

FDA Reviews NDA for 17P

The Advisory Committee for Reproductive Health Drugs for the Center for Drug Evaluation and Research of the FDA held a public hearing on August 29th to discuss the safety and efficacy of Gestiva, Adeza's 17 alpha-hydroxyprogesterone caproate injection, for the prevention of preterm delivery in women with a history of prior preterm delivery. The 6-member voting committee was supplemented with 15 professional peers with voting status. Dr. Paul Meis, PI for the Network's progesterone trial and Gwendolyn Norman, research nurse coordinator at Wayne State, assisted Adeza with their presentations. Dr. Roberto Romero, the FDA invited speaker, headlined the day's agenda with a talk "Causes of Premature Birth: The Preterm Parturition Syndrome." A series of questions were posed to the committee for individual votes following presentations by Adeza Biomedical, the FDA, a statistical consultant and nine speeches given by persons during the open public hearing. Time was also allotted for the committee to have open discussion.

By majority vote the Advisory Committee supported marketing approval of Gestiva™ for use in pregnant women with a history of preterm delivery. The Committee indicated that the data presented showed efficacy in preventing preterm birth prior to 35 weeks and that the overall safety data were adequate for approval. The Advisory Committee also recommended the collection of post marketing clinical data. Although its recommendations are not binding, the FDA final determinations are usually consistent with the Committee's recommendations and are expected to be made by October 20, 2006. If approved, it is anticipated that Gestiva™ will be publicly marketed within a couple of months.

Thyroid in Pregnancy Trial Set to Roll

In early September, the FDA ruled that an IND would not be required for the *Randomized trial of thyroxine therapy for subclinical hypothyroidism or hypothyroxinemia diagnosed during pregnancy* (TSH Trial). Since then, the final protocol has been posted on the MFMU web site, along with the manual of operations, data collection forms and the certification requirements and quiz. The University of Alabama is the first center to receive IRB approval and several other centers have IRB approval pending. The central laboratory at the University of Minnesota Medical Center is beginning to distribute supplies for the collection and shipping of specimens to the centers. Study drug will be sent as centers are certified. Work is underway to finalize the five-year infant follow-up procedures and data collection forms.

Preparations Underway for 17P & Short Cervix Trial

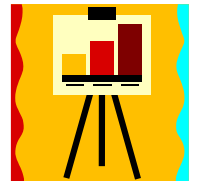
On October 18, the subcommittee for the next Network trial, *Progesterone for prevention of preterm birth in nulliparous women with a shortened cervix in the second trimester*, will be finalizing the protocol at a meeting and working on the data collection forms. It is expected that this trial will begin before the end of this year. Screening of approximately 7,000 patients will be required to yield the sample size of 800.

Two MFMU Abstracts Selected for SMFM Plenary

The MFMU Network has reached a new high with the number one and two spots in the Opening Plenary session at the 2007 SMFM meeting! Out of a field of 1,205 abstracts submitted to the Scientific Program Committee of the Society for Maternal-Fetal Medicine (SMFM) for review, only 86 (7%) were singled out to be an oral presentation at the annual meeting in February 2007. Four of these were submitted by MFMU Network investigators and two of them will be sharing the stage at the Plenary Session:

- *A randomized controlled trial of 17 hydroxyprogesterone caproate (17-OHPC) for the prevention of preterm birth in twins* (#1 Plenary - Dr. Caritis)
- *Long term follow-up of infants receiving single vs repeat courses of antenatal corticosteroids from the MFMU RCT* (#2 Plenary - Dr. Wapner)
- *Pharmacogenomics of maternal tobacco use: metabolic gene polymorphisms modify risk of adverse pregnancy outcomes* (Dr. Aagaard-Tillery)
- *4-year follow-up of children exposed to 17-alpha hydroxyprogesterone caproate (17P) in utero* (Ms. Northen, RN, BSN)

In addition, 12 posters will be presented by Network investigators at the meeting.



