

EXHIBIT

3

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION**

| | | |
|---|---|------------------------------------|
| K-V Pharmaceutical Company, |) | |
| Ther-RX Corporation, |) | |
| |) | |
| Plaintiffs, |) | CASE NO.: 3:12-cv-02088-MBS |
| |) | |
| vs. |) | |
| |) | |
| Anthony Keck, in his official capacity as |) | |
| Director of Health and Human Services |) | |
| for the State of South Carolina, |) | |
| |) | |
| Defendant. |) | |
| _____ |) | |

**AFFIDAVIT OF CHARLES S. RITTENBERG M.D.
IN SUPPORT OF DEFENDANT'S OPPOSITION TO
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

PERSONALLY APPEARED BEFORE ME, Charles S. Rittenberg M.D., who being duly sworn deposes and states as follows:

1. I am an adult over the age of 18 and am competent to testify about the facts set forth in this affidavit;
2. I am a board certified Maternal-Fetal Medicine physician (high risk obstetrician), practicing in South Carolina, and specialize in progesterone for the prevention of recurrent spontaneous preterm birth. I am also an Assistant Professor of Obstetrics and Gynecology at the Medical University of South Carolina. My Curriculum Vitae is attached as Exhibit A to this Affidavit;
3. Spontaneous preterm birth is one of the biggest problems in obstetrics today. Spontaneous preterm birth refers to early delivery brought on by preterm labor or premature rupture of the membranes leading to spontaneous labor, rather than a physician's decision to recommend early delivery to improve outcomes for mother or baby;
4. In 2003, Meis et al published the results of a National Institutes of Child Health and Human Development sponsored trial that showed 17-alpha hydroxyprogesterone caproate (17P) is efficacious in reducing recurrent spontaneous preterm birth. I have received a grant since March of 2008 from the March of Dimes, for my efforts in promoting the use of 17P for preterm birth prevention. This grant predates the FDA's approval for Makena;

5. Through this grant, I have educated health care providers, insurers, and patients about the indications for using progesterone. I have published research on prescribing patterns of 17P in preventing preterm birth, and have concluded that since the Meis publication in 2003, physicians across the United States have been using progesterone at an accelerating rate. At times, 17P has been difficult to get approved by insurers though this has not been much of a problem in South Carolina since about 2008;

6. Prior to 2000, 17P was available under the name Delalutin, which was an FDA approved drug, and had been FDA approved since 1956. Doctors have thus been using the drug 17 alpha hydroxyprogesteronecaproate for roughly 60 years;

7. After 2000, Delalutin was no longer on the market, for reasons unrelated to safety or effectiveness, and doctors went back to prescribing compounded 17P;

8. In 2003, Meis et al published the results of their study undertaken to see if 17P is effective in reducing recurrent spontaneous preterm delivery;

9. The study used a double-blind, placebo-controlled trial involving pregnant women with a documented history of spontaneous preterm delivery. All the participating subjects were women between the 16th and 20th weeks of gestation at the time of enrollment, and were randomly assigned in a two to one ratio to receive either a weekly injection of compounded 17P, or weekly injections of a placebo. These injections continued until the 36th week of gestation;

10. The study found that weekly injections of compounded 17P significantly decreased the rate of recurrent preterm delivery among eligible women, and served to reduce the likelihood of severe complications in infants;

11. I began advocating the use of, and actively prescribing, 17P for eligible women in South Carolina beginning in 2005. Through my efforts, I determined that doctors were already using 17P, but had trouble accessing it;

12. In my own practice, I found that 17P significantly increased the length of a pregnancy for women who were at high risk for preterm labor;

13. Makena became a "covered drug" for South Carolina Medicaid beneficiaries in 2011. Makena has the same formulaic makeup as 17P;

14. To date, I have never prescribed Makena for a patient, and have no personal knowledge of another physician prescribing Makena;

15. In my work, I often submit prior authorization requests for prescriptions;

16. Prior authorization requests are categorized as pharmaceutical or physician administered. Physician administered requests are sent to DHHS and document the

"medical necessity" for a prescription, and do not deter patient access to certain drugs, nor do they deter physicians from prescribing certain drugs;

17. My decision against prescribing Makena has nothing to do with Makena's prior authorization requirement;

18. Instead, I prescribe 17P because I have used the compound for years and have data to show its effectiveness among my patients, and have never had reason to doubt the practices of the compounding pharmacies that I have used;

19. Makena, as a product, has been the subject of fewer studies to test its safety and efficacy than the compounded 17P; and


20. To the best of my knowledge, the FDA has not issued any statement to indicate that 17P is any less effective, or less safe than Makena.

