Case Scenarios: When It Is Acceptable To Use Owners and Employees of Ineligible Companies in Accredited Continuing Education

Many academic and practicing physicians are also researchers and inventors. Some of these individuals play roles in biomedical start-up companies. These individuals are considered owners or employees of biomedical start-ups when their companies have begun a governmental regulatory approval process for new drugs or devices. The section on eligibility in the Standards for Integrity and Independence in Accredited Continuing Education states that:

> The ***owners*** and ***employees*** of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined in Standard 3.2.
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> Owners and employees are individuals who have a legal duty to act in the company's best interests. Owners are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Employees are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.

The Standards (in particular, Standard 3.2) do allow for owners and employees to participate as planners/faculty in accredited continuing education (CE), under the following circumstances:

a) When the content of the activity is not related to the business lines or products of their employer/company.
b) When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
c) When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

How do I determine if the content being presented is related to the product or business line?

Content relevance sometimes requires clinical expertise, so accredited providers may want to leverage their planning committee or other experts to make determinations of relevance. The goal for these reviews is to ensure that those in control of educational content do not introduce bias towards their or their employer's products or services.

To help accredited providers navigate these exceptions, the ACCME has developed a series of case vignettes on the following pages that provide examples of scenarios when the exceptions are, or are not, applicable.

Standard 3.2a: When the content of the activity is **not related** to the business lines or products of the individual's employer/company.			
#	Scenario	Meets the Exception?	Rationale
1	Dr. Marcucci invented and now is the owner of a company that has developed a compound that catalyzes skin healing and regrowth in burn patients. He has been asked to serve as a reviewer on a chapter within a curriculum on dermatologic surgical techniques, specific to the removal of small foreign objects from the skin and scalp in bombing victims.	Yes	Company product is for medical treatment of burns, but content is related to surgical techniques. No opportunity for individual to insert bias towards his company.
2	Dr. Jones is an employee of a company that produces and markets vaccines. She has been asked to speak on the logistics of supply chains as she previously worked for a company that pioneered global supply chains for vaccines requiring extremely low temperature storage.	Yes	The logistics of supply chains (even if those are used for vaccines) is sufficiently separated from the clinical use of vaccines to make it unlikely the speaker would introduce bias about her company's vaccines.
3	Dr. McMasters is part of a team of physician venture capitalists who have commercialized and are bringing to market a new stent used in the repair of damage to the aortic arch. She has been asked to be an author of an accredited enduring activity on the surgical repair of peripheral arterial atherosclerosis.	Yes	The company product is in cardiology space, which is also the area of the content. However, her company makes a product which is used for structural issues of the aorta, and she is being asked to author material related to surgery of the extremities. Therefore, it is unlikely she would have the opportunity to insert bias toward her company.

4	Dr. Tan owns a company that makes a robotic surgical knife used in laparoscopic surgery and she is invited to present in an accredited activity on the use of laparoscopic surgery in children.	No	Even though the activity is limited to a pediatric indication, the education is still related to the company product (used in laparoscopic surgery). There is opportunity for this individual to insert commercial bias towards her product.
5	Dr. Meriwether is part-owner of a company that makes a laparoscopic device to repair meniscal knee tissue and is asked to moderate a session that includes three abstract presentations on laparoscopic techniques involving advancements in knee surgery.	No	The company owned by the individual is the maker of devices similar to those being discussed. Taking on the role of moderator does not prevent the individual from inserting commercial bias toward their product.
6	Dr. Kohler is the inventor and owner of a company that has just received approval for a non-implantable neuromodulation stimulator to treat gait deficit due to symptoms of multiple sclerosis (MS). As a world-renowned expert in MS treatment, he has been asked to plan and present in an accredited activity on improving quality of life in patients with progressive neurologic disease.	No	The improvement of quality of life could include supporting patients with MS in maintaining their ability to walk. Therefore, this person would have an opportunity to insert commercial bias toward his product.

Scenarios continued on next page.

