

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

March 24, 2011

Mr. Gregory J. Divis
President
Ther-Rx Corporation
Chief Executive Officer
KV Pharmaceutical Company
Corporate Headquarters
One Corporate Woods Drive
Bridgeton, MO 63044

Dear Mr. Divis:

We are writing regarding reports of high prices that Ther-Rx Corporation¹ is charging for Makena, a drug recently approved by FDA to reduce the risk of preterm birth in women with a history of spontaneous preterm birth. News reports indicate that the company will be charging as much as \$1,500 per dose, a total cost of as much as \$30,000 for women who must take the drug over the course of a pregnancy.²

The high cost of this drug is particularly disturbing because it is not a new drug. The drug – a synthetic form of the drug progesterone – was originally approved by FDA decades ago, then later withdrawn because of lack of sales. Prior to Ther-Rx's marketing an FDA-approved version of Makena, the drug was available from compounding pharmacists for an estimated \$20.00 per dose – less than 2% of the price charged by Ther-Rx. Experts have indicated that Ther-Rx could realize as much as \$4.2 billion annually in revenues as a result of its new pricing

¹ Ther-Rx is the branded drug subsidiary of K-V Pharmaceutical Company which owns the worldwide rights to Makena. *See* KV Pharmaceutical Company, Press Release Archive, *FDA Approves Makena™, the First and Only Treatment to Reduce the Risk of Preterm Birth in Women With a Singleton Pregnancy Who Have a History of Singleton Spontaneous Preterm Birth* (Feb. 4, 2011) (online at: http://www.kvpharmaceutical.com/news_center_article.aspx?articleid=333).

² *Premie Birth Preventive Spikes from \$10 to \$1,500*, Associated Press (Mar. 10, 2011).

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policy.³ Moreover, because Ther-Rx has received an orphan drug designation for Makena, your company will be able to forestall generic competition, maintaining your exclusivity and control of prices for seven years, and potentially beyond, depending on the status of any patents protecting the product.

Ther-Rx did not invent this drug, or the use of the drug to prevent premature births. But this has not stopped your company from charging extremely high prices. The pharmaceutical industry has traditionally justified its high prices by claiming that such prices are necessary to allow companies to recoup their research costs.⁴ In this case, however, Makena was approved under the “505(b)(2)” pathway, which permits an applicant to rely on studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.⁵ The two studies cited on the FDA-approved label for Makena appear to be funded by public dollars through the National Institutes of Health (NIH).⁶ In addition, Ther-Rx has apparently set its price at the maximum level at which health care plans will still be “motivated to provide coverage” of the drug.⁷ It appears that the price of this drug is not being set on the basis of the cost to produce or research the drug, but at the maximum level that providers are willing to pay.

There are undoubtedly important advantages to Ther-Rx’s sale of an FDA-approved version of this drug. But we are concerned about the impact of the high prices for Makena on private insurers as well as Medicare, Medicaid, and other public programs, and we question whether these high prices are justified. In order for us to evaluate these issues, we ask that you provide us with the following information:

1. Any fiscal or other contributions made by Ther-Rx to the two NIH studies cited on Makena’s FDA-approved label.⁶

³ Letter from American Academy of Pediatrics, American College of Obstetrics and Gynecology, and Society for Maternal Fetal Medicine to Ther-Rx Corporation (Mar. 11, 2011).

⁴ See, e.g., House Committee on Energy and Commerce, Subcommittee on Health, Testimony of Richard I. Smith, *Hearing on Prescription Drug Price Inflation: Are Prices Rising Too Fast?*, 111th Cong. (Dec. 8, 2009).

⁵ Letter from FDA to Hologic, Inc. (Feb. 3, 2011). *See, also*, Federal Food, Drug, and Cosmetic Act, Section 505(b)(2).

⁶ Meis PJ et al., *Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate*, *New England Journal of Medicine* (June 12, 2003); Northen AT et al., *Follow-up of Children Exposed In Utero to 17 alpha-hydroxyprogesterone Caproate Compared with Placebo*, *Obstetrics and Gynecology* (Oct. 2007).

⁷ Letter from Ther-RX Corporation to Dr. Hal Lawrence, Director of Practice Affairs, American College of Obstetricians and Gynecologists (Mar. 4, 2011).

2. Any additional research costs to date incurred by, or studies conducted by Ther-Rx in obtaining FDA approval for Makena, and the expected costs of ongoing research. Please include all registry numbers listed under www.clinicaltrials.gov for any clinical trials that formed the basis for approval, and for any such trial that was published in a peer-reviewed publication, a copy of the publication. Please ensure such information includes the five postmarketing requirements as per FDA's approval letter.⁸
3. Any research or data on the bioequivalence of Makena to the compounded versions or previously FDA-approved versions of the drug.
4. Ther-Rx's promotional expenditures on Makena, and details on how these funds were spent. Please include information on promotional expenditures to date, and anticipated future expenses.
5. Ther-Rx's total cost, and estimated unit costs, to manufacture Makena, and the components of such costs.
6. Ther-Rx's expected revenues and profits from sales of Makena.
7. Ther-Rx's anticipated revenues and profits from sales of Makena to Medicare, Medicaid, and other federal or state health care programs.

We ask that you provide us this information no later than April 1, 2011. Please contact Brian Cohen of the Committee staff or Tiffany Guarascio of Rep. Pallone's staff if you have any questions about this request.

Sincerely,



Henry A. Waxman
Ranking Member



Frank Pallone, Jr.
Ranking Member
Subcommittee on Health



Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

⁸ FDA approved label of Feb. 3, 2011 (online at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021945s000lbl.pdf)