



SEALED

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

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

Plaintiff,

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.

STATE OF OKLAHOMA
CLEVELAND COUNTY J.S.S.
FILED In The
Office of the Court Clerk
MAY 02 2019

For Judge Balkman's
Consideration

In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816
Honorable Thad Balkman


William C. Hetherington
Special Discovery Master

SEALED

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 54 FILED UNDER SEAL

EXHIBIT 54

WW MEDICAL & REGULATORY OPERATIONS POLICY	DOCUMENT NO. WMRO-110	REVISED 01/26/09	OWNER Medical Affairs Medical and Scientific Affairs	EFFECTIVE DATE 1/26/09
	TITLE Independent Medical Education Grants			

1 PURPOSE

Cephalon is committed to supporting innovative, high-quality initiatives that provide healthcare professionals with evidence-based, clinically-relevant, performance-based education, in order to advance healthcare practice and improve patient outcomes.

This document outlines the submission, review and approval processes for supporting independent medical education activities (grants).

2 SCOPE

The policy applies to the following departments within Cephalon including Cephalon Oncology:

- Medical Education
- Legal
- Medical Affairs / Medical and Scientific Affairs

3 POLICY DETAILS

Cephalon supports independent medical education activities for health care professionals (HCPs) that comply with:

- FDA's Guidance for Industry on "Industry-Supported Scientific and Educational Activities" (Nov. 1997)
- American Medical Association (AMA) "Guidelines on Gifts to Physicians" and "Ethical Opinion on Continuing Medical Education"
- PhRMA Code on Interactions with Healthcare Professionals (2009)
- Applicable standards of the Accreditation Council for Continuing Medical Education (ACCME) and all relevant accrediting bodies, including the "Standards for Commercial Support of Continuing Medical Education" and the "Essential Areas, Elements and Decision-Making Criteria"

Independent medical education activities must remain independent from Cephalon and no Cephalon personnel or Cephalon agent may control any aspect of an independent education activity.

All grant support is independent of considerations of product promotion or sales. There must not be any real or perceived *quid pro quo* to purchase, prescribe, or provide favorable formulary status of any Cephalon product (i.e., it should not be perceived that a grant is being offered or solicited in exchange for a business favor even when it is not). No grant determination should be associated with perceived or proposed impact on sales or marketing. "Return on Investment" (ROI) or similar analyses should not be conducted on any independent medical education activity.

3.1 IME Grant Criteria

In order to be considered for grant support, all proposed independent medical education activities must:

- Meet a legitimate health education or medical education objective
- Serve a broad audience of healthcare professionals or healthcare organizations
- Be developed independently of Cephalon
- Be objective, balanced, and scientifically rigorous

Grant support must be used in its entirety in support of the proposed educational activity or activities.

3.1.1 Types of Grants

In general, the types of activities for which Cephalon may provide a grant include independent medical educational activities aimed at healthcare professionals, which can be accredited continuing medical or professional education (i.e., "CME" or "CPE") or non-accredited independent medical educational activities. Cephalon may provide a grant for a non-accredited activity provided the Provider requesting the funding regularly conducts educational events (such as a university, large hospital or MECC) and all the other standards in this document are met. Additionally, grants which have some aspects of physician-directed patient education, research fellowships, or grants to advance the knowledge / understanding of independent medical education may be supported.

Independent medical education grants must not:

- Support activities that are routine obligations of the recipient
- Be linked directly or indirectly to support of our products
- Support education solely directed to patients

3.1.2 Potential Requestors

Certain organizations are eligible to request financial support from Cephalon. Such organizations include but are not limited to:

1. Accredited CME organizations (Providers)
2. Non-accredited medical education/communications companies (MECCs) that regularly conduct independent medical educational events
3. Institutions, such as a universities, medical schools or large hospitals that regularly conduct independent medical educational events
4. Healthcare-related professional organizations (e.g. *American Academy of Sleep Medicine, American Academy of Pain Medicine, American Society of Clinical Oncology, American Society of Hematology*)
5. Consumer and patient advocacy organizations (e.g. *National Sleep Foundation, The Leukemia and Lymphoma Society*), provided that the proposed educational activity is primarily directed to healthcare professionals

