Frequently asked questions concerning the new policy on Promotional Medical Education

Question 1: Why has the policy changed on Duke Faculty members speaking for promotional purposes?

Answer: “Speaker’s bureaus” (i.e. promotional medical education lectures) have traditionally been an avenue for Duke Faculty to partner with biomedical companies to provide non-CME lectures or video to physicians that are promotional targets of industry. Due to recent changes at the FDA to control off-label promotion, speakers that are hired to give promotional lectures/video will be required to speak from approved company slides/script without deviation from prescribed content.

Beginning January 1, 2012, payments from biomedical companies to lecturer will also be posted on a public web site by the Federal Government.

Duke School of Medicine believes that it is important that faculty members continue to work with biomedical industries for the benefit of the public. However, academic faculty and leadership at Duke University and other similar institutions expect their faculty to speak on content of their own creation based on their expertise. This policy is keeping with Duke’s long standing traditions of academic and professional integrity.

Question 2: Why does the policy require Duke Faculty to be an expert on the topics they are speaking on for promotional medical education?

Answer: The University expects their faculty to be asked to speak at various venues around the world. The reason a faculty member should be asked to speak must be because the faculty member is a content expert for the topic to be presented. The term “expert” in the policy is not determined by faculty rank, but simply refers to the fact that the faculty member has clinical or lab experience in the appropriate field.

Question 3: Does this new policy apply to CME lectures?

Answer: No, there is specific policy that governs all CME activity.

Question 4: If I am recording a video for a company, does this policy apply?

Answer: Yes, the content from the video must be created by Duke and not by the company that is helping to produce the video.
Frequently asked questions concerning the new policy on Promotional Medical Education (cont.)

**Question 5:** If I am giving a promotional medical education (non-CME) lecture and the company does not pay me but instead pays a third party, does this policy apply?

**Answer:** Yes, this policy applies for all lectures that are non-CME and are classified as “Promotional”. The quantity and direction of payment does not change the enforcement of the policy.

**Question 6:** If I give a lecture at a national meeting of a professional society, does this policy apply?

**Answer:** The policy does not apply to educational talks at national and regional meetings (these lectures are almost always ruled by CME rules).

**Question 7:** What are the ramifications for not adhering to this policy?

**Answer:** Faculty will disclose all industry relations activities, including these lectures/videos, annually to the Duke Research Integrity Office. At any time throughout the year, faculty may be asked to submit copies of slides/script of any educational lecture for review by the compliance office. If it is determined that the faculty member is not adhering to this policy, sanctions may range from a warning to dismissal from the faculty depending on the degree of non-adherence.

**Question 8:** If I have a promotional education lecture scheduled in 2012 based on an existing contract with industry do I have to cancel this lecture?

**Answer:** If a lecture/video has already planned based on a contractual relationship that predates this policy, the faculty member can keep this commitment. No new commitments should be made after May 1, 2012.

**Question 9:** How does this policy relate to similar policies?

**Answer:** This policy supplements, but does not supersede or replace, existing policies governing Duke University School of Medicine faculty.