From: Griffin, Joseph P
Sent: Monday, September 18, 2006 11:14 AM
To: Behrman, Rachel E; Beckerman, Peter; Hommel, Carolyn - OC; Dada, Kavita
Cc: Ray, Seth; Seager Stewart, Sarah
Subject: RE: Charging for investigational drugs in a Phase 4 study
RE: Charging for a marketed drug in a trial not exempt from part 312

If someone asks us if the charging reg applies, I think we've pretty consistently said yes. Is this well-understood in the outside world? I think we believe that commercial sponsors are ordinarily sophisticated enough that they would know that they can't charge for a marketed drug in a part 312 trial unless they have prior authorization to do so (it's hard to read the regs and reach the opposite conclusion). I don't think we have the same expectation of every sponsor-investigator conducting a single site study with a marketed drug without support from the manufacturer (i.e., where drug is not provided to sponsor-investigator for free). [Redacted] But, again, when sponsors ask, I believe they are consistently told they need prior authorization to charge. And, presumably, if we were to find out independently that a sponsor was charging we would inform them of the need for prior authorization to charge.

Under what circumstances would we permit charging for a phase 4 trial?

If someone asks and makes a reasonable case for the trial being a somewhat extraordinary expense (or a not an ordinary cost of doing business), seems reasonable to allow them to charge. Because the drug is marketed, there isn't the same level of concern about charging as for an unmarketed drug so I don't think the case for extraordinary expense would have to be as compelling as for an umarketed drug (e.g., we believe the drug is at least somewhat effective and subjects could be charged for it if they hadn't had the opportunity to enroll in the study). Also, phase 4 might arguably be considered a de facto extraordinary expense because it's an unanticipated expense. On the other hand. if most new drugs have phase 4 commitments, it may be unreasonable not to anticipate the need for phase 4 studies.

[Redacted]

From: [Redacted]
Sent: Friday, September 08, 2006 2:42 PM
To: Hommel, Carolyn - OC
Subject: Phase IV

Hello Carolyn,

[Redacted] When a sponsor is conducting a phase 4 trial to fulfill the post marketing requirements, the clinical trial is referenced with an IND number. If that is the case they are obviously responsible for abiding by the regulations for 312, does that also mean that the sponsor cannot charge for the drug as well?

Thanks,
[Redacted]