STTARS Trial Ends Recruitment

Recruitment to the twins stratum of the trial, *17 alpha-hydroxyprogesterone caproate for prevention of preterm birth in multifetal gestation* (STTARS), ended February 28 with 661 patients. Only six women (less than 1%) were lost to follow-up (i.e., no date of delivery). Preliminary data were analyzed in time to submit an abstract to the Society for Maternal-Fetal Medicine (SMFM). The abstract has the honor of being selected for the Plenary Session as the lead presentation at the SMFM annual meeting in February and will be presented by the Co-PI, Dr. Steve Caritis.

The triplet stratum finished recruitment September 15, with 134 patients randomized. Co-PI, Dr. Dwight Rouse has the lead responsibility for preparing the primary manuscripts reporting the results of both strata.

Enrollment in Omega-3 Trial Ending

Recruitment for the trial, *Omega-3 fatty acid supplementation to prevent preterm birth in pregnancies at high risk*, surpassed its projected sample size of 800 on September 20 with 804 patients. October 15 will be the last day for patient enrollment. Thus far, **no** patients have been declared lost to follow-up. At this point, the trial has the high distinction of having outcome data on all patients, which is an impressive achievement!

News You Can Use

- The *National Women's Health Indicators Database*, a dynamic database of health statistics, has been renamed Quick Health Data Online. This free resource provides access to comparative, county-level health data for all 50 states, the District of Columbia and U.S. territories and possessions. It includes comprehensive data from 1998-2004 for both women and men by race/ethnicity and age concurrently and on a variety of health related topics. Tables, graphs, and maps can be created from the data on maternal and reproductive health, mortality, infectious and chronic diseases, mental health, violence and abuse, illness prevention and access to care. Just click on www.womenshealth.gov/quickhealthdata.

- The National Institutes of Health have posted seven new **Fact Sheets** on its web site regarding research results, including a fact sheet on infant health from the Pregnancy and Perinatology Branch of NICHD. This fact sheet includes information on the STTARS and Omega-3 trials in addition to other PPB research. Go to www.nih.gov/about/researchresultsforthepublic/index.htm.

- Studies show that 20% to 50% of women who have **gestational diabetes** may develop type 2 diabetes within 10 years following birth, and that their child is at increased risk for diabetes and obesity. To reduce the odds, it is suggested that one should try to keep weight down, exercise regularly and get tested for diabetes, breastfeed and help your family to eat healthy. For a free tip sheet from the National Diabetes Education Program, visit ndep.nih.gov or call 1-800-438-5383.

Kudos From the Network for Going Above and Beyond

All in a day's work ... Donna Allard, primary Omega-3 nurse at Brown, along with interpreter and data coordinator, **Margie Jimenez**, were on their way to a patient's home to start her on the compliance run-in. While stopped at an intersection, their car was hit from behind and pushed into the car in front. No one was hurt and after the accident was dealt with in the usual way, Donna and Margie proceeded to the patient's home and successfully completed the compliance visit. When finished they went to the patient's health care provider to retrieve the patient's medical record and then to the Police Station to obtain the accident report. When they finally returned to their office, they went to the Employee Health Office which then sent them to the Emergency Room for evaluation. Since their hospital is a women's specialty hospital, they were sent to the ER at the general hospital on their campus. When all was said and done, they had a very eventful day (and luckily, were unharmed), but did not lose the patient!!

Coordination, determination and appreciation...When an Omega-3 patient who was randomized at Northwestern's Evanston site moved to Utah after enrolling, **Claudia Carr** contacted **Kris Anderson**, coordinator at Utah, to get contact information so the patient could continue her participation. Utah did a fantastic job and the patient remained in the study and compliant. Some time later, **Gail Mallet**, coordinator at Northwestern received a phone call from O'Hare Airport about a package. Gail asked the shipping clerk where the box originated but she did not know since the air bill was not attached to the package. When Gail asked what was in the box, the clerk described blister packs of yellow gel capsules and 3 pairs of newborn pajamas. Gail then asked how she knew to call her. The clerk said she obtained the drug manufacturer's name from the box and phoned **Eminent** who told her to call Gail. The box finally arrived safe and sound, along with the newborn nighties which the study mom had sent as a donation to Evanston's NICU.