Further Affiant Sayeth Naught.



Charles S. Rittenberg, M.D.

SWORN AND SUBSCRIBED to me
on this 18th day of August, 2012.



NOTARY PUBLIC FOR SOUTH CAROLINA
My Commission Expires: MAY 20 2015

EXHIBIT

A

CURRICULUM VITAE

Name: Charles Rittenberg, M.D. **Birth Date:** 8/5/58
Home Address: 1002-C Middle Street **Phone:** 843-442-9665
Office Address: 96 Jonathan Lucas St. MSC 619 **Phone:** 843-792-3577 **Fax:** 792-0533

Citizenship and/or Visa Information: United States citizen

Education (Beginning with Baccalaureate Degree):

| Institution/Location | Years | Degree/Date | Field of Study |
|---------------------------------|-----------|----------------|-----------------------|
| Massachusetts Institute of Tech | 1976-81 | S.B. (02/81) | Political Science |
| Massachusetts Institute of Tech | 1981-83 | S.B. (05/83) | Computer Science |
| University of Charleston, S.C. | 1992-95 | M.S. (05/95) | Mathematics |
| Medical University of S.C. | 1996-2000 | M.D. (05/00) | Medicine |
| Medical University of S.C. | 1998-2000 | M.H.A. (08/00) | Health Administration |

Internship: Internal Medicine Preliminary year, Medical University of S.C. 2000-01

Residencies or Post Doctoral:

Obstetrics and Gynecology Residency, Medical University of S.C. 05/2001
 Maternal-Fetal Medicine Fellowship, Medical University of S.C. 09/2006

Specialty/Board Certification: OB/GYN board certified, November 2010 - present
 MFM board certified, April 2012 - present

Licensure: South Carolina permanent license 22689 Date: Issued 2002, current expires 6/30/13

Military Service: none

Faculty Appointments (Begin with initial appointment):

| Years | Rank | Institution | Department |
|----------------|---------------------|-------------------|-------------------------|
| 2005 - 2009 | Clinical Instructor | Medical U. of S.C | Obstetrics & Gynecology |
| 2009 - present | Assistant Professor | Medical U. of S.C | Obstetrics & Gynecology |

Administrative Appointments:

| Years | Position | Institution | Department |
|---------|-------------------------------|-------------|------------|
| 2004-05 | Administrative Chief Resident | MUSC | OB/GYN |

Hospital Appointments/Privileges:

| Years | Active/Inactive | Institution |
|---------------|-----------------|--|
| 2005- present | active | Medical University of South Carolina, Charleston, SC |
| 2005-09 | inactive | Colleton Regional Med Ctr. (for locums work), Walterboro, SC |
| 2005-06 | inactive | Springs Memorial Hospital (for locums work), Lancaster, SC |
| 2005 | inactive | Roper/St. Francis hospitals (for locums work), Charleston, SC |
| 2006 | inactive | Hilton Head Hospital (for locums work), Hilton Head Island, SC |

| | | |
|----------------|--------|--|
| 2009 - present | active | McLeod Regional Medical Center, Florence, SC |
| 2012 - present | active | Palmetto Richland, Columbia, SC |

Other Experience:

| Years | Position | Institution | Department |
|---------|-----------------|-------------------------|--|
| 2005-06 | locums coverage | Springs Memorial Hosp. | OB/GYN (locums coverage for Douglas Tiedt, MD) |
| 2005 | locums coverage | Roper/St. Francis Hosp. | OB/GYN (locums coverage for Ashley River OB/GYN) |
| 2005-06 | locums coverage | Colleton Med. Ctr. | OB/GYN (locums coverage for Walterboro OB/GYN) |
| 2006 | locums coverage | Hilton Head Hospital | OB/GYN (locums coverage for G. Neil Love, M.D.) |

Membership in professional/scientific societies (include offices held):

National Societies:

- American Medical Association
- American College of Obstetricians & Gynecologists
- Society for Maternal-Fetal Medicine

Local Societies:

- THEGOS Society
- South Carolina Medical Association
- Charleston County Medical Society

Editorial Positions: reviewer, Saudi Medical Journal; reviewer, Journal of Obstetrics and Gynaecology Research**Extramural Grants/award amount (current and past):**

As Principal Investigator (% time)

- Progesterone Outreach Program (10% time, total grant \$220,000, March 2008 – present)

As Co-Investigator (% time)

- MUSC Preterm Birth Prevention Project (10-50% time, total grant \$135,500, Sept 2005 – Feb 2008)
- SC Partners for Preterm Birth Prevention, 2005-2007 (total award \$1,100,000, volunteer support)
- Duke Endowment Telemedicine Grant (5% salary support, 2011-12)

Awards, Honors, Membership in Honorary Societies:

- First Honor Graduate, Masters in Mathematics, University of Charleston, S.C., 1995
- First Honor Graduate, Masters in Health Administration, MUSC, 2000
- MUSC Internal Medicine award for best attendance at educational programs, 2001
- Alpha Omega Alpha, 2003-
- 4th year medical student nominee for Faculty Excellence Awards for House Staff, 2003
- Golden Apple Teaching Award nominee, 2003
- MUSC OB/GYN Resident Interviewer/Recruiter, 2003-04
- MUSC OB/GYN Administrative Chief Resident, 2004-05
- Chief Resident J. Richard Sosnowski Award for Obstetrics and Humanism, 2005
- Faculty nominee for best teacher in University, 2011 3rd rotation

Academic Committee Activities:

University

College:

- College of Medicine Admissions Committee (Member 2002-05, 2008-11; interviewer 2002 – present)
- Clinical Sciences Subcommittee, 2009 - present
- Practice Partner Physicians Advisory Council, 2010 – 2011
- Epic Superuser Committee, 2011- present

Department:

- Academic Affairs Committee, 2004-05, 2008 – present
- Education Committee, 2009 – present

Division

- Practice Partner Committee, chair 2010 - 2011

Major Teaching Responsibilities (Current):

Undergraduate Medical Education:

- Clinical Instructor OB/GYN 2005 – 2009
- Assistant Professor OB/GYN 2009 - present
- Assistant Clerkship Director, 2009 - present

Graduate Medical Education:

- Clinical Instructor OB/GYN 2005 – present
- Assistant Professor OB/GYN 2009 - present

Graduate Studies Education

Continuing Medical Education:

- Coordinator, Fetal Board, 2008 – 09
- Co-coordinator, Perinatal M&M, 2009 - present

Major Clinical Interests and Responsibilities: Preterm birth prevention, progesterone to prevent preterm birth, multifetal pregnancy, transvaginal cervical length, healthcare delivery systems

Lectures and Presentations

Invited lectures and presentations:

- MUSC OB/GYN grand rounds, March 2007, Fetal lung maturity
- MUSC OB/GYN grand rounds, May 2008, Progesterone to prevent preterm birth
- MUSC Pediatric Pharmacology Conference, Progesterone to prevent preterm birth, March 2009
- March of Dimes Volunteer Leadership Conference, Columbia, SC, November 2008, Progesterone to prevent preterm birth
- South Carolina DHEC Preterm Birth Prevention Council, Myrtle Beach, SC, May 2009, May 2010, Progesterone to prevent preterm birth
- Progesterone to prevent preterm birth, Fetal heart rate monitoring, Hartsville Hospital, 2009, McLeod Hospital 2009
- Series of lecture around the state on Progesterone to Prevent Recurrent Spontaneous Preterm Birth and Avoiding Elective Delivery < 39 weeks for the SC Perinatal Association
- Progesterone to Prevent Recurrent Spontaneous Preterm Birth, Nanjing Drum Tower Hospital, Nanjing, China

Submitted presentations (e.g., abstract or paper presentations)

- Michalec JA, Rittenberg C, Ebeling M, Macias MM, Hulsey TC, Katikaneni, LD. Increased Neurodevelopmental Delays in Preterm Multiples with Birth Weight Less Than 1500g. American Academy for Cerebral Palsy and Developmental Medicine 61st Annual Meeting, Vancouver, BC, Canada, October 2007, presenting author, nominated for the Gayle G. Arnold Award for Excellence as best paper

Publications:

Peer Reviewed Journal Articles: Published or accepted for publication in final form

1. Rittenberg C, Sullivan S, Istwan N, Rhea D, Stanziano G, Newman R. Clinical Characteristics of women prescribed 17 alpha-hydroxyprogesterone caproate in the community setting. *American Journal of Obstetrics & Gynecology* 2007;197: 262.e1-262.e4.
2. Rittenberg C, Sullivan S, Istwan NB, Rhea DJ, Stanziano GJ, Newman RB. Women receiving 17 alpha-hydroxyprogesterone caproate hospitalized for preterm labor <34 weeks benefit from daily nursing surveillance. *Am J Obstet Gynecol* 2008;199:389.e1-4.
3. Newman RB, Sullivan SA, Menard MK, Rittenberg CS, Rowland AK, Korte J, Kirby H. South Carolina Partners for Pre-term Birth Prevention: a regional perinatal initiative for the reduction of premature birth in a Medicaid population. *Am J Obstet Gynecol* 2008;199:393.e1-8.
4. Rittenberg C, Newman RB, Istwan NB, Rhea DJ, Stanziano GJ. Preterm birth prevention by 17 alpha-hydroxyprogesterone caproate versus daily nursing surveillance. *J Repro Med* 2009;54:47-52.

Non-Peer Reviewed: Published non-peer reviewed journal articles: None

Scholarly Books and Monographs: None

Chapters in Scholarly Books and Monographs: None

1. Newman RB, Rittenberg C. "Multiple Gestation" in Gibbs RS, Karlan BY, Haney AF, Nygaard IE, eds. *Danforth's Obstetrics and Gynecology*, 10th ed. Philadelphia: Lippincott Williams & Wilkins, 2008.
2. Rittenberg C, Newman RB. "Multifetal Pregnancy" in Hillard PJA, ed. *The 5-Minute Obstetrics and Gynecology Consult*. Philadelphia: Lippincott Williams & Wilkins, 2008.

Peer Reviewed Electronic Publications: None

Non-Peer Reviewed Electronic Publications: None

Other Publications: (e.g., newspapers and magazines) None

Extramural Professional Activities:

Community Service:

2003 – present, Bethe Rittenberg Fund of the Coastal Community Foundation of South Carolina, donor/advisor
2000 – present, Massachusetts Institute of Technology Educational Council, interview/recruit prospective students
1997 – present, Charleston Interfaith Crisis Ministries/Synagogue Emanu-El

- Three times a year, as representatives of the synagogue, my family purchases and prepares dinner and purchases breakfast for eighty to one hundred shelter guests.
- In September 2002, I succeeded my wife as Chair of the synagogue Shelter Committee

1993 – 2000, Buist Academy

- Helped with activities of PTA and fund raising.
- Volunteer chaperone, Europe trip, summer 1998
- Volunteer chaperone, New York City trip, May 2000

1993 – 1997, African American Jewish Connection

- Attended monthly meetings of a group to strengthen relations between the Black and Jewish communities. Worked on project to build non-violence wall near Hampton Park. As a result of this group's work, Operation Understanding Charleston was created. Operation Understanding is a year-long program that educates a group of Black and Jewish teenagers on both heritages. The experience culminates in a summer trip to key civil rights sites around the South.

1989 – 1996, Commissioners of Public Works Trident United Way Campaign Committee

- Organized employee fund solicitation
- Chair, 1993 - 1994

1988 – 1996, 2002-05, Synagogue Emanu-El Board of Trustees, Included term as Chair of the Board of Education

1988 – 1993, Charles Towne Montessori School Board of Directors

- Included terms as Secretary, Vice Chair, Acting Chair
- Chair, Annual Fund Drive, Finance Committee
- Co-chair of Capital Campaign which raised over \$100,000, 1988-89
- With another parent, formed CTMS Partners. We established a financial vehicle that allowed the school to borrow money at a time that it was unable to get money through traditional means. We were able to identify parents and community members to borrow \$125,000 which prevented the school's closure.

1989 – 1990, Charleston Heartline Computer Coordinator

- Borrowed equipment and established a database for an organization that coordinated matching donors and recipients in the months following Hurricane Hugo striking Charleston.

1989, City of Charleston Volunteer Database Manager

- Coordinated the City's recording and recognition of cash contributions following Hurricane Hugo.