

SEALED



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA

Plaintiff,

For Judge Balkman's
Consideration

vs.

- (1) PURDUE PHARMA L.P.;
- (2) PURDUE PHARMA, INC.;
- (3) THE PURDUE FREDERICK COMPANY;
- (4) TEVA PHARMACEUTICALS USA, INC.;
- (5) CEPHALON, INC.;
- (6) JOHNSON & JOHNSON;
- (7) JANSSEN PHARMACEUTICALS, INC,
- (8) ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS;
- (9) JANSSEN PHARMACEUTICA, INC.,
n/k/a JANSSEN PHARMACEUTICALS, INC.;
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,
f/k/a ACTAVIS, INC., f/k/a WATSON
PHARMACEUTICALS, INC.;
- (11) WATSON LABORATORIES, INC.;
- (12) ACTAVIS LLC; and
- (13) ACTAVIS PHARMA, INC.,
f/k/a WATSON PHARMA, INC.,

Defendants

SEALED

STATE OF OKLAHOMA
CLEVELAND COUNTY J.S.S.
FILED In The
Office of the Court Clerk
MAY 02 2010

In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

DEFENDANTS TEVA PHARMACEUTICALS USA, INC.,
CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC,
AND ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.'S
MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT

EXHIBIT 57 FILED UNDER SEAL

EXHIBIT 57

MARKETING POLICY ON GRANTS

A. Policy

All third-party funding requests must be submitted to and receive approval from the Cephalon Grants Committee. Under no circumstance may financial support be offered proactively and no promises of funding may be made by a Cephalon employee until approval by the Cephalon Grant Committee has been granted.

B. General Standards for All Grants

1. The following Cephalon standards must be adhered to in connection with the provision of all grants under this Policy:
 - The activity must meet a legitimate health education or medical/scientific objective.
 - The grant request must be unsolicited.
 - The activity must be developed and conducted independently of Cephalon and must be objective, balanced and scientifically rigorous.
 - The grant cannot be linked directly or indirectly to a product endorsement.
 - The grant may not be made to encourage off-label use.
 - The grant must be used in its entirety in the support of the event/activity.
 - The activity cannot be within the scope of any routine activities of the healthcare entity or directed at generating business for that entity.
 - The grant must follow the rules and guidelines of any applicable medical association, congress or accrediting body.
 - The grant can be used to defray program expenses such as speaker expenses, modest meals or receptions, conference room rental, and/or AV equipment rental. Grant funds cannot be used to offset expenses not directly related to the educational program, such as entertainment or travel/lodging expenses for non-faculty attendees.

2. All grant support must be independent of considerations of product purchases or prescriptions.
 - Grants must be given independently of considerations of product purchases or prescriptions (e.g., they should not preferentially be given to organizations or entities that can generate sales of any Cephalon product.)
 - Grants must not be given to (a) meet a customer's request for product discounts, (b) to "meet a gap" with competitor product pricing, or (c) to fulfill Cephalon's business needs. There must not be any real or perceived *quid pro quo* to purchase, prescribe, or provide favorable formulary status for any Cephalon product (i.e., there should be no perception that a grant is being offered in exchange for a business favor).
 - The decision to provide an educational grant should never be made based on a perceived or proposed impact on sales or marketing. "Return on Investment" (ROI) or similar analyses may not be conducted regarding grants.

3. Grants may be made only to an organization, such as professional organizations, patient advocacy organizations or conference sponsors. Grants may not be provided to: (i) an individual healthcare professional; (ii) physician private practice groups; (iii) a charity, foundation or clinic associated with, or controlled by, a physician private practice group.

C. Support for Professional Organizations/Societies/Patient Advocacy Organizations

Grants may be provided to professional societies of healthcare professionals (e.g., American Association of Pain Management) and/or patient advocacy organizations to support academic achievement awards, research awards, and fellowship support. Specific examples include a professional society fellowship/young investigator award, support for a society's local dinner or annual meeting, or an awards ceremony for medical excellence.

D. “Corporate Sponsorship” Grants

Cephalon may be asked to support an educational activity by providing a grant in a fixed amount in order to become a corporate sponsor of the event at a particular level (e.g., “Platinum Sponsor,” “Gold Level”). Please Note: If the sponsorship is for a specific educational program at the event, then it should be processed as a grant under this policy. If, however, the sponsorship is for a meeting but the funding is not for any particular educational program at the event, then it should be processed through Corporate Contributions.

Grant funds may be provided only to support the educational activity. Thus, funds may not be allocated for administrative charges, entertainment, general overhead or other similar expenses. In addition, the grant cannot be used to reimburse travel, lodging, time or personal expenses of attendees at the supported activity, except in limited cases (i.e., support for medical or other students, residents, or fellows at certain national or regional meetings). Funding may also not be offered to compensate for the time spent by healthcare professionals attending the event. If the corporate sponsorship includes display/exhibit space, the amount of the grant supporting that activity must be specified.

