research and Development in line with this Policy; and
    - (d) as otherwise approved by the MSRC.
  - (ii) The materials are contained in a textbook which has been approved by MSRC.
  - (iii) Restricted Materials may continue to be disseminated for twelve (12) months from the approval date. After expiration of this period, such Restricted Materials must be re-submitted to the appropriate Committee for review in accordance with this Policy.
  - (iv) Commercial personnel must be instructed that they should not discuss any unapproved use information contained in Restricted Materials and that all

inquiries relating to Unapproved Uses of Company products must be referred to Medical Information.

### 2.7 Telephone Solicitations, Faxing and Texting

2.7.1 All external Company communications and associated materials, made by the Company or by any agent or third party vendor on behalf of the Company, must comply with the Telephone Consumer Protection Act, 47 U.S.C. §227 ("TCPA") and its incorporated Junk Fax Act of 2005. All such communications and materials that are to be faxed must be submitted for review or re-review, including any fax cover sheets and opt-out language (as further described in Schedule 2.7), to either PMRC in accordance with the PMRC SOP and this Policy, or the Legal Department pursuant to any other applicable policy. Specific instructions regarding compliance with the TCPA are contained in Schedule 2.7 to this Policy.

### 2.8 Social Media Networks/Internet

2.8.1 Any confidential information or defamatory statements about the Company or its Employees should not be disclosed or posted by any Company Employees on Social Media Networks and/or the Internet in conformance with the Sunovion Systems and Confidential Information Policy. Access to and disclosures on such Media Networks and/or the Internet are monitored as appropriate.

### SECTION 3 COMMUNICATIONS REVIEW

### 3.1 Review Committees

- 3.1.1 In order to ensure compliance with applicable legal and regulatory requirements concerning drug advertising, promotion, sale, and scientific exchange, the Company requires multi-disciplinary review and approval prior to use by a duly appointed committee ("Committee" or "Committees") of all written, printed or graphic materials concerning its Products intended for external use, as well as internal sales training and other specified scientific and medical information materials.
- 3.1.2 The Company appoints Committees for such review including: the Promotional Materials Review Committee ("PMRC"), the Medical and Scientific Material Review Committee ("MSRC"), and the Corporate Communications Committee or CCC. PMRC shall have approval authority over materials produced in accordance with Section 4; MSRC, shall have approval authority over materials produced in accordance with Section 5; CCC shall have approval authority over materials produced in accordance with Section 6. The Committees may appoint product, content or brand-specific sub-committees to review the relevant material for those Committees and the Chair shall be responsible for the development of SOPs guiding those reviews in detail.

### 3.2 Promotional and Scientific Committees

3.2.1 The PMRC and the MSRC shall each include as a core membership group a representative from the following departments: Regulatory Affairs, Medical Affairs and Legal Affairs. In addition, PMRC shall include a representative from Marketing as a core member.

- 3.2.2 Regulatory Affairs shall be the Chair of each PMRC Committee and shall have the power to organize, manage and control the affairs of the Committee directly and/or through the Promotional Materials Compliance Management department. PMCM will manage the process and daily activity of the PMRC. Regulatory Affairs shall be responsible for developing, revising and instituting SOPs to implement this Policy.
- 3.2.3 Medical Affairs shall be the Chair of the MSRC, and shall have the power to organize, manage and control the affairs of the Committee directly or through other departments. Medical Affairs shall be responsible for developing, revising and instituting SOPs to implement this Policy.

### 3.3 Corporate Communications Committee and the Media

- 3.3.1 In order to ensure compliance with requirements when communicating with investors or the Investment Community, where appropriate, and the Media, the Company requires multi-disciplinary review of such materials prior to dissemination through the CCC. The CCC shall include representatives from the following departments: Regulatory Affairs, Medical Affairs, Legal Affairs, a designee from Dainippon Sumitomo Pharma America, Inc., and may also include the Chairman of the Company or his/her designee.
- 3.3.2 The CCC shall coordinate the review and approval of all materials intended for the Investment Community, where appropriate, and the Media through the CCC which shall have approval authority over materials produced in accordance with Section **6** of this Policy.
- 3.3.3 The Communications Department shall be the Chair of each CCC meeting and shall have the power to organize, manage and control the affairs of the Committee directly or through other departments. The Communications Department shall be responsible for developing, revising and instituting SOPs to implement this Policy.

### 3.4 Executive Review Committee

- 3.4.1 Prior to dissemination or publication of any material, all materials must be approved by the respective Committee. In the event that the Committee does not reach agreement with respect to the content of, and proper form for dissemination of, certain material, the material at issue shall not be disseminated by or on behalf of the Company. The appropriateness of the committee decision may be appealed by the Sponsor to an Executive Review Committee ("ERC") consisting of the below or his/her designee:
  - (i) The head of Regulatory Affairs and Corporate Quality Assurance;
  - (ii) The head of Medical Affairs, and:
  - (iii) The head of Legal Affairs
  - (iv) If the material at issue sources from PMRC, the ERC shall also contain the head of the Marketing.
  - (v) If the material at issue sources from CCC, the ERC shall also contain the head of the Business Planning and Communications Department.
- 3.4.2 In the event that the ERC does not unanimously reach agreement with respect to the content and proper form of dissemination of the appealed material, the material at issue shall not be disseminated by or on behalf of the Company.

