From: OC GCP Questions
Sent: Monday, May 05, 2014 6:46 PM
To: [redacted]
Subject: RE: Market Research during Clinical Trial Phase

Dear [Redacted],

To respond to your question, I searched previous responses from FDA's Office of Good Clinical Practice. I was unable to find any past responses that answered your question directly. However, a Warning Letter issued by FDA appears to apply in part to your question. In that Warning Letter it states, "It is also well established that participants in research studies are likely to be highly sensitive to, and compliant with, information presented in a research environment." Further, the applicable footnote 5 states, "Martin Orne concluded that research participants respond to the demands placed on them in the research environment by attempting to be 'good' subjects and providing 'good' data. . . This results in subjects providing the types of responses that they perceive that the experimenters are likely to seek." See pages 2-3, and footnote 5, at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM170613.pdf.

In general, the study protocol should be evaluated to determine whether certain study interventions or associated activities are allowed, discouraged, or prohibited. The institutional review board (IRB) or ethics committee overseeing the study should be consulted to ensure protection of the rights and welfare of the research participants. For frequently asked questions concerning IRBs, see FDA's guidance document at http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm. See, in particular question and answer 50 (repeated below), that might be helpful:

> **50. May the "compensation" for participation in a trial offered by a sponsor include a coupon good for a discount on the purchase price of the product once it has been approved for marketing?**
> No. This presumes, and inappropriately conveys to the subjects, a certainty of favorable outcome of the study and prompt approval for marketing. Also, if the product is approved, the coupon may financially coerce the subject to insist on that product, even though it may not be the most appropriate medically.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
Kathleen Pfaender, RN, JD
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of Medical Products and Tobacco
Federal Food and Drug Administration
WO32/5129
301-796-8346

employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Friday, May 02, 2014 5:25 PM
To: OC GCP Questions
Subject: Market Research during Clinical Trial Phase

Hello,

I am seeking out information on behalf of a pharmaceutical company's marketing department.

I am interested to know if patients undergoing clinical trials for a specific treatment or device are allowed to participate in market research studies by the sponsoring pharmaceutical company for the treatment or device they are trialling. Can you please advise is there are any legal or ethical barriers that would prevent this?

Many thanks and kind regards,

[Redacted]