Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee
March 3, 2003

Questions to the Committee

1. Since neonates born to HIV-infected mothers may be tested for HIV infection in the first 48 hours and at 4 weeks, HIV-infected infants can be diagnosed as early as one month of age. The U.S. Public Health Service guidelines recommend treating HIV-infected infants less than one year of age with combination antiretroviral as soon as possible after diagnosis. All HIV-exposed infants are treated with prophylactic antiretroviral(s) for six weeks after birth.

    - Should only HIV-infected neonates be studied?

    - Is it ethical to study antiretroviral drugs in HIV-exposed neonates, most of whom are not infected? What is the benefit to the uninfected child?

2. Given that an estimated 300 to 400 HIV-infected infants are born annually each year in the United States, that some of these infants are diagnosed after the first several months of life, and that it is difficult to enroll neonates in studies,

    - Are too few HIV-infected infants born annually in the United States to justify asking for studies in this population?

    - Is FDA asking sponsors to study antiretroviral drugs in resource poor countries because there are so few HIV-infected infants in the United States? If so, is that appropriate?

    - If studies are conducted in resource poor countries (where the rate of underlying diseases, malnutrition, infant mortality, and pharmacogenetics, etc. may differ substantially from the U.S.), can we extrapolate results from these studies to the US population?

3. Should we continue to request pharmacokinetic and safety studies for <u>every</u> antiretroviral drug under development?

4. If not:

    - What should the criteria be for deciding which drugs should be studied (e.g., new class, resistance profile, safety issues, pharmacokinetic parameters)?

    - Who should develop these criteria and who should make the decision?