IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

K-V PHARMACEUTICAL COMPANY and **THER-RX CORPORATION,**

Plaintiffs,

v.

JULIE HAMOS, in her official capacity as Director of the Illinois Department Healthcare and Family Services, **THERESA A. EAGLESON**, in her official capacity as Administrator of the Division of Medical Programs of the Illinois Department of Healthcare and Family Services, **RANDY D. MALAN**, R.Ph., FASCP, in his official capacity as Bureau Chief of the Illinois Bureau of Pharmacy and Clinical Support Services, **MICHELLE R.B. SADDLER**, in her official capacity as Secretary of the Illinois Department of Human Services, **DEBBY SAUNDERS**, in her official capacity as Bureau Chief of the Illinois Bureau of Maternal and Child Health Promotion, and **GINA RUTHER**, in her official capacity as Acting Chief of the Illinois Bureau of Child Care & Development

Case No. 12 C 6697

Defendants.

COMPLAINT AND APPLICATION FOR PRELIMINARY INJUNCTION

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GLOSSARY OF TERMS

Term	Meaning
17P	hydroxyprogesterone caproate — the active ingredient used in Makena®
API	active pharmaceutical ingredient
CMS	Centers for Medicare & Medicaid Services
FDA	United States Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
GMP	good manufacturing practice standards promulgated by FDA
HHS	United States Department of Health and Human Services
HFS	Illinois Department of Healthcare and Family Services
MCO	managed care organization
MDRA	Medicaid Drug Rebate Agreement
NDA	New Drug Application

Case: 1:12-cv-06697 Document #: 1 Filed: 08/21/12 Page 3 of 37 PageID #:3

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HHS United States Department of Health and Human Services

HFS Illinois Department of Healthcare and Family Services

MCO managed care organization

MDRA Medicaid Drug Rebate Agreement

NDA New Drug Application

I. INTRODUCTION

1. This case involves the refusal of the Illinois Department of Healthcare and Family Services (HFS) to cover and pay for Makena® (sterile injections of hydroxyprogesterone caproate) in compliance with federal law. Makena® is the only U.S. Food and Drug Administration (FDA) approved drug for pregnant women with a rare, but severe, condition causing life-threatening spontaneous preterm birth.

2. Preterm birth is a terrible medical condition. It is the leading cause of newborn deaths in the United States, and afflicts thousands of women in Illinois each year. Even where death is avoided, premature birth often results in life long and expensive medical complications.

3. In February 2011, FDA, in what FDA Commissioner Margaret Hamburg, M.D., heralded as an important advance, approved Makena®. Citing "fiscal considerations," HFS announced that it would continue to pay for cheaper, unapproved compounded preparations of hydroxyprogesterone caproate (commonly referred to as, "compounded 17P") while subjecting Makena® to a so-called "prior authorization" policy. In reality, HFS's prior authorization policy is *a de facto*, highly burdensome and effective but unlawful exclusion of Makena® that, on information and belief, has resulted in coverage of Makena® for only three Medicaid beneficiaries in the entire State of Illinois. This systemic denial of medical care to the poor and vulnerable is not only unlawful, but defies recent warnings by the two lead federal agencies—FDA and Centers for Medicare & Medicaid Services (CMS)—regarding states' legal obligation to cover the FDA-approved drug and to stop encouraging and paying for unlawful preparation of compounded versions of the drug that are not customized to meet the documented special medical needs of individual patients.

Case: 1:12-cv-06697 Document #: 1 Filed: 08/21/12 Page 4 of 37 PageID #:4

I. INTRODUCTION

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medical needs of individual patients.

4. Plaintiffs KV Pharmaceutical Company (K-V) and its wholly-owned subsidiary Ther-Rx Corporation ("Ther-Rx," collectively, "KV") hold the exclusive rights to market and sell Makena®. KV seeks a preliminary and permanent injunction prohibiting the defendants, in their official capacities at HFS, from using sham restrictions (1) to deny women on Medicaid in Illinois who have high-risk pregnancies access to Makena®—women already burdened with the many difficulties and costs associated with at least one other preterm child, and (2) to require these underprivileged pregnant women and their clinicians to use untested and unapproved compounded preparations or to forego treatment for their medical condition altogether.