# SECTION 4 PROMOTIONAL MATERIALS (ADVERTISING AND LABELING)

Promotional materials for use in advertising and promotion of Company products must be accurate, present all material information about the product's benefits and risks (i.e., "fan balance") and be compliant with all applicable regulations and in accordance with the Promotional Materials Review & Disposition Process SOP. Claims shall not be stronger than the scientific evidence warrants, and there must be disclosure of the limitations of the supporting data being presented or relied upon. Sales representatives and other Employees engaged in any manner of promotion may use only PMRC-approved materials and may not alter approved materials in any manner.

### 4.1 General Guidelines and Restrictions on Use

- 4.1.1 All materials used in Company advertising and promotion must:
  - be truthful and not misleading;
  - reflect a fair balance of benefits and risks;
  - include the full prescribing information (labeling) or a brief summary (advertising), except for approved reminder advertising or labeling, as described below, and except for broadcast advertisements where there must be adequate provision made for consumers to obtain further detailed full prescribing information; and
  - be approved by the PMRC.
- 4.1.2 Approved promotional labeling, such as detail pieces, brochures, handouts, website information, and the like, which have been previously approved by PMRC or ERC, as the case may be, shall be accompanied by the approved full prescribing information.
- 4.1.3 Approved advertising shall include a brief summary relating to effectiveness, contraindications, warnings, precautions, and safety information, except for broadcast advertisements where there must be adequate provision made for consumers to obtain further detailed full prescribing information.
- 4.1.4 Reminder advertising or labeling may be used for products that do not have a black box warning. Approved reminder advertising or reminder labeling need not include a discussion of the benefits and risks of the drug or full prescribing information. (See also Section 4.5 on Reminder Advertising).
- 4.1.5 Public relations materials and events related to marketed products or to promote therapeutic awareness are subject to PMRC and CCC review and approval.

### 4.1.6 During Detailing

4.1.6.1 During Details, Company representatives are permitted to provide to Health Professionals only messaging contained in PMRC-approved promotional materials and

related, approved, training materials. Company representatives must comply at all times with all Company policies and guidelines during such Details.

- 4.1.6.2 Company representatives must comply with the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications SOP including:
  - (i) Company representatives are permitted to use PMRC-approved Promotional Reprint Carriers and enclosed reprints of scientific articles as permitted under the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications SOP.
  - (ii) Company representatives must follow the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications SOP when dealing with Non-Promotional Reprint Carriers and refer Health Professional follow-up questions to Medical Information, per Section 5.4 of this Policy.
- 4.1.6.3 All materials used in promotion must be PMRC-approved and such approved materials may not be changed without full PMRC re-review and approval. Company representatives may not add or attach handwritten notes, use highlighting or photocopies of approved materials, or annotate or tab pages of promotional materials. Dissemination or use of such materials, often called "homemades" or "homebrews", shall result in discipline up to and including termination of employment.

### 4.2 Claims in Promotional Materials

- 4.2.1 Claims in promotional materials must be accurate and may not be false or misleading.
- 4.2.2 Claims must also be based on appropriate substantial scientific evidence and be consistent with the approved product full prescribing information. The more specific a claim, the more specific the evidence must be to support it and claims must only be as strong as the evidence that supports them.
- 4.2.3 Graphs or other presentations of study data must be accompanied by information about study design, number of patients enrolled, statistical significance of the study endpoints and other material information that a Health Professional would need to know in order to understand the graph or data presented. References to or excerpts from data sets, studies and/or publications must not be used if they have been superseded, rendered obsolete or substantially challenged by the consensus of the scientific community. Any non-clinical studies forming the basis of a claim must be identified clearly and may not be used to suggest or imply clinical relevance where none has been established. Quotations and studies must be referenced.
- 4.2.4 Mechanism of action, in itself, should not be the basis for a safety, efficacy, or comparative claim, unless such a claim is stated in the approved full prescribing information.
- 4.2.5 Testimonials or endorsements should be consistent with, and not contrary to, the approved full prescribing information, have proper contextualization, be representative of typical patient response in pivotal trials, and be otherwise consistent with the FTC Guidances Concerning Use of Endorsements and Testimonials in Advertising.

### 4.3 Fair Balance in Promotional Materials

- 4.3.1 Fair balance means that promotional materials must be truthful, must represent a product accurately and must present relevant side effects, warnings, precautions and contraindications with a prominence and readability reasonably comparable to the presentation of efficacy information.
- 4.3.2 Promotional materials should not contain out-of-context quotations that may distort the actual meaning of the quoted source or omissions of material facts that cause statements in the promotional materials to be misleading.
- 4.3.3 Comparisons between Company products and competitive products must be supported by appropriate evidence (see below).

