



**CUMBERLAND PHARMACEUTICALS INC. &
CUMBERLAND EMERGING TECHNOLOGIES;
POLICY FOR MANAGING CONFLICTS OF
SIGNIFICANT FINANCIAL INTERESTS**

I. INTRODUCTION

A. GENERAL POLICY

The principles articulated herein are intended to provide guidance in the management of formal relationships between Cumberland Pharmaceuticals Inc. and its affiliates ("Cumberland") and their external constituencies in order to ensure that the design, conduct, and reporting of National Institutes of Health (NIH) and other externally funded research activities ("Sponsored Research") will not be biased by any conflicting financial interests. Under the Public Health Service (PHS) and National Science Foundation (NSF) final rules on *Objectivity in Research* (*Federal Register*, July 11, 1995), each investigator is required to disclose a listing of his/her significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding by the PHS or the NSF. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the Sponsored Research, Cumberland will report the existence of such conflicting interests as required by the sponsor and act to protect the resulting research from bias owing to the conflict of interest. This policy statement is intended to satisfy current Federal rules for disclosure with regard to externally funded Sponsored Research where funds are provided by the NIH, PHS, NSF, as well as State of California statutes involving conflict of interest situations.

B. SCOPE

This policy and the associated procedures are applicable immediately to all Sponsored Research activities carried out by Cumberland employees, consultants, scientists, trainees, technicians and other agents of the research collaborators ("Cumberland associates"). The policy and the associated procedures are derived from the final rules on *Objectivity in Research* promulgated by the PHS and NSF that were published in the *Federal Register* of July 11, 1995 and the National Institute of Health (NIH) 2011 Revised Regulations on Financial Conflict of Interest. These procedures will be followed whenever Cumberland or its associates submit a request for funding from any external agency.

C. RESEARCH COMPLIANCE STATEMENT

The Compliance Statement for Cumberland:

It is Cumberland's responsibility to assure the integrity of all aspects of Sponsored Research while, simultaneously, taking care not to discourage the development of external funding opportunities. The purpose of this document is to identify situations where potential conflicts of significant financial interest are likely to arise and to establish a process whereby such conflicts are either avoided or at least managed equitably to the satisfaction of all concerned parties.



D. MANAGING CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST

This document articulates Cumberland policy on the identification and management of significant financial conflicts of interest between outside constituencies and the associated Sponsored Research funding activities carried out by Cumberland. While this policy focuses upon identifying and managing conflicts of significant financial interest, its primary purpose is to promote compliance with the standards of *Objectivity in Research*.

II. DEFINITIONS

A. CONFLICT OF SIGNIFICANT FINANCIAL INTEREST (CSFI):

CSFI is considered to occur whenever a Cumberland associate, or a family member of the associate, has an existing or potential financial or other material interest that impairs, or appears to impair, a Cumberland associate's independence and objectivity in the discharge of his/her responsibilities to and/or for Cumberland; or, alternatively, CSFI is considered to occur whenever a Cumberland associate receives financial or other material benefit through inappropriate use of knowledge or information confidential to Cumberland. It also refers to any SFI that could directly and significantly affect the design, conduct, or reporting of Sponsored Research.

B. CUMBERLAND ASSOCIATE:

Is any individual employed on a full- or part-time basis by Cumberland and is receiving, or will receive, compensation for such employment. This includes Consultants, Agents, and Research Collaborators of Cumberland.

C. INVESTIGATOR:

Refers to the principal investigator, co-principal investigators, or any other Cumberland associate responsible for the design, conduct, or reporting of externally funded Sponsored Research activities.

D. FAMILY MEMBER:

This includes Cumberland associates' spouse and children or other adults who qualify as dependents under the Internal Revenue Code definitions.

E. PROJECT:

Means any externally funded Sponsored Research activity conducted by Cumberland associates on behalf of the company



F. INVESTIGATOR'S COMPANY RESPONSIBILITIES

Refers to an investigator's professional responsibilities on behalf of Cumberland, and as defined by Cumberland in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service panels such as Institutional Review Boards (IRB) or Data Safety Monitoring Boards (DSMB).

G. FINANCIAL INTEREST (FI):

Anything of monetary value, whether or not the value is readily ascertainable.

H. SIGNIFICANT FINANCIAL INTEREST (SFI)

A SFI exists when one or more of the following conditions exist with regard to interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the investigators' Cumberland responsibilities:

- a. The value of remuneration received from a publically traded entity in the twelve months preceding the disclosure and the value of any equity interest at the time of disclosure when aggregated exceeds \$5,000.

For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (i.e., consulting fees, honoraria, paid authorship), and equity interest includes any stock, stock options, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.

- b. The value of remuneration received from a non-publically traded entity in the twelve months preceding the disclosure when aggregated exceeds \$5,000, or if any equity interest is held
- c. Intellectual property rights (i.e., patents, copyrights) are held upon receipt of income related to such rights and interests.

