



Disclosure of Financial Interest

In accordance with policies of the Accreditation Council for Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE), University of Kentucky UK HealthCare CE Central (UKHCCEC) requires all faculty members with an opportunity to affect the content of a continuing education activity to disclose any relevant financial relationships during the past 12 months with commercial interests. Relevant financial relationships also include relationships of a spouse or significant other.

A commercial interest is any proprietary entity producing, marketing, re-selling or distributing health care goods or services consumed by or used on patients. Excluded from the definition of commercial interests are non-profit or government organizations, non-health care related companies, liability insurance companies, health insurance providers, group medical practices, and for-profit hospitals, rehabilitation centers and nursing homes.

Relevant financial relationships with commercial interests and conflicts of interest resulting from those relationships must be revealed to the audience and resolved prior to the activity. Persons refusing to disclose or resolve relevant financial relationships will be disqualified from being a part of the planning and implementation of this CE activity.

Name: _____ Affiliation: _____

My spouse, significant other, or I **have not** had any relevant financial relationships during the past 12 months.

My spouse, significant other, or I **currently have or have had** the following relevant financial relationships (in any amount) during the past 12 months:

Commercial Interest	Role*	Type of Compensation Received**

***Role:** speaker, author, consultant, independent contractor (including research), employee, investor, advisory committee member, board member, review panelist, or investigator

****Compensation Received:** salary, royalty, intellectual property rights, consultant fee, honorarium, ownership interest (excluding diversified mutual funds), or other financial benefit (Indicate compensation category only, not amount received.)

I do do not intend to discuss an off-label use of a product during this activity.

PLEASE SIGN AND DATE AT THE BOTTOM OF PAGE 3 AFTER READING THE FACULTY GUIDELINES AND CHART COMPARING CERTIFIED CONTINUING EDUCATION WITH FDA REGULATED SPEAKER PROGRAMS.



Faculty Guidelines

UK HealthCare CE Central (UKHCCEC) requests all faculty participants in continuing education (CE) activities to comply with the following accreditation standards and policies:

- Faculty must complete and sign a Disclosure of Financial Interest form and resolve any conflict(s) of interest with commercial interests prior to planning and implementing a CE activity.
- Faculty must comply with the following requirements for content validation:
 - All clinical recommendations in a CE activity must be based on evidence that is accepted in the medical profession as adequate justification for their indications and contraindications in patient care.
 - All scientific research referred to, reported, or discussed in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, and analysis.
- Faculty contributions to this activity will be fair and balanced, objective, and scientifically rigorous.
- All clinical recommendations made by faculty for patient care will be based on the best available evidence, and a balanced view of therapeutic options will be given.
- Activity content and format will promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial entity.
- Scientific or generic names of products will be used, or if a trade name is used, trade names including the trademark symbol of all like products will be used.
- If off label use of any product is discussed, faculty will disclose that the use or indication in question is not currently approved by the FDA for labeling or advertising.
- Faculty contributions will be independently reviewed prior to the CE activity to ensure fair balance and content validity.
- Faculty contributions to the CE activity will be evaluated by participants for quality and fair balance (i.e., commercial bias).
- Faculty cannot receive any direct remuneration or gift from a commercial interest, nor can faculty permit a commercial interest any level of control regarding activity content.



UKHCCEC recommends that faculty complete the free, 30-minute National Faculty Education Initiative (www.nfeinitiative.org) online training that explains the differences between certified CE activities and commercial promotional speaker programs. See the chart below for a comparison.

Characteristics	Certified Continuing Education	FDA Regulated Speaker Programs
Responsible Entity	<ul style="list-style-type: none"> National or State Accredited CE Provider (Examples include Medical School, Pharmacy School, Hospital/Health System, Specialty Society, Medical Education and Communication Company) 	<ul style="list-style-type: none"> Pharmaceutical/Medical Device Manufacturer (Commercial Interest)
Educational Content	<ul style="list-style-type: none"> Evidence-based content for optimum patient outcomes, patient safety, discussed in context of disease management Must be independently developed, fair balanced and free of bias 	<ul style="list-style-type: none"> Approved disease state education FDA approved product safety and efficacy discussion Developed and monitored by manufacturer - distinct from CE
Regulatory Bodies	<ul style="list-style-type: none"> ACCME, AAFP, AOA, ACPE Can discuss evidence based non-FDA approved uses (Advise learners) Independent of influence of commercial interests/supporters Content must be free of commercial bias and be evidence-based 	<ul style="list-style-type: none"> FDA - Limits product education to approved uses OIG - Separation of CE grant decision/support from sales and marketing educational funding PhRMA and AdvaMed - Support FDA and OIG Regulations
Relationships	<ul style="list-style-type: none"> Relationship between faculty and CE Provider is contractual Faculty must disclose financial relationships to CE provider to determine any conflicts of interest. 	<ul style="list-style-type: none"> Relationship between faculty and commercial company is contractual Faculty speak for the company Disclosure of other relationships encouraged, but not required
Conflicts of Interest (COI) and their Resolution	<ul style="list-style-type: none"> Conflicts of interest (COI) identified and resolved by CE provider If COI cannot be resolved, the CE Provider ensures that individual with a COI will not have control over content Content will withstand validation for scientific rigor 	<ul style="list-style-type: none"> Disclosure of relationships that suggest COI encouraged, but not required
Origin of Need	<ul style="list-style-type: none"> Independent assessment of knowledge, skill, competence and/or performance gaps 	<ul style="list-style-type: none"> Market research New product use
Educational Outcomes	<ul style="list-style-type: none"> Meet the educational objectives of the CE activity that improve physician or pharmacist competence, performance and/or patient health status Appropriate and balanced discussion of all treatment options 	<ul style="list-style-type: none"> Disease awareness Appropriate, safe and effective use of a product/service
Role of Faculty	<ul style="list-style-type: none"> Independent subject matter expert, scientist and/or clinician Evidence-based, balanced presentation Clinical opinion of faculty with full disclosure of the evidence 	<ul style="list-style-type: none"> Agent/spokesperson for the sponsoring company Limited to use of company prepared and approved presentation
Succinct Summary	<ul style="list-style-type: none"> Independent Focus: Improve healthcare provider competence/performance resulting in improved patient care 	<ul style="list-style-type: none"> Promotional Focus: Appropriate, safe and effective use of a product/device or disease awareness

By signing below, I certify that the information I have provided is accurate to the best of my knowledge. I have read and agree to comply with the Faculty Guidelines and understand the differences between certified CE activities and FDA regulated commercial promotional speaker programs.

Signature _____

Date _____