

# CaseMed-Pregnancy Resource Newsletter

## December 2007

### MEDICAL STUDIES

***Two successful pregnancies in chronic myeloid leukemia patient treated with imatinib***  
***Garderet L, Santacruz R, Barbu V, et al***  
***Haematologica, 2007; 92(1): e9-10***

According to the authors, physicians do not know when to stop imatinib treatment in women with CML or know what the risks are for the fetus and the mother. Garderet and colleagues present a case of a CML patient treated with imatinib who has two healthy children, now 3 years and 10 months of age. The mother was in complete molecular remission, relapsed during pregnancy and reverted to remission in both cases after delivery.

***Atrial and ventricular rate response and patterns of heart rate acceleration during maternal-fetal terbutaline treatment of fetal complete heart block.***  
***Cuneo BF, Zhao H, Strasburger JF, et al***  
***Am J Cardiol, 2007; 100(4): 661-5***

Terbutaline is used to treat fetal bradycardia in the setting of complete heart block (CHB); however, little is known of its effects on atrial and ventricular beat rates or patterns of heart rate (HR) acceleration. This study compared fetal atrial and ventricular beat rates before and after transplacental terbutaline treatment (10 to 30 mg /day) by fetal echocardiography in 17 fetuses with CHB caused by immune-mediated damage to a normal conduction system or a congenitally malformed conduction system associated with left atrial isomerism. While receiving terbutaline, 9 of the 17 fetuses underwent fetal magnetocardiography to assess maternal HR and rhythm, patterns of fetal HR acceleration, and correlation between fetal atrial and ventricular accelerations (i.e., AV correlation). The researchers conclude that the pathophysiologic heterogeneity of CHB is reflected in the differing effect of terbutaline on the atrial and ventricular pacemaker(s) and varying patterns of HR acceleration. However, regardless of the cause of CHB, terbutaline augments HR but not AV correlation, suggesting that its effects are determined by the conduction system defect rather than the autonomic control of the developing heart.

***Risks of congenital malformations and perinatal events among infants exposed to antidepressant medications during pregnancy***  
***Davis RL, Rubanowice D, McPhillips H, et al***  
***Pharmacoepidemiol Drug Saf, 2007; 16(10): 1086-94***

The purpose of this study was to evaluate risks for perinatal complications and congenital defects among infants exposed in utero to antidepressants. The researchers identified 2201 women who were prescribed an antidepressant during pregnancy and who delivered an infant within one of five large managed care organizations. Rates of congenital anomalies or perinatal complications were compared to infants whose mothers were not prescribed antidepressants during pregnancy. Results showed that Selective Serotonin Reuptake Inhibitors (SSRIs) and Tricyclic

Antidepressants (TCAs) did not show a consistent link with congenital anomalies. The risk of preterm delivery was found to increase in infants exposed to antidepressants. The authors conclude that both SSRIs and TCAs used during the third trimester appeared to increase the risk for perinatal complications and their use should be managed carefully among pregnant women with depression.

***Fetal malformations associated with mycophenolate mofetil for lupus nephritis***

***El Sebaaly Z, Charpentier B, Snanoudj R  
Nephrol Dial Transplant, 2007; 22(9): 2722***

No abstract is available.

***Randomized comparison of intravenous terbutaline vs nitroglycerin for acute intrapartum fetal resuscitation***

***Pullen KM, Riley ET, Waller SA, et al  
Am J Obstet Gynecol, 2007; 197(4): 414.e1-6***

The purpose of this study was to compare terbutaline and nitroglycerin for acute intrapartum fetal resuscitation. One hundred and ten women had nonreassuring fetal heart rate tracings in labor; 57 women received terbutaline, and 53 women received nitroglycerin. The researchers conclude that while terbutaline provided more effective tocolysis with less impact on maternal blood pressure, no difference was noted between nitroglycerin and terbutaline in successful acute intrapartum fetal resuscitation.

***Pharmacology of antiepileptic drugs during pregnancy and lactation***

***Pennell PB, Gidal BE, Sabers A, et al  
Epilepsy Behav, 2007; 11(3): 263-9***

Most women with epilepsy require continuous treatment during pregnancy, making antiepileptic drugs (AEDs) one of the most frequent chronic teratogen exposures. Therapeutic decisions should balance the risks to the developing fetus of AED exposure and of not treating or undertreating the epilepsy. The International AED Pharmacology Work Group of the Health Outcomes in Pregnancy and Epilepsy (HOPE) Forum identified four pharmacology topics critical to enhancing maternal and fetal outcomes for pregnancies exposed to AEDs: (1) hormonal therapies and endogenous changes: bidirectional interactions with AEDs; (2) pharmacokinetic alterations during pregnancy, the role of therapeutic drug monitoring, and the influence on seizure control and maternal and fetal outcomes; (3) multidrug transporters and their various roles during pregnancy; (4) breastfeeding in mothers taking AEDs. The report provides an overview of these key topics, highlights gaps in the current knowledge, and provides future directions for needed research.