5. HFS's policy and actions violate and are in direct conflict with the drug-access provisions of Title XIX of the Social Security Act, 42 U.S.C. § 1396a *et seq.* (the "Medicaid Act"). HFS is knowingly promoting and paying for unlimited use of compounded 17P -- conduct that violates and conflicts with the Federal Food, Drug, and Cosmetic Act's drug-approval requirement (21 U.S.C. § 355(a), 353(a)) and the Illinois Practice of Pharmacy Act. Finally, HFS -- in denying pregnant women on Medicaid who are at risk for a second premature birth access to this important FDA approved drug -- is acting in a manner contrary to the best interests of Medicaid beneficiaries in Illinois in violation of and in conflict with the requirements of 42 U.S.C. §§ 1396r-8 and 1396a(a)(19). These unlawful actions by Illinois and similar unlawful actions by other states,[1] have placed KV, which has recently filed for bankruptcy protection and hopes to reorganize under Chapter 11 of the U.S. Bankruptcy Code, on the verge of financial failure. KV is almost entirely dependent upon sales of Makena®. Illinois has a significant Medicaid population, and Illinois's systemic failure to cover Makena® has contributed

Case: 1:12-cv-06697 Document #: 1 Filed: 08/21/12 Page 5 of 37 PageID #:5

4. Plaintiffs KV Pharmaceutical Company (K-V) and its wholly-owned subsidiary Ther-Rx Corporation ("Ther-Rx," collectively, "KV") hold the exclusive rights to market and sell Makena®. KV seeks a preliminary and permanent injunction prohibiting the defendants, in their official capacities at HFS, from using sham restrictions (1) to deny women on Medicaid in Illinois who have high-risk pregnancies access to Makena®—women already burdened with the many difficulties and costs associated with at least one other preterm child, and (2) to require these underprivileged pregnant women and their clinicians to use untested and unapproved compounded preparations or to forego treatment for their medical condition altogether.

5. HFS's policy and actions violate and are in direct conflict with the drug-access provisions of Title XIX of the Social Security Act, 42 U.S.C. § 1396a et seq. (the "Medicaid Act"). HFS is knowingly promoting and paying for unlimited use of compounded 17P -- conduct that violates and conflicts with the Federal Food, Drug, and Cosmetic Act's drug-approval requirement (21 U.S.C. § 355(a), 353(a)) and the Illinois Practice of Pharmacy Act.

Finally, HFS -- in denying pregnant women on Medicaid who are at risk for a second premature birth access to this important FDA approved drug -- is acting in a manner contrary to the best interests of Medicaid beneficiaries in Illinois in violation of and in conflict with the requirements of 42 U.S.C. §§ 1396r-8 and 1396a(a)(19). These unlawful actions by Illinois and similar unlawful actions by other states,1 have placed KV, which has recently filed for bankruptcy protection and hopes to reorganize under Chapter 11 of the U.S. Bankruptcy Code, on the verge

of financial failure. KV is almost entirely dependent upon sales of Makena ®. Illinois has a significant Medicaid population, and Illinois's systemic failure to cover Makena ® has contributed

materially to the company's looming potential failure. Further, because KV holds the exclusive rights to market and sell this important product, the injunctive and declaratory relief sought is necessary to ensure that Medicaid beneficiaries in Illinois have the same chance to improve the health of their unborn children as women with private insurance.

II. BACKGROUND

6. Preterm birth is the number one cause of newborn death in the United States. It is a terrible medical condition, which often has life-long ramifications for the child, his or her family, and the affected health care, educational, and social security systems. This condition plagues the United States as a whole. According to a widely acclaimed report published by the March of Dimes in May 2012—*Born Too Soon: The Global Action Report on Preterm Birth* — the United States ranked an abysmal 131st in the world (12 preterm births per 100 births), below countries such as Somalia and Afghanistan.

7. Prematurity costs the United States more than $26 billion annually, a large portion of which is borne by Medicaid, which covers an estimated 50 percent or more of Makena®-eligible patients. (Sadly, preterm birth affects the already vulnerable poor even more than the general population.) The March of Dimes reports that the "[m]edical costs of a preterm baby are much, much greater than they are for a healthy newborn." Citing a report published by the Institute of Medicine (2006), the March of Dimes noted that the cost of preterm birth in the United States was at least $26.2 billion in 2005, an average of $51,600 per infant born prematurely, and that the average first-year medical costs were about 10 times greater for a preterm infant ($32,325) than for a full-term infant ($3,325).