### 4.4 Comparative Claims in Promotional Materials

- 4.4.1 Promotional claims that state or suggest that a drug's safety or effectiveness is comparable or superior to another drug must be supported by appropriate evidence. Appropriate evidence in this context is generally considered to be at least one adequate and well-controlled head-to-head clinical study using comparable dosage regimens that are consistent with each product's labeled dosage. The results of these studies must have both clinical and statistical significance before any claims may be made in promotional materials and must be approved pursuant to Company's applicable SOPs.
- 4.4.2 Safety or effectiveness comparisons based on full prescribing information are not acceptable when the parameter that is being compared would require a comparative study (e.g., statements regarding relative safety or efficacy). Statements concerning intrinsic products properties (e.g., dosage form), and certain other general statements (e.g., approved dosing regimens) may be permissible as long as they are presented in appropriate context and are not misleading.

### 4.5 Reminder Advertisements or Labeling in Promotional Materials

- 4.5.1 Reminder advertising or reminder labeling is a promotional item which makes no representation, claim, or implied claim about a product. A reminder advertisement is a short promotional piece that contains the brand and established names of the product and may contain information regarding dosage type, strength (e.g., 2.5 mg tablets), active and inactive ingredients and pricing information. Reminder advertisements do not include indications or dosage recommendations; accordingly, they are not required to include the brief summary or meet the fair balance requirements that apply to other promotional materials. Any mention of, or reference to, the drug's effectiveness, safety, use or dosing regimen removes the piece from this exception.
  - 4.5.2 Reminder pieces are not permitted for drugs that carry black box warnings.

### 4.6 Direct-to-Consumer ("DTC") Advertisements

4.6.1 Advertisements directed to consumers are subject to the same review

requirements as promotional materials directed to Health Professionals. DTC advertisements should, however, be presented in consumer-friendly language, and expressly state, as necessary, that the product is "Prescription (Rx) only." In general, DTC advertisements should make clear that consumers should discuss with their treating Health Professionals whether a Product is an appropriate option for them to consider. In other words, the DTC advertisement should reinforce, and not undermine, the Health Professional-patient relationship.

4.6.2 It is not possible in a television or other form of broadcast DTC advertisement to include the "brief summary" or package insert. Instead the advertisement must contain a "major statement" of the product's principal risk(s), and adequate references must be made in the advertisement for ways in which the consumer may obtain the full prescribing information or review the brief summary. For example, the DTC advertisement may reference a product web site, the availability of package inserts through Health Professional's offices, or print advertisements with brief summaries running concurrently with the broadcast advertisement.

### 4.7 Healthcare Formulary Communications

- 4.7.1 The Company recognizes that healthcare economic information ("HCEI") about FDA-approved uses is needed by managed care experts and other Health Professionals responsible for evaluating the benefits, costs and other consequences of competing therapies, particularly in managed care formulary settings. Where HCEI information is provided outside the formulary setting, then standard FDA rules for advertising and promotion may apply. Where HCEI is provided to formulary committee members (or the functional equivalent) all HCEI materials must be:
  - (i) Supported by competent and reliable scientific evidence;
  - (ii) Related to an approved labeled indication;
  - (iii) Disseminated only to a formulary committee, or other similar entity or persons, that are responsible for the selection of drugs for a managed care organization, or other similar organization; and/or
  - (iv) Reviewed by PMRC or other Departments as appropriate.
- 4.7.2 Any HCEI materials for use in advertising and promotional activities must be reviewed and approved in advance by the PMRC.
- 4.7.3 Information other than HCEI provided to managed care organizations and other formulary decision makers, or as described in the PMRC SOP, is subject to the Company and FDA rules and policies on promotion and scientific exchange.

### 4.8 Websites

4.8.1 Company websites should identify the nature of any particular page/site (e.g., consumer, Health Professional, investigator) and except for pages of general access should, depending on the nature of the site, require verification or limited access (e.g., the use of a preassigned code for clinical investigators). Websites intended for consumers should be written in consumer-friendly language.

- 4.8.2 If the Company or an affiliate has an international or foreign website, such sites should clearly be differentiated from the U.S. website and, to the extent practicable, subject to separate access. Further, the international or foreign website should not be sponsored by any U.S. affiliate and the homepage of such sites should include a conspicuous statement that the products or uses identified in the website may not be approved in all jurisdictions where the Company or its affiliate market products and local labeling should be consulted for the scope of any approval in particular jurisdiction. Any links between a U.S. and non-U.S. Company website may only be provided at the homepage level of the respective sites, unless approved otherwise by the appropriate committees.
- 4.8.3 It may be appropriate to establish links to and from reputable third party websites. The Company may not provide links on its sites to content on third party sites that consists primarily of information about Unapproved Uses or Unapproved Drugs, and it also is not permitted to arrange for links from third-party sites with information primarily about Unapproved Uses or Unapproved Drugs to Company websites. However, links from Company websites to reputable medical information sites (e.g., The American Lung Association) that contain information on Unapproved Uses may be appropriate, provided that the link does not direct users to pages containing the Unapproved Use information, and users are given a clear indication (e.g., a pop-up) when they are leaving a Company website and going to a third-party site.
- 4.8.4 Websites generally should include fair balance and a prominent link to the full prescribing information, on every page that contains a product claim. The full prescribing information should be kept current and updated each time the labeling for the product is revised.