6. Other organizations that regularly educate such as national private foundations providing or supporting broad education initiatives

Certain persons or organizations are not eligible to receive financial support from Cephalon. Such organizations include but are not limited to:

1. Individual physicians
2. Private practice groups
3. Groups of physicians that have formed "foundations" or "associations,"
4. Family- or physician-controlled private foundations
5. Pharmacy Benefit Managers (PBMs)
6. Group Purchasing Organizations (GPOs)
7. Managed care organizations
8. Health plans or pharmacies
9. Providers who have had an unsatisfactory review by a Cephalon Medical Education team

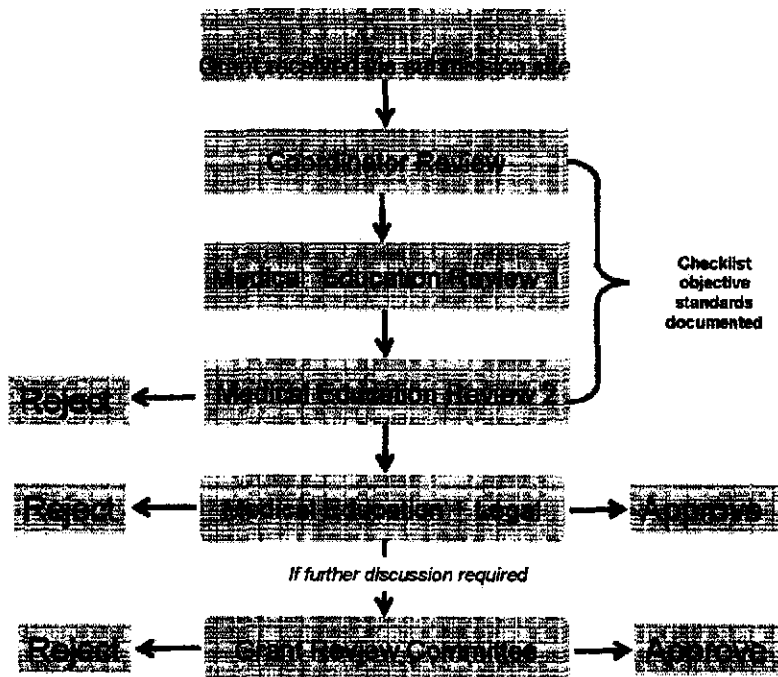
3.2 Grant Review Process

3.2.1 Grant Requests Less than \$25,000:

1. All grant requests must be submitted through the online grant management system (<https://cns.cephalongrants.com/> or <https://oncology.cephalongrants.com/>). The grant management system acts as the grants repository and houses all documents pertaining to grants, email communications and status of grant processing.
2. Grants are evaluated by Medical Education personnel against a checklist of requirements (maintained by Medical Affairs / Medical and Scientific Affairs), which is completed and retained with grant documents and uploaded to the grants management system. Grants are subject to a tiered review process which includes at least two members of Medical Education or Medical and Scientific Affairs departments, with representation from senior management in these functions, authorized by the Vice President of Medical Affairs / Medical and Scientific Affairs.
3. Grants which fail to meet grant standards are rejected by the most senior member of the Medical Education Department.
4. Grants which meet grants standards are approved by the most senior member of the Medical Education department and Legal.
5. Grants less than \$25,000 may be submitted to Grant Review Committee (GRC) at the discretion of senior members of the Medical Education team, if there are significant queries requiring a further review.

- Quality assurance of this process is managed through a quarterly report of all approved and rejected grants to a representative of the Legal and Compliance departments. Legal and/or Compliance may randomly choose grants from these lists to check for compliance with this process.

