Reply to Beckerman

To the Editor—Dr. Beckerman has suggested a different interpretation of our results based on descriptive data [1]. Although the 1998–2002 cohort had a very preterm delivery rate of 5.6% for a PI-sparring regimen, versus 0.8% for a PI-based regimen, and a rate of 6.4% versus 0.8% for very low birth weight [2], these are simply descriptive data, and neither a protective effect nor a risk effect can be calculated or attributed. Our conclusions are based on the results demonstrated in our table 3, where a logistic regression model adjusting for confounding variables demonstrates the significantly increased risk of preterm delivery for a PI-based combination regimen. We believe it to be a strength of our study to adjust for these potential confounders due to the completeness of our data in contrast to the previous US multisite study [3]. It is reassuring to see that no category of antiretroviral therapy was associated with a significantly increased risk of very preterm delivery, low or very low birth weight. Antiretroviral therapy was categorized by treatment era to adjust for the different therapies used during the 12 years of study, so, although there were only 10 patients receiving a PI-based regimen in 1995–1997, this was adjusted for in the logistic regression model. Although the US multisite study was based on a larger cohort [3], the numbers of women receiving a PI-based regimen were almost identical.

We concluded that a decision to initiate combination therapy with a PI in pregnancy should be made with caution. We do not advise against PI use, especially in light of the finding that there is no increased risk of prematurity before 32 weeks, a gestational age that causes the most concern to perinatologists, neonatologists, and parents. However, many US providers initiate a PI-based regimen in all pregnant women, even if the latter do not need it for their own health, in the belief that PIs provide the most protection against perinatal transmission. In our most recent unpublished data, of 110 infants born in 2005 to HIV-infected mothers, of whom 32% received a PI-based regimen, the perinatal transmission rate was 0%. Similarly, of 97 infants born in 2006, 31% of whose mothers were receiving a PI, the perinatal transmission rate was 0%. Hence, we do not believe that a PI-based regimen is necessary for women who do not need a PI for their own health, especially since, to achieve adequate viral suppression, a PI-based regimen requires >90% adherence [4]. Suboptimal adherence can result in an increased risk of development of resistance or toxicities among these women. Nonadherent women may limit their therapy options for future pregnancies or for those situations when therapy is indicated for maternal health.

We again recommend that this important question be appropriately resolved with a large multicenter randomized clinical trial of combination ART during pregnancy for women who do not require ART for their own health but simply for the prevention of perinatal transmission.

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References