When a grant is given to help underwrite medical conferences or meetings, responsibility for, and control over, the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings and must be independent of Cephalon.

E. Support for Independent Medical Education Programs

These types of programs include accredited continuing medical education programs (“CME”) and non-accredited independent medical education programs and can involve live events and enduring materials (e.g., publications, CD-ROMs, etc.). In general, there is a reasonable likelihood that Cephalon products will be discussed as

part of the educational program. Individuals from Marketing that receive this type of grant request must direct the entity requesting the grant to either submit the request to Cephalon's medical education department or via Cephalon's website at www.cephalongrants.com.htm

F. Research Grants

Physicians or institutions sometimes request assistance from Cephalon in the form of free product or funding for clinical research. All research grants, provision of study product or other support must be made based upon scientific merit as determined by internal Cephalon committees that have been established to review these requests. Cephalon employees should direct physicians or institutions to submit any such requests via Cephalon's website at www.cephalon.com.

G. Processing Requests

1. All grant requests must begin with a written request from the institution or organization on its letterhead and signed by an appropriate organizational representative (e.g., education or conference coordinator). The request should be submitted to Cephalon at least forty-five (45) days in advance of the program date.
2. Cephalon employees may not assist in drafting or otherwise preparing the request.
3. Cephalon employees (e.g., marketing) may forward a written grant request from an institution or organization to the Grant Committee, but the request should not be accompanied by any written or oral explanation or comment by the Cephalon employee on whether the grant should be awarded.

4. All written requests must contain the following relevant information:
 - A description of the specific purpose/intended use of the grant. It is not acceptable to list only a generic description as the purpose of the expense (e.g., “educational program”);
 - For any grant request in excess of \$2,500, a budget describing how the funds will be expended;
 - Any available documents, such as a brochure, pamphlet, and/or flyer, that describe the purpose/intended use of the grant;
 - Information about any expected deliverables; and
 - If the grant request includes exhibit or display space, the request letter should indicate that exhibit/display space will be provided.

5. A Draft Funding Request Form (attached as Attachment A), signed by the requesting Cephalon employee, must also be submitted along with the written request for funding.
 - Signatures must occur prior to submission to the Grant Committee

6. In advance of a grant being reviewed, no promises, oral or written, regarding the funding of the grant may be made by a Cephalon employee to the entity requesting the grant.

7. Decisions made by the Cephalon Grant Committee will be communicated to the requesting Department or individual who in turn communicates the decision to the requesting organization.

H. Letter of Agreement

To help expedite the review process by the Cephalon Grant Committee, it is recommended that the entity requesting funding execute a pre-approved Cephalon Grant Agreement attached to this Policy as Attachment B. If any changes are made to the Cephalon Grant Agreement, or the entity insists on using its own agreement form, the agreement must be approved by the Legal Department before any commitment for funding can be made.

I. Approval by Cephalon Grant Committee

All third-party funding requests must receive approval from the Cephalon Grant Committee and no promises of funding may be made by a Cephalon employee until approval by the Cephalon Grant Committee. In determining whether funding will be provided, the Grant Committee will assess, among other things, whether the proposed program has a legitimate scientific and/or educational purpose, whether the program topic is within Cephalon's scope of interest, whether the program provider is reputable and whether the proposed program meets the requirements of this Policy. The program provider's purchasing, prescribing, or formulary practices will not be taken into account in determining whether financial support will be provided.

Attachment A – DRAFT GRANT REQUEST

FORM AND INSTRUCTIONS

INSTRUCTIONS

Cephalon Employee: Complete the top part of the form. Fax form with backup documentation to the Grant Committee *at least 45 days prior to date of proposed program*.

Grant Committee: Will notify Cephalon employee of its decision.

Form: DRAFT FUNDING REQUEST -- MARKETING

Date of Submission to Grant Committee: _____ Amount: _____

NOTE:

- Submission must be 45 days prior to program date
- Grant request must be submitted on letterhead of Institution/Organization making request
- ≥\$2500 must have budget breakdown

Name of Entity Requesting Grant: _____

Street Address: _____

City: _____ State: _____ Zip: _____ Tax ID#: _____

- Type of Entity:
- Accredited continuing medical education provider;
 - University/Hospital/Medical School;
 - Clinic;
 - Professional Healthcare-Related Organization;
 - Consumer Healthcare-Related Organization;
 - Conference Sponsor;
 - Other: (please explain) _____

Program Date: _____ Title: _____ & Location: _____

Type of Program: Support for Professional/Patient Advocacy Organization. Describe organization and activity: _____

-
- Corporate Sponsorship (e.g., "Platinum Sponsor," "Gold Level")
- Other _____

Is the program accredited (CME/CE) Yes No
Is Cephalon the only sponsor of program: Yes No
Will funding Support Enduring Materials: Yes No
Was Cephalon involved in the funding Request to Date? Yes No If Yes, describe _____