Angels of Mercy at WSU... Gwendolyn Norman, research nurse coordinator, has the following to say about her staff. "I have to share how proud I am of my staff and how they have become 'angels of mercy' for many of the patients who participate in our clinical trials, doing so much above and beyond what is expected. **Anita Millinder** worked with a CAPPS patient who had no stable home, was sleeping on floors in various unsafe locations and often had no food. Anita

found her a safe residence, took her shopping for groceries and clothing and helped her obtain the very necessary supplies for her newborn. **Patricia Lockhart** enrolled a STTARS participant who was living in a shelter with triplets on the way and feeling hopeless about life. Pat rolled up both sleeves and started to work on improving the patient's sense of self worth and optimism for the future. She brought the woman to her church to help establish a support system and Pat is now the proud godmother of 3 strong healthy babies. And currently **Debra Driscoll** is helping a former BEAM patient who is enrolled in Omega-3, with 5 small children and deplorable living conditions...no running water, no electricity, no refrigeration and no furniture. Debbie enlisted the help of family and friends to take a convoy of furniture, appliances, clothes and food to the home. Friends also helped repair the patient's car and home. Debbie contacted social services and the landlord to make sure that all of the violations in the home were being corrected. When the patient went into labor she called Debbie and said she had no one to watch her children. Debbie took them into her home and kept them during their mother's hospital stay. WSU's own staff, as well as staff from Children's Hospital and other research nurses have now joined in to offer much needed assistance to this family. Gwen closes her message by saying that when it comes to her staff, there is no limit to the size of their hearts and no limit to her pride in them.

People in the News

From the Oregon Health and Sciences University:

- **Lowell Davis, MD**, is Professor of Obstetrics and Gynecology and head of the Division of MFM at the OHSU. He completed a medical degree from the University of Kentucky in Lexington (1980), residency from the Medical College of Wisconsin (1984) and fellowship at the University of Texas Southwestern Medical School (1986). His funded research is in the area of fetal cardiovascular function, coronary vascular growth and regulation of amniotic fluid volume. He has served as the secretary treasurer for the Perinatal Research Society and currently is the Program Director of the Oregon K12 BIRCWH program. He enjoys woodworking, building bamboo fly fishing rods and using them whenever possible.



- **Ellen Liarson, RN, MN, ANP**, is the newly hired research nurse coordinator. She received her MN from the University of Washington in 1985 after earning undergraduate degrees in psychology from the University of Puget Sound and Nursing from Eastern Washington University. She has worked as a nurse practitioner in the areas of internal medicine and women's health care with a focus in family planning. The majority of her practice has been in



infectious disease clinical research. She joined OHSU in 2005 to teach at the School of Nursing. Her interests include quilting, cross-country skiing and reading.

- Congratulations to **Julia Zachary, Sr.** Research Scientist at the BCC, and her team for being the U.S. Tennis Association Senior League's Mid-Atlantic Champions. After gaining first place in Montgomery County (MD), her team went on to beat other area Virginia and Washington, D.C., level 3.0 teams during the Sectional playoffs. Facing strong competition, they only lost one of 9 matches before winning the Mid-Atlantic title. Now it's on to the Nationals in Tucson later in October where 17 teams will battle for first place.

- To celebrate one of those "Big Ones", **Karen Dorman** began training last Spring for the MS 150, a bike ride in Eastern North Carolina to fund research for Multiple Sclerosis. On the weekend of September 9-10, she achieved her goal and her team, UNC Wellness, was the fourth highest contributor, helping the event raise about one million dollars. She thanks those from the Network who financially supported her effort.