### 4.9 Speakers' Bureau Presentations

- 4.9.1 The Company may engage certain Health Professionals to speak on its behalf regarding approved Company products. Any such Health Professionals ("Speakers") must first complete training, as per the Company policies and procedures.
- 4.9.2 Speakers shall use slide kits prepared by the Company and approved by the PMRC. Speakers shall follow the PMRC's instructions regarding the use and presentation of the slides, including any instructions regarding the use and presentation of slides in response to questions from or a request for information by, a Health Professional concerning an Unapproved Drug or Unapproved Use.
- 4.9.3 No material unapproved by the PMRC shall be utilized at Company sponsored presentations and all presentations must provide some educational or patient care benefit.
- 4.9.4 All Speakers Bureau presentations must be consistent with the full prescribing information of Company products and shall not address or discuss Unapproved Uses of Company products except in response to a truly unsolicited request for such information by an independent participant. Slide kits prepared for Speakers should not include, as part of their formal presentations, any discussion concerning Unapproved Uses.
- 4.9.5 Any discussion relating to Unapproved Uses by the Speaker in response to an unsolicited request should be directly responsive to the question asked, avoid drawing conclusions with respect to the safety and effectiveness of the drug for the Unapproved Use, and should affirmatively state that the drug has not received FDA approval for this use. Specially designated and segregated back-up slides may be provided to Speakers for use solely in

response to an unsolicited request for information in order to help ensure that the information that the Speaker provides in response to such a request is accurate and appropriately qualified

4.9.6 Speakers must not initiate discussions about any information or uses that are inconsistent with the full prescribing information of Company products.

### 4.10 Training Materials

- 4.10.1 All materials developed for the training of Company representatives or agents of the Company who Detail to Health Professionals shall be reviewed and approved by the PMRC prior to use.
- 4.10.2 All such sales training materials shall be labeled for internal use only and not for Detailing, except as may be approved by the relevant Committee. All such materials shall be consistent with the approved full prescribing information of approved Company products and related to educating the Employees about medical or marketplace information related to Company products.
- 4.10.3 All guidances on the use of Educational Materials shall be followed in relevant training materials.

### 4.11 Filing of Promotional Materials

- 4.11.1 All advertising and promotional labeling materials for approved drugs must be filed with the FDA at the time of first use or publication unless required by regulation or order (e.g., 21 CFR § 314.550) to be filed prior to dissemination.
- 4.11.2 Regulatory Affairs shall be responsible for determining when such filings are necessary in relationship to the specific materials in question and making such filings with FDA.

# SECTION 5 SCIENTIFIC AND EDUCATIONAL COMMUNICATIONS

The Company may present non-promotional information to Health Professionals at certain approved scientific or educational venues consistent with this Section 5. All such materials must be approved by the appropriate review committee or Department prior to use or in accordance with applicable SOPs.

### 5.1 Third-Party Scientific and Educational Meetings

### 5.1.1 <u>General Matters</u>

5.1.1.1 The Company may present scientific information at appropriate independent scientific and educational meetings, conferences and similar activities ("Third-Party Meetings") through the Clinical Research and Medical Affairs Departments. These may include meetings convened by professional associations, academic institutions, the government or accredited continued medical information (CME) providers.

- 5.1.1.2 The Company should participate in Third-Party Meetings only if they are held at an appropriate location where: (a) the gathering is primarily dedicated, in both time and effort, to objective scientific and educational activities and discourse, and (b) the main incentive for bringing attendees together is to further their knowledge on the topic being presented.
- 5.1.1.3 At such Third-Party Meetings, disclosure shall be made to participants that the meeting or communication is sponsored in part by the Company. Consultants to the Company shall disclose their consulting relationship in connection with such meetings or communications if they are participating in any way as a speaker, faculty or the like. The Consultant may not act as a consultant for, or representative of, the Company at the Third-Party Meeting. Any presentation by the Consultant should consist solely of his or her own work, prepared independently of the Company.

