

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™



The Society for
Maternal Fetal Medicine

March 11, 2011

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

Dear Mr. Goedeke,

Thank you for your letter of March 4, 2011 to the American College of Obstetricians and Gynecologists (the College) explaining Ther-Rx's approach to introducing FDA-approved Makena™. The College, the American Academy of Pediatrics (AAP) and the Society for Maternal-Fetal Medicine (SMFM) are strong advocates for quality health care for women and the leading professional associations of physicians who specialize in the healthcare of pregnant women and their newborns. The College and SMFM members deliver more than 80% of pregnant women in the United States. AAP, the College and SMFM also believe that a full array of clinical services should be available to women without costly delays or the imposition of financial barriers. Thus, AAP, the College and SMFM appreciate that Ther-Rx recognizes its responsibility and obligation to fight against preterm birth, which annually affects over 500,000 births of which 130,000 to 140,000 may medically qualify for treatment with Makena™. However, AAP, the College and SMFM strongly believe that Ther-Rx's approach to introducing Makena™ does not go far enough to address the access of Makena™ to women who could potentially benefit from this therapy. We note that this particular treatment has been available to women until FDA approval, and that this less expensive option may no longer be available to them.

Since the announcement about the availability of Makena™, AAP, the College, SMFM, and other medical organizations have received numerous emails and calls critical of the cost of the therapy. At \$1,500 per injection, Makena™ is extremely expensive. This is especially true when you consider that ideal treatment starts at approximately 16-18 weeks gestation and continues until 36 weeks gestation. This means that a woman will receive as many as 20 doses during her pregnancy at a cost of approximately \$30,000. Frankly, in our current climate of controlling health care costs in the United States an added cost of \$30,000 for as many as 140,000 pregnancies per year, or 4.2 billion dollars, is a staggering figure.

Unfortunately, the financial assistance that Ther-Rx is offering, as described below, is not sufficient and does not extend to certain groups of women.

- **Insured patients** with annual household incomes of up to \$100,000 who apply for and are eligible for copay assistance will have a copay of \$20 or less per injection for Makena™.
- **Uninsured patients** with annual household incomes of up to \$60,000 who apply for and are eligible for patient assistance will receive Makena™ at no cost. Uninsured patients with annual

household incomes between \$60,000 and \$100,000 will be able to acquire Makena™ at a cost that is comparable to the average copay assigned by commercial insurance plans.

There are significant gaps in the number of pregnant women who could potentially benefit from this therapy yet may not receive it. Uninsured patients with an annual household income greater than \$100,000 will not be eligible for the financial assistance package. Thus, at a cost of \$30,000 per pregnancy these women will most likely not be able to afford Makena™. Women with high insurance deductibles may find it difficult to afford Makena™. Questions also exist about an insured patient's out-of-pocket costs for the therapy.

As you are aware, Medicaid programs are crumbling financially. It is unclear whether state Medicaid programs, which cover the majority of these high-risk pregnancies, will be willing or able to pay for the cost of treatment. Further, it remains unclear how women who are undocumented immigrants will be treated under this program and whether these women will have adequate access to treatment.

Furthermore, AAP, the College and SMFM are concerned about the effectiveness and efficiency of the Makena™ Care Connection. AAP, the College and SMFM are worried that this will create a bureaucratic barrier for pregnant women receiving therapy in a timely and efficient manner. Low income woman who potentially can benefit from the financial assistance program are also among the most vulnerable of populations in the US and suffer from other barriers, including health literacy which would prevent them from accessing this program.

For these reasons and for the health of the pregnant women of this country, AAP, the College and SMFM hope that Ther-Rx reevaluates its pricing structure and ensures that patients who could potentially benefit from Makena™ have timely and efficient access to this medication regardless of their ability to pay. Ther-Rx should also consider establishing a registry to identify patients who are "eligible" for assistance and did not receive it and for those patients who may have benefitted from Makena™ but could not afford it.

Respectfully submitted,



O. Marion Burton, MD, FAAP
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George Saade, MD
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