

THE GRACE STUDY, A GROUND BREAKING HIV CLINICAL TRIAL FOCUSED ON WOMEN AND PEOPLE OF COLOR

RECOGNIZING TIBOTEC THERAPEUTICS FOR CONDUCTING THE GRACE STUDY, A GROUND BREAKING HIV CLINICAL TRIAL FOCUSED ON WOMEN AND PEOPLE OF COLOR IN THE UNITED STATES

HON. DANNY K. DAVIS
OF ILLINOIS
IN THE HOUSE OF REPRESENTATIVES
WEDNESDAY, OCTOBER 21, 2009

- Mr. DAVIS of Illinois. Madam Speaker, I rise today to commend and congratulate Tibotec Therapeutics, part of the Johnson & Johnson family of companies, for demonstrating continued innovation and corporate responsibility in the fight against HIV/AIDS by conducting the groundbreaking GRACE study. GRACE, which stands for Gender Race and Clinical Experience, is the largest study to date in treatment-experienced women with HIV to examine gender and race differences in response to an HIV therapy. Findings from this historic study were recently presented at the International AIDS Society conference in Cape Town, South Africa.

- In the United States, women are increasingly affected by HIV/AIDS, accounting for more than one quarter of all new HIV/AIDS diagnoses, with African American and Latina women representing seventy-nine percent of women living with the disease. People of color, both women and men, have been historically underrepresented in clinical trials in the United States, and HIV/AIDS disproportionately impacts our African American and Latino communities. In my home State of Illinois, there are over 35,000 people living with AIDS: African Americans represent 50% of these cases, and Latinos represent 13%. In terms of new HIV infections, African American women are infected at a rate fifteen times higher than white women, and Latino women are infected at a rate almost four times as high as white women.

- In recent HIV studies of treatment-experienced patients, women accounted for less than 11 percent of the patients being studied, on average. This trial was designed to help overcome some of the barriers, identified by the advisors, which have historically deterred women and people of color from participating in clinical studies, including stigma, lack of child care, transportation and personal support systems. Based upon advisor and community input, study participants could obtain assistance to cover costs associated with their participation in the study,

including funds for travel and childcare, as well as food vouchers. Through innovative strategies like these, the GRACE study was able to enroll nearly seventy percent women, sixty percent African Americans and twenty-two percent Latinos. I am proud to say that two of the study sites in this historic clinical trial are located in my congressional district.

- Results of the GRACE study showed that there were no statistical differences in the safety, tolerability or effectiveness of the HIV regimens used in the study between male and female participants, or for people of different ethnicities. Importantly, from my perspective, the GRACE study clearly showed that, with the appropriate commitment from the trial sponsor and input from affected communities and providers, clinical trials can, indeed, enroll meaningful numbers of women and racial and ethnic minorities.

With the GRACE study, Tibotec Therapeutics and Johnson & Johnson continue to demonstrate their leadership and corporate social responsibility as innovators and leaders in the pharmaceutical industry. I commend them for their continuing commitment to the fight against HIV/AIDS and for their leadership in addressing the disproportionate impact of the HIV/AIDS epidemic on women and people of color.