3.2.2 Summary: Grant Requests Less than \$25,000:

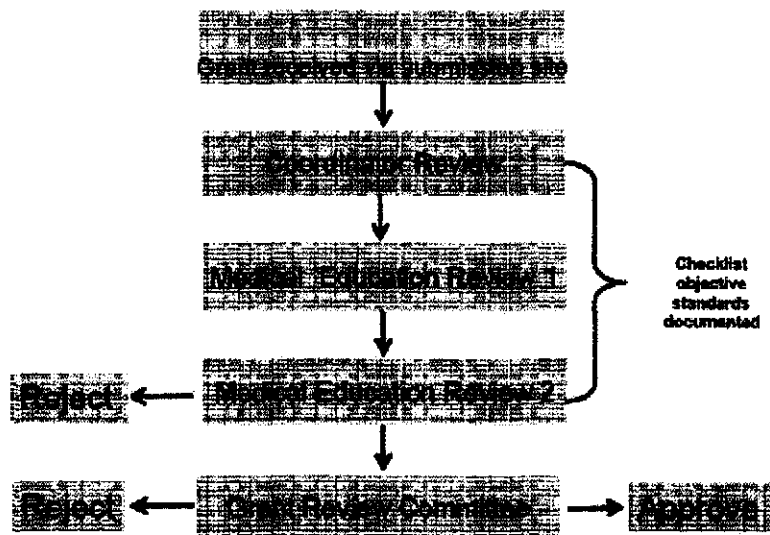


3.2.3 Grant Requests \$25,000 and Above

- All grants must be submitted through the online grant management system (<https://cns.cephalongrants.com/> or <https://oncology.cephalongrants.com/>). The grants management system acts as the grants repository and houses all documents pertaining to grants, email communications, and status of grant processing.
- Grants are evaluated by Medical Education personnel against a checklist of requirements (maintained by Medical Affairs / Medical and Scientific Affairs) which is completed and retained with grant documents and uploaded to the grants management system. Grants are subject to a tiered review process which includes at least two members of Medical Education or Medical and Scientific Affairs departments, with representation from senior management in these functions, authorized by the Vice President of Medical Affairs / Medical and Scientific Affairs.
- Grants which fail to meet grant standards may be rejected by the most senior member of the Medical Education Department.

4. Grants which meet grants standards are submitted for consideration by the Grant Review Committee (GRC).
5. Quality assurance of this process is managed through a quarterly report of all rejected grants to a representative of the Legal and Compliance departments. Legal and Compliance may randomly choose grants from these lists to check for compliance with this process.

3.2.4 Summary: Grant Requests \$25,000 and Above



3.2.5 Grant Review Committee (GRC)

GRC is comprised of senior members of the Medical Education, Medical Affairs / Medical and Scientific Affairs and Legal departments. All GRC members must appoint a designee.

3.3 Conflict of Interest

Cephalon may not provide a grant to a Provider or MECC if such entity provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon. This standard applies even if the consulting services are for one product / disease area and the grant relates to another Cephalon disease area of interest.

If, however, such company has established a separate affiliated company that conducts non-promotional medical education activities and there are sufficient firewalls separating the activities of the two affiliates, then Cephalon can provide a grant to such affiliated company even if its sister company is providing marketing or other promotional activities to Cephalon. Examples of such firewalls include separate personnel, office space, IT support, servers, and phone lines, with communication between companies limited to company procedures and logistics. The Provider should have procedures for resolution of commercial conflict. In such instances, firewall documents must be requested and reviewed by Legal, prior to submission to

GRC. The information provided will be evaluated, together with the grant, on a case by case basis.

At the time of grants request, Cephalon requires disclosure of the following:

- Provider employs personnel who have a financial relationship with Cephalon.
- Provider employs personnel who have a personal relationship with any personnel employed by Cephalon.
- Provider employs personnel who have been previously employed by Cephalon
- Provider sub-contracts personnel who were previously employed by Cephalon and who have a role in content development

The information provided will be evaluated, together with the grant, on a case by case basis.

4 RESPONSIBILITY

Medical Affairs and Medical and Scientific Affairs, in consultation with the Legal and Compliance departments, will maintain and update this policy as appropriate.

Approving Vice Presidents: Robert Kaper, Joseph Leveque