### 5.1.2 <u>Information about Unapproved Drugs or Unapproved Uses</u>

- 5.1.2.1 The Company may be present at Third-Party Meetings where the subject matter being discussed relates to one of the Company's Unapproved Drugs or an Unapproved Use of an approved Company drug. The Company's participation in the meeting shall be limited to a corporate booth or exhibit providing general background information about the Company and the medical field in which it is conducting research, and may include reference to research results as described below. Such booth or exhibit shall be placed either in the scientific rather than in the promotional section of the meeting, or, if a standard Medical Information booth, may be incorporated in a distinctively separate section of the promotional setting.
- 5.1.2.2 Guidelines for Company communications at such Third-Party Meetings are as follows:
  - No statements, except as provided for below, may be made that suggest or imply the safety or effectiveness of an Unapproved Drug or Unapproved Use.
  - An abstract, poster, oral presentation or other limited description of scientific research conducted by or for the Company may be presented when:
    - the abstract, poster, oral presentation contains only scientific information such as research results and no conclusions about the safety or effectiveness of an Unapproved Drug or Unapproved Use except as specific to the patient population observed in the particular study;
    - (ii) the information is presented in a truthful, non-misleading and balanced manner, including appropriate disclosure of limitations of the data being presented, in a manner that meets scientific standards of research and data disclosure; and
    - (ii) the research is relevant to the subject matter of the meeting.

- Company representatives may give presentations related to such abstracts, posters, oral presentations or limited descriptions of scientific research. In response to unsolicited questions beyond the scope of the poster or limited description of scientific research, a statement may be made by the Company speaker that the Company is investigating the safety and effectiveness of the Unapproved Drug or Unapproved Use. In response to further unsolicited requests for information, the inquirer may be invited to submit a written request to the Company's Medical Information Department.
  - All communications regarding scientific research presented at a meeting shall be conveyed by medical and scientific representatives of the Company, not by sales and marketing representatives.

### 5.1.3 <u>Information About Approved Drugs at Third-Party Meetings</u>

- 5.1.3.1 The Company may provide PMRC-approved promotional information about an approved drug at the commercial exhibit areas of Third-Party Meetings so long as the information is truthful, not misleading, and includes a fairly balanced discussion of the benefits and risks of the drug. Promotional information disseminated at Third-Party Meetings may include:
  - Labeling and reminder advertising that complies with the requirements in the Company guidelines.
  - Reprints of scientific articles relating to the approved uses of the approved drug, together with a copy of the approved full prescribing information.
  - Discussions of the drug by sales, marketing, medical and/or scientific personnel consistent with the approved full prescribing information.
- 5.1.3.2 Company medical and scientific representatives may provide MSRC-approved scientific material about approved uses of Company's products such as abstracts, posters, oral presentations or presentations at Third-Party Meetings as long as the information is truthful, not misleading, and includes a fairly balanced discussion of the information being presented.

### 5.2 Presentations by Company Employees at Third Party Meetings

5.2.1 Company Employees who wish to speak at Third-Party Meetings must seek approval and comply with the provisions of the May 3, 2010 Memorandum, in advance of such meeting. The Memorandum is attached as Schedule 5.2 to this Policy.

### 5.3 Publications

- 5.3.1 The Company may publish scientific or academic work performed by itself and/or in conjunction with outside medical professionals expert in the area under study ("Publications").
- 5.3.2 The content of Publications must generally be related to areas in which the Company has products or is conducting research for future products. All Publications must be

designed to be submitted to peer-reviewed publications for review and, if submitted for and accepted for publication, must be published in peer-reviewed journals. Any support provided by the Company must be provided in a manner consistent with the publication's policies and with full disclosure of such support from the Company.

- 5.3.3 Publications may contain discussions of Unapproved Drugs or Unapproved Doses for approved drugs. The discussions must be truthful, not misleading, and scientifically balanced, and must not contain conclusions about the safety or effectiveness of an Unapproved Drug or Unapproved Use except as specific to the patient population observed in the particular study.
- 5.3.4 The Company must clearly indicate in any publication whenever: (i) the Company has sponsored or paid for any portion of a Publication; and (ii) when any Company Employee or paid consultant has participated in the authoring or editing of a Publication. Anyone listed as an author on a Publication must meet applicable standards for authorship as outlined by the International Committee of Medical Journal Editors' "Uniform Requirements for Manuscripts Submitted to Medical Journals".
- 5.3.5 Scientific Communications are reviewed through a multidisciplinary review process established by the Clinical Research and Medical Affairs Departments.
- 5.3.6 Provisions of Scientific Communications beyond the approved intended venue (e.g., use or distribution of abstracts, posters, or presentations outside the scientific forum of a Third-Party Meeting) must be further approved by the MSRC.

#### 5.3.7 Journal Supplements

5.3.7.1 Sunovion may support the publication of independent peer-reviewed journal supplements, provided the journal publisher is solely responsible for all aspects of the supplement, including the content, author selection, and distribution of the intended supplement. Sunovion representatives may not provide suggestions regarding topics, authors, or distribution, even if requested by the journal publisher. Support for journal supplements must be reviewed and approved in accordance with the Sunovion Grant Policy. Following publication, such peer-reviewed journal supplements may not be distributed further by Sunovion unless they are first reviewed by the PMRC to ensure compliance with applicable policies and FDA regulations.

### 5.4 Medical Information

- 5.4.1 The Company has established a medical information department ("Medical Information") to respond to unsolicited requests from Health Professionals and consumers for Approved and Unapproved Use information regarding Company's products. Responses are generated by the Medical Information Department and are then reviewed through a multi-disciplinary review process established by Medical Information.
- 5.4.2 <u>Consumers.</u> Medical Information responses shared with consumers shall be limited to information contained within the product's full prescribing information.

