

UNIVERSITY OF NORTH DAKOTA SCHOOL OF MEDICINE AND HEALTH SCIENCES
OFFICE OF CONTINUING MEDICAL EDUCATION

DOCUMENTATION DISCLOSURE OCCURRED

Title of Activity:

Date of Activity:

Name of Presenter:

How Disclosure was made: ☐ Announced ☐ Evaluation ☐ Slide ☐ Disclosure Sheet
(Must use two methods and check appropriate boxes)

Presenter (Check appropriate boxes)

Information that the presenter(s) ☐ did / ☐ did not have financial relationship (s) to disclosure with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Nature of Financial Relationship(s)/Name of Ineligible Company if had:

Information that the presenter ☐ had / ☐ did not have discussion of trade names in the presentation was disclosed.

Description if trade names used:

Information that the presenter ☐ had / ☐ did not have discussion of any off-label and/or indication in question is not currently approved by the FDA for labeling or advertising.

Description if off-label usage discussed:

Presenter ☐ agreed / ☐ disagreed with the presenter/speaker attestations. (Presenter/Speaker Attestations on page 2.)

Specify which attestation was not agreed:

Providing/Joint Providing Unit(s) (List all Providing and Joint Providing Units): _____

Information that the Providing Unit(s) ☐ did / ☐ did not have relevant financial relationship (s) to disclosure with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Nature of Financial Relationship(s)/Name of Ineligible Company if had:

Planning Committee

Information that the Planning Committee ☐ did / ☐ did not have relevant financial relationship (s) to disclosure with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Nature of Financial Relationship(s)/Name of Ineligible Company if had:

Signature

Presenter/Speaker Attestations:

Please indicate your understanding of, and willingness to comply with, each statement below by checking the appropriate box. If you have any questions regarding your ability to comply, please contact UND SMHS CME as soon as possible.

- | | |
|--|---|
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | I have disclosed to the UND SMHS CME all financial relationships, and I will disclose this information to learners verbally and in print. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | The content and/or presentation of the information with which I am involved will promote quality or improvements in healthcare and <i>will not</i> promote a specific proprietary business interest of an ineligible companies*. Content for this activity, including any presentation of therapeutic options, will be well-balanced, evidence-based and unbiased. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | I have not, and will not accept any honoraria, additional payments or reimbursements beyond that which has been agreed upon directly with the UND SMHS CME. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | I understand that UND SMHS CME may need to review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance as requested. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | If I am presenting at a live event, I understand that an UND SMHS CME monitor may be attending the event to ensure that my presentation is educational, and not promotional, in nature. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | If I am discussing specific health care products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any single company.

Please describe if trade names are to be used: |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | If I have been trained or utilized by an entity or its agent as a speaker (e.g., speaker's bureau) for ineligible companies*, the promotional aspects of that presentation will not be included in any way with this activity. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | If I am providing recommendations involving clinical medicine, they will be based on evidence that is accepted with the profession of medicine as adequate justification for their indications and contraindications in the care of patients. I will convey the limitations of the content being taught, and the severe and most common risks of treatments that are discussed. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | If I am presenting research funded by a company, the information presented will be based on generally accepted scientific principles and methods, and will not promote the ineligible company(ies)*. All scientific research referred to, reported or used in the activity in support of justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection, and analysis. |
| <input type="checkbox"/> Agree <input type="checkbox"/> Disagree | If I am discussing any product use that is off label, I will disclose that the use or indication in question is not currently approved by the FDA for labeling or advertising.

Please describe if off-label usage is to be discussed: |