***Antiepileptic drug exposure and major congenital malformations: the role of pregnancy registries***

***Tomson T, Battino D, French J, et al  
Epilepsy Behav, 2007; 11(3): 277-82***

The use of antiepileptic drugs (AEDs) in pregnancy is associated with an increased risk of fetal malformations. Although it is known that AEDs may differ with respect to the type of malformations they can induce, earlier studies have generally lacked the power to demonstrate differences between AEDs in their overall teratogenic potential. Furthermore, there is an urgent need to assess the clinical teratogenic potential of the newer-generation AEDs. Epilepsy and

pregnancy registries have been established to provide such information, which is essential for the rational management of women with epilepsy with childbearing potential. This review provides a critical discussion and comparison of important methodological aspects for AED and pregnancy registries along with a summary of results published so far.

***Teratology public affairs committee position paper: Pregnancy labeling for prescription drugs: Ten years later***  
***Public Affairs Committee of the Teratology Society***  
***Birth Defects Res A Clin Mol Teratol, 2007; 79(9): 627-30***

No abstract is available.

***Selection of controls in case-control studies on maternal medication use and risk of birth defects***  
***Bakker MK, de Walle HE, Dequito A, et al***  
***Birth Defects Res A Clin Mol Teratol, 2007; 79(9): 652-6***

According to the authors, in case-control studies on teratogenic risks of maternal drug use during pregnancy, the use of normal or malformed controls may lead to recall-bias or selection bias. This can be avoided by using controls with a genetic disorder. However, researchers are hesitant to use these as controls because it is unknown whether their selection is independent of exposure status. The aim of this study was to investigate whether first trimester drug use among mothers of children with genetic disorders is representative for the "general pregnant population". Bakker and colleagues conclude that with the exception of antimigraine medication, first trimester drug use among mothers of infants with genetic disorders is representative for the general pregnant population.

***New cases of thalidomide embryopathy in Brazil***  
***Schuler-Faccini L, Soares RC, de Sousa AC, et al***  
***Birth Defects Res A Clin Mol Teratol, 2007; 79(9): 671-2***

While thalidomide is the best known human teratogen, it also has a potent immunomodulatory property which has allowed it to be used for a number of approved and off-label uses in dermatologic, oncologic, infectious and gastrointestinal conditions. No cases of thalidomide embryopathy have been recorded in the U.S. or Latin America since 1998 and 1996 respectively. However, the Teratogen Information Service (TIS) Porto Alegre, recorded three new cases of thalidomide embryopathy born in Brazil since 2005. Considering that these three cases were not registered through a systematic surveillance system, but that came to the authors' attention through a series of coincidental random events, it can be assumed that the actual occurrence of affected babies by thalidomide continues being as frequent as denounced ten years ago.

***Maternal fish oil supplementation in pregnancy modifies neonatal leukotriene production by cord-blood-derived neutrophils***  
***Prescott SL, Barden AE, Mori TE, et al***  
***Clin Sci, 2007; 113(10): 409-16***

The objective of this study was to examine the effects on neonatal neutrophil function following supplementation in pregnancy. Pregnant women with allergic disease were randomized to receive either fish oil (3.7 g of n-3 long-chain PUFAs (polyunsaturated fatty acids) /day) or a placebo supplement for the final 20 weeks of pregnancy. Leukotriene production by neonatal neutrophils was measured after stimulation with the calcium ionophore A23187. This was examined in

relation to supplementation, cell membrane fatty acid levels and mononuclear cytokine production. Prescott and colleagues conclude that maternal dietary changes can modify neonatal neutrophil function. This has implications for the early immune programming, which can be influenced by the inflammatory milieu of local tissues during initial antigen encounter. It also provides evidence of another pathway through which long-chain PUFAs status can influence early immune development.

***Early elective insulin therapy can reduce hyperglycemia and increase insulin-like growth factor-I levels in very low birth weight infants***

***Beardsall K, Ogilvy-Stuart AL, Frystyk J, et al  
J Pediatr, 2007; 151(6): 611-7***

The objective of this study was to investigate the use of insulin throughout the first week of life in very low birth weight (VLBW) infants (birth weight <1.5 kg) to improve glucose control and increase insulin-like growth factor-I (IGF-I) levels. IGF-I is the dominant hormone involved in fetal growth, and low levels have been implicated in neonatal morbidities, such as retinopathy of prematurity. The authors conclude that early insulin therapy improves blood glucose control and increases IGF-I bioactivity levels. This could result in less morbidity associated with hyperglycemia and reduced IGF-I levels.