### 5.4.3 Health Professionals.

- 5.4.3.1 Medical Information may respond to inquiries regarding Company products through letters or verbally sourcing such answers from approved responses that are consistent with and derived from the product's full prescribing information or through available pre-clinical/clinical data from completed trials. All Medical Information inquiries received must be unsolicited and responses must be limited to the information sought. Within the category of information sought, the response must be balanced and complete (e.g., relevant negative as well as positive information must be provided). All responses must always be documented.
- 5.4.3.2 Medical Information may also provide copies of scientific articles related to Approved and Unapproved Company Drugs, as well as Approved and Unapproved Uses of Company products in response to an unsolicited request from a Health Professional. Complete copies of the requested scientific studies must be provided.
- 5.4.3.3 If the question arises from an interaction, either promotional or scientific, with a Health Professional by a Company representative or consultant, the request must be submitted to Medical Information by or on behalf of a Health Professional and be reasonably specific about the type of information sought.
- 5.4.4.3 The request cannot in any way be solicited by a Company representative or person acting on behalf of the Company.
- 5.4.4.4 When a response is provided relating to an Unapproved Drug or Unapproved Use, the cover letter should include no other information on the safety or effectiveness of the Unapproved Drug or Unapproved Use. The cover letter should include a statement such as: "The materials provided with this letter include information on [DRUG or USE OF DRUG] that is currently not approved in the United States by the Food and Drug Administration." No claims may be made regarding the safety or effectiveness of an Unapproved Drug or Unapproved Use. In addition, the information provided must be tailored to the request, and there must be disclosure of any relevant limitations on the data being provided (e.g., whether it is based on a post hoc analysis).

### 5.5 Clinical Research and Medical Affairs Departments

### 5.5.1 Research

- 5.5.1.1 The Company has Employees in the Clinical Research and Medical Affairs Departments whose specialized background makes them suitable for: (a) exchanging potential research and other ideas with leading clinician and academic Health Professionals, and (b) providing verbal medical information responses to unsolicited requests from Health Professionals for scientific information.
- 5.5.1.2 When discussing potential research and other scientific ideas, the Clinical Research and Medical Affairs Departments shall conduct its interactions with Health Professionals under the auspices of CFR 312.7(a), and shall limit those interactions to discussions: (i) pertaining to possible new research the Company or the Health Professional is conducting or may be considering conducting; or (ii) about existing research done by or known to the Company which may have a bearing on issues relevant to the Health Professional and the Company, its products or line of research.

- 5.5.1.3 The Clinical Research and Medical Affairs Departments may disseminate any Scientific Communication or other published material that is approved for such uses by the MSRC. However, if a staff member of either the Clinical Research and/or Medical Affairs Department is asked by a Health Professional for Company information that the Health Professional intends to use to educate or train other Health Professionals, such staff person shall provide such information with the caveat to the Health Professional that it should not be used for CME purposes. The staff person who provides any such information shall document the request in accordance with any and all applicable SOPs.
- 5.5.1.4 The Clinical Research and Medical Affairs Departments may provide verbal responses to unsolicited requests for information on Unapproved Drugs or Unapproved Uses where the request is genuinely unsolicited, the response is tailored to the request, no claim is made regarding the safety or effectiveness of the Unapproved Drugs or Unapproved Uses, clear disclosure is made that the information relates to an Unapproved Drugs or Unapproved Uses, and clear disclosure is made of any relevant limitations on the data being provided (e.g., whether it is based on a post hoc analysis). Unsolicited requests may also be forwarded to Medical Information. All responses must always be documented.

#### 5.5.2 Clinical Trials

- 5.5.2.1 Any materials for dissemination or communication to external parties for use in conjunction with a Company sponsored clinical trial or in connection with a Third-Party Meeting as described in Section 5.1 above, must be reviewed and approved through all required processes as described herein, including, as applicable, by the MSRC or the process contained in Section 5.2.5. In addition to any Company internal review process, all clinical trial materials requiring approval by other third party groups must be reviewed by such third party (for example, an Independent Review Board).
- 5.5.2.2 Communications to subjects/patients must be compliant with federal regulations regarding the protection of human subjects and the promotion of investigational drugs, including specific Informed Consent requirements, and with Company policies and procedures.

### 5.6 Health Professionals as Preceptors

- 5.6.1 To the extent allowed by Company policy, the Company may engage certain physicians as preceptors for Company representatives.
- 5.6.2 All such engagements and any related materials must be reviewed through Sales Training and any other Department as applicable, and must be in compliance with this Policy.

# SECTION 6 INVESTMENT COMMUNITY, MEDIA AND OTHER COMMUNICATIONS

### 6.1 General Guidelines

6.1.1. All communications to the Investment Community, where appropriate, and through any Media are to be approved through the CCC and should be truthful and not

misleading. Particular care should be taken to ensure that communications do not omit material facts that could cause statements in the communication to be misleading.

