LSUHealthNewOrleans

School of Medicine Office of Medical Education

Name:	Role in Course:	Presenter/Faculty Planner
Title of Activity:		
Date of Activity:		

The intent of disclosure is not to prevent a participant with financial or other relationships from making a presentation, but rather to provide participants with adequate information about the relationship(s).

Disclosure of Financial Relationships & FDA Off-Label Use

Conflict of Interest

The Louisiana State University School of Medicine-New Orleans (LSUSOM-NO) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) and is required to identify and resolve all potential conflicts of interest (COI) with any individual (which we define to include a spouse/partner) who may be in a position to influence and/or control CME activities. It is the policy of the LSUSOM-NO to ensure balance, independence, objectivity and scientific rigor in all of its CME activities. To view the mechanism for resolving CME COI, please click here: http://www.medschool.lsuhsc.edu/medical_education/CME/Policy.aspx.

Definition

A conflict of interest will be considered to exist if the individual as defined above has received **financial benefits** (e.g., grants, research support, honoraria, employee, consultant, board of directors, stockholder, licensing agreement) in any amount from a **commercial interest** (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients) within the past 12 months.

All individuals in a position to influence and/or control the content of LSUSOM-NO sponsored CME activities are required to disclose to LSUSOM-NO and subsequently to learners that the individual either has no financial relationship or any financial relationship with the manufacturer(s) of any commercial product(s) and/or providers of commercial services that may be discussed in CME activities. All disclosure information provided to LSUSOM-NO will be reviewed to ensure that no conflicts of interest exist prior to the confirmation of the individual for the educational assignment. Additional information may be requested. It is the responsibility of the individual to notify LSUSOM-NO of any changes in the disclosure information provided since the submission of this LSUSOM-NO Disclosure of Relevant Financial Relationships form.

To view the ACCME's full policy on the Updated Standards of Commercial Support, please click here: (www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf)

Q1: To the best of your knowledge, do you and/or your spouse/partner have a financial relationship with a commercial interest? (This includes any entity producing, marketing, re-selling or distributing health care good or services consumed by or used on, patients)

Yes

No, I nor my spouse/partner have a financial relationship with a commercial interest.

Q1a: If you answered "yes," please list the company and relationship below.

Types of support can include:

Salary Royalties Intellectual Property Rights Consulting Fee Honoraria Ownership Interest (stock, stock options, other ownership [excluding diversified mutual funds]) Speakers Bureau Membership on advisory committees, review panels Board Memberships Other activities from which remuneration is received or expected In-kind donations

Commercial Interest	Entity with	Nature of Relevant Financial Relationship	
	Relationship	(include all those that apply)	
		What Was Received?	For What Role?
Ex: Pharmaceutical Company X	Self	Honoraria	Speaker
Ex. XYZ Publisher	Spouse	Royalties	Author

Please complete the following additional questions (Required):

Q2. I agree:

I understand failure or refusal to disclose within the established timeframe will require LSUSOM-NO to identify a replacement. I will uphold LSUSOM-NO standards to ensure balance, independence, objectivity and scientific rigor in my role in planning or presentation of LSUSOM-NO's CME activity. All recommendations involving clinical medicine in my CME activity will be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in support or justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection and analysis. Furthermore, I will not present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. I agree to comply with all applicable federal and state laws and regulations relevant to this activity.

Q3: I agree:

Disclosure of Off-Label (Unapproved/Investigational) Uses of Products

I understand and agree to abide by FDA regulations and will clearly delineate utilization of "off label" use of drugs or devices for the audience. LSUSOM-NO CME faculty are required to disclose to LSUSOM-NO office of CME and to learners when they plan to discuss or demonstrate pharmaceuticals and/or medical devices that are not approved by the FDA and/or medical or surgical procedures that involve an unapproved or "off-label" use of an approved device or pharmaceutical.

To view the FDA policy on Disclosure of Off-Label product use, please click here (<u>http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm</u>)

Signature

Date

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