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[1] Georgia's similar policy was recently held to be in violation of federal law. *See* August 9, 2012 Order on Motion for Preliminary Injunction in *K-V Pharmaceutical Co, et al. v. Cook et al.*, No. 12-CV-

Case: 1:12-cv-06697 Document #: 1 Filed: 08/21/12 Page 6 of 37 PageID #:6

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8. Preterm birth plagues the State of Illinois as well. In its most recent (2011) annual report, the March of Dimes gave Illinois an overall grade of "C", reflecting the state's preterm birth rate of 12.4 percent (slightly more than one out every eight births).

9. Since March 2011, FDA-approved Makena® has been available. Clinical studies have shown that Makena® reduces the risk of preterm birth in women who have (i) a pregnancy in which a single baby develops in the uterus (a "singleton pregnancy") and (ii) a history of singleton spontaneous preterm birth. Despite the poor record in Illinois in preventing preterm births, HFS adopted a so-called "prior authorization" policy on May 9, 2011 (updated in May 2012) that requires Medicaid beneficiaries to use untested and unapproved therapies and virtually foreclosing access to FDA-approved Makena® (the "Makena® prior authorization policy").

10. Compounded formulations, including compounded 17P, are not generic drugs. Like Makena®, generic drugs are FDA regulated and approved and are manufactured in accordance with strict FDA good manufacturing practice (GMP) standards. Compounded products, however, are prepared in individual pharmacies without regard to these standards. Federal law requires that where an FDA approved product exists, compounding of the same or copies of the drug must stop with limited and narrow exceptions. 21 U.S.C. § 353(a). FDA has repeatedly cautioned that compounded 17P has never been studied for clinical effectiveness or safety, and lacks an FDA finding of "manufacturing quality."[2]

11. In November 2011, and on two separate occasions in June 2012, FDA reminded the public that FDA-approved drugs such as Makena® "provide a greater assurance of safety and

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2491-CAP, attached as Exhibit 1.

[2] FDA, *Questions and Answers on Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate* (June 29, 2012), *available at*

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effectiveness than do compounded drugs."[3] Most recently, FDA issued Makena®-specific Questions and Answers (the "June 29 Makena® FAQs"), which stated: (1) when "there is an FDA-approved drug that is medically appropriate for a patient, the FDA-approved product should be prescribed and used," and (2) that the compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding. Ex. 2. FDA cautioned that compounding is appropriate only:

> *to produce a drug tailored to an individual patient's particular medical needs*, based on a valid prescription from a licensed medical practitioner. For example, compounding may occur if a patient needs a medication to be produced without a dye or preservative due to an allergy, or needs a medication in a liquid or suppository form because the patient cannot swallow a pill. *Id.* (Emphasis added).

In the June 29 Makena® FAQs and in a statement it released on June 15, 2012 (the "June 15 FDA Statement"), FDA stated that it looks to see "whether the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product." Exs. 2, 6.

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http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm310215.htm (last visited August 21, 2012), a true and correct copy of which is attached as Exhibit 2.

[3] *Id.*; *see also* FDA, *FDA Statement on Makena*, (Mar. 30, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm (last visited August 21, 2012); a true and correct copy of which is attached as Exhibit 3; *Fiscal Year 2012 Budget Request for FDA: Hearing Before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies*, 112th Cong. 10 (Mar. 17, 2011) (Statement of Margaret A. Hamburg, M.D., Commissioner of the U.S. Food And Drug Administration, Department Of Health And Human Services), a true and correct copy of which is attached as Exhibit 4; FDA, *FDA Statement on Makena*, (Nov. 8, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm279098.htm (last visited August 21, 2012), a true and correct copy of which is attached as Exhibit 5; FDA, *Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate*, (June 15, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm (last visited August 21, 2012), a true and correct copy of which is attached as Exhibit 6.

