AMERICAN COLLEGE of NURSE-MIDWIVES®
With women, for a lifetime®

March 28, 2011

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

Dear Mr. Goedeke,

Thanks so much for your prompt response to our letter regarding the cost of Makena as a newly FDA-approved medication for the treatment of women at risk for preterm labor. You requested that we share with you our specific concerns about the structure and functioning of the Makena Care Connection. We appreciate the opportunity to do so.

First, however, we note that a meeting has been arranged in the near future with representatives of medical organizations that have expressed concerns about the cost of Makena and the Makena Care Connection process. We are disturbed that ACNM and AWHONN were not invited to participate in these meetings. ACNM members are the primary maternity care provider for more than 300,000 women each year and serve a disproportionate share of low-income women, many of whom are members of vulnerable populations who are at increased risk for preterm birth. We believe that we are uniquely qualified to speak to the challenges faced by these women and request the opportunity to participate. We also invite you to contact us to arrange opportunities to work with ACNM to learn more about midwifery practice in the US and the critical role that certified nurse-midwives (CNMs) and certified midwives (CMs) play in serving vulnerable populations.

ACNM's Review of Makena Care Connection

Time and cost are critical issues for women who are at risk for pre-term birth and can have a significant impact on the success of preventive interventions. In discussions with representatives at Makena Care Connection, we were told that the process takes at least a week to a week-and-a-half. ACNM believes that this delay is unacceptable for the women we serve.

Here are the steps to the process as described to us by representatives of Makena Care Connection:

8403 Colesville Road, Suite 1550, Silver Spring, MD 20910-6374 240.485.1800 fax: 240.485.1818
www.midwife.org

- Women at risk for pre-term delivery must download the form and attach all insurance information, including copies of their insurance card (front and back) for all insurance and drug plans. The forms must be filled out completely. We estimate that this would take at least 15 minutes of provider time, plus additional time from the support staff. If the provider is not available to complete the form, there can be even more delays.
- After the completed form is received, Makena Care Connection verifies all insurance information.
- The consumer is called to confirm that all information has been verified and that the prescription will be sent to a dispensing pharmacy. Cost of the prescription is not disclosed.
- After Makena reviews the insurance information, we understand that the dispensing pharmacy must do the same review to see if the drug plan covers the drug.
- The prescription cost first goes to Makena which then notifies the patient on cost.

Many women who are at risk for pre-term delivery cannot afford to wait a week or more to complete this process.

Moreover, after completing the process there is no guarantee that the drug will be available at a price that will be affordable. Considering the stunningly high cost of Makena, we were surprised in reviewing the Makena Care Connection process to find that there is no mention that Makena can be obtained for free or at a reduced cost. We further note that Makena is not covered by Medicaid and there is no obvious assistance for women who do not have private health insurance.

Thank you for the opportunity to explain ACNM's concerns in further detail. We look forward to hearing more about upcoming opportunities to work with Ther-Rx to expand access to Makena for women at-risk of pre-term delivery.

Sincerely,

Lorrie Kline Kaplan, CAE
Executive Director

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