- 6.1.2 When discussing approved Company products, except for the presentation of new study data (discussed next), Investment Community, where appropriate, and Media communications should be consistent with statements about the products which are approved through PMRC. Written materials produced by the Company should contain a website address for the full prescribing information. For products with black box warnings, any written communication should include a copy of the black box warning at the end of the communication.
- 6.1.3 Any requests for information that are received by an Employee regarding an Approved Drug, Unapproved Drug or Unapproved Use of approved products must be handled in accordance with this Policy and should be appropriately directed to either Medical Information (Section 5.4) or the Communications Department.

### 6.2 Press Releases

- 6.2.1 All press releases shall be approved through the CCC, or other appropriate committee as applicable, and be consistent with all relevant laws and regulations.
- 6.2.2 Press releases may not be used in a promotional or scientific manner unless separately approved for such a purpose through either the PMRC or MSRC process consistent with this Policy.
- 6.2.3 The Communications Department shall first determine whether any communication intended for or through Media, including product marketing or therapeutic awareness public relations materials or events, is appropriate for CCC, PMRC or MSRC.

### 6.3 Study Data and Reprints

6.3.1 Any Investment Community and Media communications that discuss study data should generally be accompanied by information about the study design, number of patients enrolled, statistical significance of the study endpoints, dosing regimen, patient population, duration of treatment, and other material information bearing on the overall quality of the study. Such information should be balanced against the study limitations and safety considerations.

### 6.4 Unapproved Drugs or Unapproved Uses

6.4.1 It is possible to provide current/updated information to any third parties concerning studies investigating Unapproved Drugs or Unapproved Uses of approved products. This is typically accomplished via a press release issued at the conclusion of a study, upon publication of a study report or presentation of study data at a third party meeting. Such communications should be directed specifically to the Media or the Investment Community, where appropriate, and not to the general public or to Health Professionals, except that press releases may be directed to the media or general public. These communications should be limited to an adequate (as discussed above) description of the findings of the study (e.g., in the study there were [x] responders) and should avoid any conclusive statements with respect to safety, effectiveness or utility of the drug for an Unapproved Use, including improper quotations from the report/article or authors of such. It is particularly important that these types of

communications include clear information on the regulatory status of the product as well as identify any Unapproved Drugs or Unapproved Uses as unapproved. If press releases including such Unapproved Uses information are archived on the Company website, they should be posted under the media or news sections, and must not be included on any product-specific websites.

### SECTION 7 GENERAL

### 7.1 Amendment

7.1.1 Management reserves the right to amend this Policy as appropriate at any time without prior notice, pursuant to Corporate Policy 1.0, "Origination, Revision, Communication and Archiving of Sunovion Inc. Corporate Policies."

### 7.2 Failure to Comply

7.2.1 EMPLOYEES WHO VIOLATE ANY COMPANY POLICIES AND PROCEDURES WILL BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.

### 7.3 Violations

7.3.1 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 the Company's Compliance Hotline as set forth in subsections 7.3.1.1 and 7.3.1.2 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.

7.3.1.1 Toll free telephone number. 866-886-1348 7.3.1.2 Via the internet at: www.ethicspoint.com

# SECTION 8 RELEVANT POLICIES AND DOCUMENTS

Code of Conduct and Ethics

Distribution of Medical Journal Articles and Medical or Scientific Reference Publications SOP

Speakers Bureau Program Requirements Sunovion Inc.

**Grant Policy** 

Meals, Medically Relevant and Other Items, and Entertainment Policy Sunovion Inc.

Health Professional Consultant Policy

PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, as revised July 10, 2008)

Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731, May 5, 2003)

Promotional Materials Review & Disposition Process

Systems and Confidential Information Policy

Instructions on Compliance with TCPA

Memo on Industry Conferences or Other Third-Party Meetings

### Instructions on Compliance with TCPA

1. The opt-out language must appear set off by itself at the top or the bottom of the first page of the fax, and should be in a font and size easily recognized and read. One suggestion is to include the language in a black box to make it stand out from the rest of the content.

Here is an example of appropriate opt-out language to use:

If you wish to discontinue receiving faxes from this sender, make your optout request to us by email at [email address], by fax at [fax number], or by telephone at [telephone #]. Specify the telephone number(s) of the fax machine(s) or machine(s) covered by your request. Failure to comply with your opt-out request within the shortest reasonable time not to exceed 30 days is unlawful.

At least one opt-out mechanism must be cost-free to the recipient (including a toll-free telephone number, local number for local recipients, toll-free fax number, Web site address, or e-mail address). A telephone number and fax number for opt-out requests must be included, regardless of whether the recipients also have email or Web site options for submitting opt-out requests. The opt-out mechanisms must permit recipients to make opt-out requests 24 hours a day, seven days a week.