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12. CMS issued a companion statement on June 15 (the "June 15 CMS Statement") that cross-referenced the June 15 FDA Statement and reminded state Medicaid agencies that they *must* cover Makena® in compliance with federal law and "without imposing unreasonable conditions."[4]

13. Despite coverage requirements under the Medicaid Act, these recent federal statements, and KV's repeated offers to pay substantial supplemental rebates, HFS has refused to change its unlawful policy. HFS's refusal makes it necessary for Plaintiffs to seek this Court's intervention for a preliminary injunction and a final judgment: (1) declaring that HFS's policy regarding Makena® violates the requirements of the Medicaid Act and ordering HFS immediately to rescind and revise its policy; (2) declaring that HFS must cover Makena® without unreasonable restrictions or conditions; (3) declaring that HFS may cover and pay for compounded 17P only in those limited situations where the treating physician documents that his or her patient has a specific medical need for a compounded variation rather than Makena®; (4) declaring that HFS must ensure that all Medicaid managed care organizations in Illinois make Makena® available to their Medicaid beneficiaries without unlawful restrictions or conditions; (5) declaring that HFS must ensure that all Medicaid managed care organizations in Illinois limit their coverage of compounded 17P to those limited situations where the treating physician demonstrates that his or her patient has a specific medical need for a compounded variation rather than Makena®; and (6) ordering all ancillary relief necessary to allow clinically-eligible Medicaid beneficiaries in Illinois access to Makena®, including an order that HFS notify all relevant persons of the court-mandated changes to its coverage policy.

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[4] CMS, *Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate*, June 15, 2012, a true and correct copy of which is attached as Exhibit 7.

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13. Despite coverage requirements under the Medicaid Act, these recent federal statements, and KV’s repeated offers to pay substantial supplemental rebates, HFS has refused to change its unlawful policy. HFS’s refusal makes it necessary for Plaintiffs to seek this Court’s intervention for a preliminary injunction and a final judgment: (1) declaring that HFS’s policy regarding Makena® violates the requirements of the Medicaid Act and ordering HFS immediately to rescind and revise its policy; (2) declaring that HFS must cover Makena® without unreasonable restrictions or conditions; (3) declaring that HFS may cover and pay for compounded 17P only in those limited situations where the treating physician documents that his or her patient has a specific medical need for a compounded variation rather than Makena®; (4) declaring that HFS must ensure that all Medicaid managed care organizations in Illinois make Makena® available to their Medicaid beneficiaries without unlawful restrictions or conditions; (5) declaring that HFS must ensure that all Medicaid managed care organizations in Illinois limit their coverage of compounded 17P to those limited situations where the treating physician demonstrates that his or her patient has a specific medical need for a compounded variation rather than Makena®; and (6) ordering all ancillary relief necessary to allow clinically-eligible

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III. THE PARTIES

A. Plaintiffs K-V and Ther-Rx

14. Plaintiff K-V is a corporation organized under the laws of the state of Delaware, and maintains its principal place of business at 2280 Schuetz Road, St. Louis, Missouri 63146. K-V advertises, sells and distributes its drugs through Ther-Rx. Under Medicaid law, K-V is considered a pharmaceutical manufacturer and distributor, and holds the rights to Makena® and its regulatory approval by FDA. K-V has committed over a quarter of a billion dollars to acquire and develop Makena® and to bring it to market with FDA approval.

15. Plaintiff Ther-Rx is a corporation organized under the laws of the state of Missouri, is a wholly-owned subsidiary of K-V, and is a pharmaceutical distributor. Ther-Rx has its principal place of business at the same address as K-V. For ease of reference, Plaintiffs K-V and Ther-Rx are referred to collectively as "KV."

16. KV is a participant in the Medicaid program. K-V's wholly-owned subsidiary Ther-Rx has entered into a Medicaid Drug Rebate Agreement (MDRA) with the Department of Health and Human Services (HHS). Pursuant to that agreement, KV pays significant rebates to the Medicaid program for covered outpatient drugs dispensed to Medicaid beneficiaries. In return, KV's FDA-approved drugs, including Makena®, must be covered by state Medicaid agencies, including HFS.

17. Because KV is almost entirely dependent on sales of Makena® to generate income, HFS's so-called prior authorization policy has caused KV to lose significant revenue it would have received from sales of Makena® in Illinois—revenue that is very much needed to allow the company to reorganize and restructure and to sustain the company's operations. As a result, and unless injunctive relief is ordered, KV's available cash will soon be depleted, KV may cease to exist, and Makena® may no longer be available to pregnant women.

Case: 1:12-cv-06697 Document #: 1 Filed: 08/21/12 Page 10 of 37 PageID #:10

III. THE PARTIES

A. Plaintiffs K-V and Ther-Rx

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