- If you don't regularly watch CBS' *The Early Show*, you probably have missed seeing our talented and fearless Program Scientist, Dr. **Catherine Spong**, who has been making almost monthly appearances to discuss pregnancy-related issues with Co-anchor Hannah Stern or Renee Syler on the *HealthWatch* segment. Topics have included depression and antidepressants during pregnancy, manipulating the menstrual cycle, cesarean deliveries and prenatal diagnosis.

Welcome to 5 New BCC Staff:

- **Madeline Murguia Rice, PhD**, has been at the GWU Biostatistics Center for about 4 years as the PI of a cardiovascular trial. Originally from California, she most recently hails from the University of Washington in Seattle where she worked on a study of aging. As an Associate Professor of Epidemiology and Biostatistics at GWU, she teaches courses on study design and epidemiological methods in older populations. Madeline is excited about studying the other end of the lifespan and will be assisting PI Elizabeth Thom, PhD, on study design and analyses, in addition to the new trial of 17P and short cervix. She enjoys walking, tennis and the amusing men in her life - her cat, Cosmo, and husband John.

- **Mira Shapiro** recently received a Masters of Science in Biostatistics from the University of Massachusetts Amherst and is the statistician for the new TSH trial. After receiving her undergraduate degree in statistics and computer

science from GWU, she became a specialist in performance and capacity planning. As an independent consultant, Mira has worked for Apple Computer, Wall Street companies and marketing firms for more than 20 years. Her husband is a high school math teacher and they have a 10 year old son. Besides being passionate about crossword puzzles, Mira enjoys folk music and Samoyed dog rescue activities.

- **Robert Palugod** is the new research assistant for the Omega-3 trial. He received his BA in statistics from the University of North Florida. Before joining the BCC, he was a research analyst for a financial company. He is a big Redskins football fan and enjoys playing basketball. He intends to start taking classes soon for his masters in statistics at GWU.

- **Elizabeth Fricks** is a recent graduate of the University of Missouri where she majored in music and minored in business. An internship with a NIH subcontractor, where she worked on an adverse events team, brought her east to the Washington area. She liked the D.C. area, decided to stay and applied for the RA

position at the BCC. She is the TSH research assistant, along with Barbara Binns. She enjoys kickball, softball and tennis and is starting classes at GWU towards a business degree.

- **Eric Cardenas** is the new RA for the STTARS trial. He is from Venezuela but has spent the last seven years in the U.S. Eric received his degree in economics, with minors in statistics and math, from the University of Maryland. His previous job was at the Inter-American Development Bank. He has already started classes for his masters in statistics at GWU and in his free time he enjoys reading and movies.

Brain Teaser Contest

3	0	1
4	0	0
3	7	1

Four out of 6 responders got the correct answer to the July contest! The winner, by being the first, was **David Colombo** at OSU! The correct answer is shown.

It's a GIRL!!

Congratulations to **Mark Klebanoff** on his recent acquisition of Lizzy (although it may be renamed Vicky because of its tail letter!), a 30 year old (1976 model) Cessna Cardinal with 2200 hours of flying time. Mark flew it to Maryland from its previous home in Massachusetts in mid-September. She carries 3 to 4 people, and with full tanks it can fly around 800 miles at around 160 mph. So far Mark has taken it to Lancaster for lunch and done some practice flying. He hopes to use it for weekend trips to places like North Carolina, New England, Upstate New York and Cleveland (to see the Rock and Roll Hall of Fame!).



On the Light Side



MUFMU CALENDAR



Steering Committee Meetings

2006

October 19-20

2007

January 18-19

April 26-27

Professional Meetings

SMFM: February 5-10, 2007, San Francisco

SGI: March 14-17, 2007, Reno

Publication Deadlines

October 30 - SGI Abstract Deadline

December 15 - Manuscripts from SMFM abstracts due (if intended for the SMFM issue)