***Reduction of HIV-1 drug resistance after intrapartum single-dose nevirapine***

***Lockman S, McIntyre JA  
Lancet, 2007; 370(9600): 1698-705***

No abstract is available.

***Single-dose tenofovir and emtricitabine for reduction of viral resistance to non-nucleoside reverse transcriptase inhibitor drugs in women given intrapartum nevirapine for perinatal HIV prevention: an open-label randomised trial***

***Chi BH, Sinkala M, Mbewe F, et al  
Lancet, 2007; 370(9600): 1668-70***

Intrapartum and neonatal single-dose nevirapine are essential components of perinatal HIV prevention in resource-constrained settings, but can induce resistance to other non-nucleoside reverse transcriptase inhibitor drugs. The researchers aimed to investigate whether this complication would be reduced with a single peripartum intervention of tenofovir and emtricitabine. Chi and colleagues conclude that a single dose of tenofovir and emtricitabine at delivery reduced resistance to non-nucleoside reverse transcriptase inhibitors at 6 weeks after delivery by half; therefore this treatment should be considered as an adjuvant to intrapartum nevirapine.

***Implementation of a conservative checklist-based protocol for oxytocin administration: maternal and newborn outcomes***

***Clark S, Belfort M, Saade G, et al  
Am J Obstet Gynecol, 2007; 197(5): 480.e1-5***

The purpose of this study was to examine the effects of a conservative and specific checklist-based protocol for oxytocin administration on maternal and newborn outcome. The protocol was based on maternal and fetal response to oxytocin rather than infusion rate. The results of the study reveal that implementation of a specific and conservative checklist-based protocol for oxytocin infusion based on maternal and fetal response results in a significant reduction in maximum

infusion rates of oxytocin without lengthening labor or increasing operative intervention. Cesarean delivery rate declined system-wide following implementation of this protocol. Newborn outcome also appears to be improved.

***ACOG Practice Bulletin No.87 November 2007: Use of psychiatric medications during pregnancy and lactation***  
***American College of Obstetricians and Gynecologists***  
***Obstet Gynecol, 2007; 110(5): 1179-98***

No abstract is available.

***Antithrombotic therapy and pregnancy: consensus report and recommendations for prevention and treatment of venous thromboembolism and adverse pregnancy outcomes***  
***Duhl AJ, Paidas MJ, Ural SH, et al***  
***Am J Obstet Gynecol, 2007; 197(5): 457.e1-21***

Venous thromboembolism and adverse pregnancy outcomes are potential complications of pregnancy. This consensus group was convened to provide concise recommendations, based on the currently available literature, regarding the use of antithrombotic therapy in pregnant patients at risk for venous thromboembolic events and adverse pregnancy outcomes.

***Magnesium sulfate compared with nifedipine for acute tocolysis of preterm labor: a randomized controlled trial***  
***Nassar AH, Usta IM***  
***Obstet Gynecol, 2007; 110(5): 1170-1; author reply 1171***

No abstract is available.

***Inhaled nitric oxide for preterm infants: a systematic review***  
***Barrington KJ, Finer NN***  
***Pediatrics, 2007; 120(5): 1088-99***

The objective of this study was to determine whether, for preterm newborn infants with respiratory disease, inhaled nitric oxide reduced the rates of death, bronchopulmonary dysplasia, intracranial hemorrhage or neurodevelopmental disability. The authors searched Medline, EmBase, Healthstar, and the Cochrane Central Register of Controlled Trials as well as the abstracts of the Pediatric Academic Societies. Results revealed that inhaled nitric oxide as rescue therapy for very ill preterm infants undergoing ventilation does not seem to be effective and may increase severe intracranial hemorrhage. Later use of inhaled nitric oxide to prevent bronchopulmonary dysplasia does not appear to be effective. Early routine use of inhaled nitric oxide for mildly sick, preterm infants seem to decrease the risk of serious brain injury and may improve rates of survival without bronchopulmonary dysplasia.

***Neonatal hyperparathyroidism and pamidronate therapy in an extremely premature infant***  
***Fox L, Sadowsky J, Pringle KP, et al***  
***Pediatrics, 2007; 120(5): e1350-4***

In their study, Fox and colleagues describe the use of pamidronate to control marked hypercalcemia in an extremely premature infant with neonatal hyperparathyroidism that resulted from an inactivating mutation (R220W) of the calcium-sensing receptor. Despite improvement in bone mineralization and subsequent parathyroidectomy with normalization of the serum calcium

level, the combination of chronic lung disease, osteomalacia, and poor thoracic cage growth ultimately proved fatal. The authors conclude that pamidronate therapy appears to be safe in the short-term and effective in helping control hypercalcemia even in the very premature infant, allowing for planned surgical intervention when it becomes feasible.

