Participation of Women and Racial Subgroups in Late Phase Clinical Trials of New Molecular Entity Drugs and Biologics Approved by the Food and Drug Administration between 2007-2009

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Background: Data from late phase clinical trials (LPCTs) are used to determine the safety and efficacy of new therapeutic products. As demographic subgroups may respond to treatments differently, it is important to have adequate participation of different subgroups in LPCTs to determine potential differences in treatment outcomes. This study examines the participation of women and racial subgroups in LPCTs reviewed by the Center for Drug Evaluation and Research (CDER) and approved by the FDA from 2007-2009.

Methods: New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) were retrieved from the electronic document rooms for CDER and Center for Biologic Evaluation and Research (CBER) and reviewed for LPCT demographic data. Data was then analyzed by year and therapeutic category.

Results: From 2007-2009, 57 NDAs and 13 BLAs were approved. Sex-specific (n=5) and pediatric (n=3) drugs were excluded from review. Biologics (n=2) that submitted LPCT data from previously approved products were excluded. Women’s participation in LPCTs for new drugs was 38.8% (2007), 48.0% (2008), 42.3% (2009), and 43.2% (overall). Racial subgroup participation was 77.1% (White), 8.7% (Black), 7.1% (Asian), 3.3% (Hispanic), 3.7% (other), and 5.0% (unspecified). Women’s participation in drug LPCTs was lowest for anti-viral indications (12.0%) and highest for special pathogen indications (62.1%). Women’s participation in biologic LPCTs was 48.5% (2007), 61.6% (2008), 58.1% (2009), and 57.3% (overall). Biologic LPCT racial subgroup participation was 84.4% (White), 4.4% (Black), 3.4% (Asian), 3.3% (Hispanic), 2.0% (other), and 0.1% (unspecified). Women’s participation in biologic LPCTs was lowest for oncology indications (30.5%) and highest for neurology (82.3%).

Conclusions: There were no recognizable trends of women’s participation in new drug and biologic LPCTs. The lower mean participation of women in drug LPCTs compared to biologic LPCTs may be due, in part, to sex differences in the prevalence of the medical conditions the drugs were approved to treat.

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