Will Cephalon have future involvement? Yes No If Yes, describe _____

Is the requestor of this grant or anyone else involved in this proposed program also providing marketing, promotional or any other type of consulting services for Cephalon for any product? Yes No If Yes, describe _____

Requestor Signature: _____ Print Name: _____

GRANT COMMITTEE APPROVAL Yes No Date: _____
If no, state reason: _____

For Budgetary Purposes Only - Product: (Check One)
 Actiq Gabitril Provigil Trisenox Vivitrol Other: _____

ATTACHMENT B

GRANT AGREEMENT

This Agreement is entered into as of this _____ day of _____, 200__ by and between Cephalon, Inc. ("Cephalon") and _____ ("Grant Recipient") located at _____. Cephalon has reviewed Grant Recipient's request for a grant to support the program described on Exhibit A ("Program"). Cephalon has determined that the Educational Program has the potential to significantly further medical knowledge and patient care. Accordingly, Cephalon agrees to provide funding for the Program under the conditions set forth below. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program that will provide medical/scientific information to attendees.

1. Purpose of Program: The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The program is not a repeat performance of a prior program.
2. Independence: Grant Recipient and its advisors and consultants will exercise full control over the planning and implementation of the Program. Cephalon will not assist in the development or implementation of any aspect of the Program, and will have no influence over the content of any materials or information related to the Program. No member of any committee established by Grant Recipient to develop, implement and oversee the Program may be an employee of Cephalon.
3. Selection of Speakers: Grant Recipient shall retain full responsibility for the selection of and speakers, moderators or other faculty.
4. Objectivity and Balance: The Program will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner.
5. Grant: Cephalon will provide support for the Program by means of an educational grant in the total amount of \$_____. If the Program is canceled or terminated prior to completion, Grant Recipient shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. Grant Recipient shall have full responsibility for all funding arrangements of the Program.
6. Use of Funds: The grant must be used in its entirety in the support of the Program. Funds may not be allocated for the purchase of capital equipment, administrative charges, general overhead or other similar expenses. In addition, the grant cannot be used to reimburse for travel, lodging, time or personal expenses of attendees at the supported activity, except in limited cases (i.e., support for medical or other students, residents, or fellows). Funding should also not be offered to compensate for the time spent by healthcare professionals attending the event. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the Grant Recipient, and Grant Recipient shall have final decision making authority in connection with any such activities.

7. **Disclosure:** Grant Recipient shall ensure that Cephalon's financial support is acknowledged in all materials and communications regarding the Program. Grant Recipient will ensure that the Program discloses any limits on the data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion) and/or when a product is not approved in the United States for the use under discussion.
8. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room as, or in the obligatory path to, the Program. No product advertisements will be permitted within the Program or handouts.
9. **No Obligation:** The Grant does not impose on Grant Recipient its advisors, consultants, or any other individual involved with or attending the Program, any obligation or requirement to purchase, order, or prescribe, or to arrange for or recommend the purchasing, ordering, or prescribing of, any product.
10. **Invitations/Enduring Material:** Attendees of the Program will be selected by the Grant Recipient. The Grant Recipient shall be responsible for distributing materials about the Program, including invitations and reminder notices.
11. **Compliance:** Grant Recipient represents that the Program, including development of the Program, as well as its financial arrangements, interactions and meetings with physicians, shall conform to the AMA Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the PhRMA Code on Interactions with Healthcare Professionals, and, if applicable, with the ACCME Standards for Commercial Support and the Food and Drug Administration's December 3, 1997 Final Guidance for Industry Supported Scientific and Activities.
12. **Termination of Grant:** Cephalon shall have the option immediately to terminate its funding of the Program if Grant Recipient fails to fulfill any of its obligations described in this Agreement.
13. **No Waiver:** No failure to exercise any right or demand performance of any obligation under this Agreement shall be deemed a waiver of such right or obligation.
14. **Additional Safeguards:** If Grant Recipient also performs services related to the sales and marketing of Cephalon products, the Grant Recipient will establish appropriate safeguards to ensure that its personnel involved with the sales and marketing services are not also involved with the CME program activities.
15. **Trademarks and Logos:** Grant Recipient shall not use any trademark or logo owned by Cephalon without the written consent of Cephalon.
16. **Releases:** Grant Recipient agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the development and implementation of the Program and of any written materials prepared in connection therewith.
17. **Risk Minimization Action Plan:** Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all Grant Recipients. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in

minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. Grant Recipient agrees that it is aware of the RiskMAP(s) and the key safety messages.

18. No Additional Terms: No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

GRANT

RECIPIENT: CEPHALON INC.

By: _____
[Signature of Corporate Officer]

By: _____

Name: _____

Name: _____

Title: _____
[Title of Corporate Officer]

Date: _____

The above signatory is a duly authorized corporate officer of the Grant Recipient

Date: _____

Tax ID No.: _____

Exhibit A
Description of Program

Exhibit B

ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of

oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.