Disclosure of SFIs should also include occurrences of any reimbursed or sponsored travel related to Cumberland responsibilities. Disclosed details shall include: purpose of travel, identity of the sponsor/organizer, destination, and duration. Disclosure is not required if travel is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

SFI Disclosure Exclusions:

- 1) Salary, royalties, or other remuneration paid by Cumberland to the investigator if the investigator is currently employed or otherwise appointed by Cumberland and ownership interests in Cumberland
- 2) intellectual property rights assigned to Cumberland and agreements to share in royalties related to such rights;



- 3) income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in the vehicles;
- 4) income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- 5) income from service on advisory committees or review panels for a federal, state or local government agency, institute of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

I. NEGATIVE FINDING:

Means a determination has been made that no conflict of significant financial interest exists.

J. POSITIVE FINDING:

Means a determination has been made that a conflict of significant financial interest does exist and, therefore, appropriate administrative action will be required as outlined under III.D. below.

III. POLICY STATEMENT

A. MANDATORY DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST:

In accord with relevant Federal and State of California regulations, Cumberland is required to identify and manage any potential conflicts of significant financial interests that may be inherent in the personal financial interest of an investigator involved in Sponsored Research. Cumberland, therefore, requires investigators to disclose to Cumberland, any significant financial interest, including those of his/her family members, which would reasonably appear to be affected by the project being funded by external government agencies.

Investigators participating in or proposed to participate in Sponsored Research are required to provide updated SFI disclosure information. Screening for SFIs will be conducted using Cumberland's SFI screening form at the time the application is submitted to the sponsor, before expenditure of any awarded funds or resources, and then annually during the award period for any Sponsored Research. Investigators shall promptly initiate disclosure to Cumberland after any change in reportable SFI disclosure information, according to the sponsor's time requirements.



B. IDENTIFICATION OF CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST:

In conjunction with the administrative review of applications for Sponsored Research, Cumberland's Financial Disclosure Review Team (FDRT) will review each Financial Disclosure submitted and shall make a determination whether or not a CSFI exists. If the FDRT determines that no CSFI exists, the resulting negative findings will be filed in Cumberland's FDRT files. For negative findings, no further review is required.

In those instances where there are subrecipients under a prime award to Cumberland, the Research Subaward Agreement executed between Cumberland and each subrecipient organization will clarify which organization's SFI financial disclosure policy will apply to subrecipient investigators and subrecipient reporting requirements.

C. APPEAL OF POSITIVE FINDINGS:

Investigators may appeal a resulting positive finding to the FDRT leader for a review of the CSFI determination reached by the FDRT. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award. In reviewing positive findings, the FDRT leader will be guided and managed by the following principles:

- 1) Assure adherence to all relevant Cumberland policies;
- 2) give full considerations to the nature and extent of the financial interests in the relationship of the investigator, and/or the investigator's family members, with the external constituencies;
- 3) give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and
- 4) consult fully with the investigator and obtain additional information from the investigator, as deemed appropriate to the management of the apparent CSFI.

D. MANAGING POSITIVE FINDINGS OF SIGNIFICANT FINANCIAL INTEREST:

Following the determination of a positive finding, or upon receipt of the review by the FDRT leader, the FDRT will make a final determination involving one of the administrative actions:

- 1) Accepting the Sponsored Research award;
- 2) not accepting the Sponsored Research award; or
- 3) accepting the Sponsored Research project award subject to suitable modifications in the award documentation or in the investigator's, or his/her family's, affiliation with the external constituencies involved. Reasonable modifications under option 3) above might include one or more of the following actions:
 - a) Public disclosure of the identified financial interest;
 - b) utilization of additional independent investigators and/or reviewers in the Sponsored Research;
 - c) research plan modifications;
 - d) investigator agrees not to participate in certain portions of the Sponsored Research;
 - e) investigator and/or his/her family member(s) divest certain SFI's related to the positive finding.



E. COMPLIANCE:

If an investigator fails to disclose a SFI as required under this policy, the investigator may be subject to disqualification and prevented from participating in the Sponsored Research impacted by the SFI. Intentional disregard for this policy, including non-adherence to the agreed upon management plan, will be considered misconduct and may be the basis for further administrative procedures. Additionally, Cumberland will conduct retrospective reviews in cases of non-compliance or whenever a CSFI is not identified or managed in a timely manner, to determine what went wrong and then revise relevant SOP's to ensure it doesn't happen again.

F. TRAINING:

Cumberland's core team (full-time employees) will complete training annually. Investigators will complete training prior to engaging in research related to any externally funded grant or contract, and at least every four years.

G. REPORTING :

Information on any identified CSFI affecting a Sponsored Research project will be reported by Cumberland to the sponsor or awarding agency according to the individual sponsor's reporting requirements.