Standard 3.2b: When the content of the accredited activity is limited to **basic science research**, such as pre-clinical research and drug discovery, or the **methodologies of research**, and the individual does not make care recommendations.			
#	Scenario	Meets the Exception?	Rationale
7	Dr. Abdullah is employed by a company that makes a novel pacemaker that modulates heart rhythm with breathing and is asked to be an abstract reviewer for the basic science research track of a large annual cardiology meeting.	Yes	The individual's control of content is limited solely to abstracts that are at the level of basic science research.
8	Professor Elliot is employed by a company that is developing targeted treatment for specific types of reproductive cancers based on the patient's genome. She is also the principal investigator for research funded by her employer on the involvement of a previously unstudied gene on the growth of tumor cells. She would like to present an abstract on the early results of this research at an accredited activity.	Yes	The individual's control of content is limited to a basic science study.
9	The Association for Cutting Edge Rheumatologists has learned about a new monoclonal antibody therapy for psoriatic arthritis that is showing promise in early animal studies. The paper that was published about the study is authored by a group of individuals, all of whom report part-ownership of the ineligible company that is funding the research. The association has invited the company to present the data from this research at its mid-year meeting.	Yes	The research is pre-clinical and therefore may be presented by owners of the company.
10	Dr. Seto is the Chief Medical Officer of a new biologics company that has just begun Phase 2 clinical trials of a groundbreaking therapy for the treatment of Crohn's disease. The trial has begun enrolling patients, and Dr. Seto has been invited to present the data from the Phase 1 trial on the safety of the new biological that led to the start of the Phase 2 study.	No	The research is NOT pre-clinical and, if presented, must be presented by someone who is not an employee of the company.

11	Dr. Howe is the owner of a company that has been very successful in bringing new products to market. He has been asked by an accredited provider to speak about the FDA 501(k) process for approval of devices to a group of orthopedic surgeons at a conference on new approaches to total hip replacement. Dr. Howe's presentation, which has been submitted to the provider for review, contains an introductory section discussing the characteristics of his company's latest prosthetic hip implant and how it was successful in achieving clearance by the FDA.	No	The individual in control of content is going beyond the process of device/regulatory approval and is discussing the advantages of his company's product.

Standard 3.2c: When the individual is participating as a technician to teach the safe and proper use of medical devices, and does not recommend whether or when a device is used.			
#	Scenario	Meets the Exception?	Rationale
12	The Society for Ultrasonic Imaging is implementing an accredited activity that includes hands-on sessions designed to support learners in developing skills in imaging difficult-to-reach areas of anatomy. A medical device company has offered to provide its state-of-the-art, ultrasound devices as in-kind support to the activity. In addition, its technical managers will be onsite to support the learners in applying the imaging probe at separate manikin stations. Because of the popularity of this emerging technique, 12 employees of the company will serve in this role. The activity director, who is also a consultant to the device company, and serves on its board of directors, will lead the activity, starting with a talk on the indications and contraindications of the device, followed by a demonstration of a manikin simulation on a large video screen of the safe and proper use. At the same time, the technical managers will help individual learners at the 12 stations.	Yes	The employees are providing technical support to the learners and are not recommending whether or when to use the device. Since the activity director is a consultant, rather than an owner or employee, that relationship can be mitigated and disclosed.

13	Dr. Malone is inventor of the Malone Injector, a new device for follicular unit excision (FUE), and he is an owner of the company that manufacturers it. Dr. Malone has been asked by an accredited provider to serve as a technician to teach the use of several techniques for FUE during a hands-on workshop on new techniques in hair grafting. The provider has received in-kind support from the three leading FUE device makers. The provider has given Dr. Malone, and the other faculty who are teaching the proper and safe use of these devices, explicit instructions to avoid any discussion in the activity about whether or when to use any specific FUE device.	Yes	The provider has taken appropriate steps to ensure that the faculty are not making clinical recommendations that could allow them to insert commercial bias toward their company's products.
14	Dr. Potash is presenting on a new smoking cessation product, which she invented, that recently received FDA approval. She also owns the company that will be marketing the product. This medication is given using an implantable dispensing device. She will discuss different approaches to smoking cessation (without mentioning her product) and demonstrate the safe and proper implantation of the device on a volunteer.	No	The presenter is going beyond teaching the safe and proper use of the device to include information about ways to help patients stop smoking cessation. This could create a reasonable opportunity to market smoking cessation products (including hers) to the learners.