- 2. If the fax has more than one page, each page must include the opt-out language.
- 3. Unsolicited faxes may only be sent to those entities or individual with which Company has (1) an existing business relationship and from whom Company has (2) obtained the fax number either (a) by voluntary communication from the recipient in the context of the existing business relationship (i.e., the recipient gave the fax number to Company) or (b) from a publicly available directory, advertisement or Internet site to which the recipient voluntarily gave its fax number, unless such listing indicates that the recipient does not wish to receive unsolicited advertisements by fax. It is the responsibility of Company and its agents/vendors to ensure and document that the recipient voluntarily gave its fax number to the publicly available directory. This option does not include directories or other listings compiled by a third party. It is very important that no unsolicited faxes be sent to persons or other entities with whom Company does not have an existing business relationship. Moreover, these persons or other entities must have voluntarily communicated their fax numbers to Company in the context of the relationship or to the general public in such a manner that Company can show they understood they might receive unsolicited advertisements by fax.
- **4.** "Sunovion Inc." must be identified somewhere on the fax.
- **5.** Each fax must include a date/time stamp. This typically is included automatically when materials are sent through a fax machine. It is your responsibility to confirm that the manner in which you are faxing materials will produce a date and time stamp on the fax.
- **6.** A process must be in place to timely honor opt-out requests such that Company and its vendors and agencies do not send the person or entity requesting the opt-out any further unsolicited advertisements. In no event should Company or its vendors and agencies take more than 30 days to honor an opt-out request.

### **Industry Conferences or Other Third-Party Meetings**

As you know, it is vitally important that all employees at Sunovion protect confidential company information from unauthorized disclosures, whether internal or external. The purpose of this Memo is to remind you of the requirements for all Sunovion employees related to obtaining permission to attend or speak at third-party conferences and also reminds all employees of the obligations we share to protect confidential information from unauthorized disclosures of any type. Given the importance of its confidential business information to Sunovion, you will be required to acknowledge that you have reviewed and understand this Memo by clicking on your email's voting button.

### **Industry Conferences or Other Third-Party Meetings**

As many of you are aware, Sunovion has had a longstanding tradition of supporting professional development opportunities for all of its employees. While Sunovion respects your interest in acquiring new skills and enhancing your knowledge base by participating in externally sponsored events, the following procedures continue to remain in place for obtaining approval to attend or speak at any third party events or conferences.

Obtaining Approval for Attendance at Third Party Events: Attendance at any conference or meeting sponsored by third parties must be approved in advance and in writing by your department head as well as your department Vice President. Such approval is now required for any non-Sunovion sponsored event (e.g., industry conferences, medical conventions, etc.). If you have already signed up for a conference, please make sure you reconfirm your attendance with your department head.

Obtaining Approval for Speaking Engagements and Presentation of Materials: All speaking invitations (e.g., lectures, presentations, panel moderation and panel participation) at conferences or meetings sponsored by third parties must be approved in advance and in writing by the employee's Departmental Vice President, or in the case of a Department Vice President, by a Sunovion Executive Committee member. All materials including written presentations, lecture notes, slides or speaking points will need to be approved in advance and in writing and must be submitted for approval no less than one week prior to any planned presentation. The contact person for such approval is Susan Adler at extension 4006 or Susan.Adler@Sunovion.com. Please refer to our External Communications Policy for further information about external communications.

### **General Confidentiality Obligations**

I also want to remind you of the general obligations all employees have to protect confidential company information from any unauthorized disclosures. The Sunovion Code of Conduct and Ethics (the "Code") states that:

Confidential information is any information or data that has not been disclosed to the public that you have encountered as a result of your position with the Company. This includes, for example, (but is not limited to) customer lists, marketing or strategic plans, any specifics — including prices — regarding deals offered to individual customers, research reports, acquisition plans, marketing plans, or potential equity interests. It also includes business proprietary or trade secret data such as chemical formulas. Personal information regarding employees also constitutes confidential information.

Confidential and business proprietary information are the property of Sunovion, not of any individual employee. Accordingly, you should regard all confidential or business proprietary information to which you gain access at work as the property of Sunovion. You must not therefore, disclose such confidential or business proprietary information to anyone who does not work within the Company without first receiving the proper authority to do so. Furthermore, such information should not be shared with other employees except on a need-to-know basis in order for them to perform their own jobs.

Unauthorized disclosure of Sunovion's confidential information, whether internal or external, is a serious breach of the Code and is cause for disciplinary action, up to and including termination for employment.

### **Confirm Your Understanding**

This memo further reaffirms your obligations under the Invention, Non-Disclosure and Personal Conduct Agreement and Code of Conduct and Ethics, both of which you signed as a condition of employment with Sunovion as well as the procedures and requirements for disclosure of Company confidential information to any party.

Please join Sunovion in redoubling our efforts to protect confidential company information from disclosure to others and from needless dissemination inside the company. By so doing, you help the company attain its business goals, comply with laws covering such information and reduce the chances that information may be even inadvertently disclosed to competitors or other third parties.

If you have any questions regarding this message, please contact the Chief Compliance Officer or a member of the Compliance or Legal Affairs Departments.

Thank you very much for your cooperation.