March 18, 2011

Scott E. Goedeke
Sr. Vice President, Marketing
Ther-Rx Corporation
One Corporate Woods Drive
Bridgeton, MO 63044

Dear Mr. Goedeke,

On behalf of the American College of Nurse-Midwives (ACNM) and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), we are writing to express our significant concerns regarding the cost of Makena™ as a newly FDA-approved medication for the treatment of women at risk for preterm birth. We recognize that Ther-Rx has attempted to address the financial and access issues that women will face in receiving a multi-dose treatment that costs $1,500 per injection. However, we urge Ther-Rx to take further steps to fulfill its pledge to ensure that women in need of treatment with Makena™ will receive it in a timely manner and without undue financial burden.

ACNM is the oldest women's health organization in the United States, with roots dating back to 1929. Our members -- certified nurse-midwives (CNMs) and certified midwives (CMs) -- attended 316,811 births in the US in 2008, 96.1% of which were in hospitals.[1] This represents 8.0% of all births in the US. Many of our members care for disadvantaged, uninsured and vulnerable populations at increased risk of preterm birth.

AWHONN is a nonprofit membership organization dedicated to the health of women and newborns. Our 24,000 members are staff nurses, nurse practitioners, nursing school faculty, certified nurse-midwives, and nurse executives who work in hospitals, independent practices, universities, and community clinics throughout the United States.

After reviewing the cost structure outlined for access to Makena and the proposed functioning of the Makena Care Connection, we are not convinced that women in need will be able to negotiate the complex reimbursement and communication channels required to secure timely, effective treatment. We are deeply concerned that delays or inability to afford treatment will occur, causing unnecessary harm to women and their newborns.

ACNM and AWHONN urge Ther-Rx to lower the price of Makena, and to remove the barriers which will prevent access to this important therapy.

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[1] Martin JA, Hamilton BE, Sutton PD, Ventura SJ, Matthews TJ, Osterman JK. Births: Final data for 2008. National vital statistics reports; vol 59 no 1. Hyattsville, MD: National Center for Health Statistics. 2010.

Respectfully submitted,

Holly Powell Kennedy CNM, PhD, FACNM, FAAN
President, ACNM

Kathleen Hale, BSN, CNA, MHA, RN
President, AWHONN