***Protease inhibitor treatment of HIV-1 infected women may protect against extreme prematurity and very low birth weight***

***Beckerman KP***

***J Infect Dis, 2007; 196(8): 1270-1; author reply 1271***

No abstract is available.

***Epilepsy in pregnancy***

***Tomson T, Hiilesmaa V***

***BMJ, 2007; 335(7623): 769-73***

No abstract is available.

***Pharmacokinetics of sulfadoxine-pyrimethamine in HIV-infected and uninfected pregnant women in Western Kenya.***

***Green MD, van Eijk AM, van Ter Kuile FO, et al***

***J Infect Dis, 2007; 196(9): 1403-8***

While sulfadoxine-pyrimethamine (SP) is among the most commonly used antimalarial drugs during pregnancy, the pharmacokinetics of SP are unknown in pregnant women. According to the researchers, HIV-infected (HIV(+)) women require more frequent doses of intermittent preventive therapy with SP than do HIV-uninfected (HIV(-)) women. Green and colleagues investigated whether this reflects their impaired immunity or an HIV-associated alteration in the disposition of SP. They conclude that pregnancy significantly modifies the disposition of SP, whereas HIV status has little influence on pharmacokinetic parameters in pregnant women.

***Does a maximum dose of oxytocin affect risk for uterine rupture in candidates for vaginal birth after cesarean delivery?***

***Cahill AG, Stamilio DM, Odibo AO, et al***

***Am Obstet Gynecol, 2007; 197(5): 495.e1-5***

The objective of this study was to determine whether the maximum dose of oxytocin impacts the risk of uterine rupture in women who attempt vaginal birth after cesarean delivery (VBAC). Results showed that in VBAC attempts, a dose-response relationship of maximum oxytocin and uterine rupture exists. These results provide evidence for vigilance when higher doses of oxytocin are given to patients who attempt VBAC.

***Long-term effects of caffeine therapy for apnea of prematurity***

***Schmidt B, Roberts RS, Davis P, et al***

***N Engl J Med, 2007; 357(19): 1893-902***

Methylxanthine therapy is commonly used to for apnea of prematurity but in the absence of adequate data on its efficacy and safety. This study examines the long-term effects of methylxanthines on neurodevelopment and growth. Schmidt and colleagues randomly assigned 2006 infants with birth weights of 500 to 1250 g to receive either caffeine or placebo until therapy for apnea of prematurity was no longer needed. The primary outcome was a composite of

death, cerebral palsy, cognitive delay (defined as a Mental Development Index score of <85 on the Bayley Scales of Infant Development), deafness, or blindness at a corrected age of 18 to 21 months. In conclusion, caffeine therapy for apnea of prematurity improves the rate of survival without neurodevelopmental disability at 18 to 21 months in infants with very low birth weight.

***The use of olanzapine in pregnancy and congenital cardiac and musculoskeletal abnormalities***  
**Yeshayahu Y**  
***Am J Psychiatry, 2007; 110(1): 61-7***

No abstract is available.

***Lamotrigine in pregnancy. Clearance, therapeutic drug monitoring, and seizure frequency***  
**Pennell PB, Peng L, Newport DJ, et al**  
***Neurology, 2007; Nov 28 [Epub ahead of print]***

The objective of this study was to characterize the magnitude and course of alterations in total and free lamotrigine (LTG) clearance (Cl) during pregnancy and the postpartum period, to assess the impact of therapeutic drug monitoring (TDM) on seizure frequency, to determine the ratio to individual target LTG concentration that is associated with increased seizure risk, and to evaluate maternal postpartum toxicity. The researchers analyzed 305 samples in 53 pregnancies. The study found that although 39 percent of women reported an increase in seizure activity during their pregnancy, 33 percent actually reported a decrease in seizures and 28 percent no change. The health of the babies born was similar to that found in women who do not have epilepsy.

## LAY PRESS NEWS

***Canadian experts recommend boost in folic acid***  
***CTV.ca, 2007; December 13***

As many as half of certain birth defects could be prevented if women of childbearing age consumed more folic acid, says a panel of experts as they release new guidelines about the vitamin. It's long been known that folic acid supplements can help prevent neural tube defects, such as spina bifida. All Canadian women of child-bearing age have been advised to take a multivitamin containing 0.4 mg of folic acid every day. But now the experts from the Society of Obstetricians and Gynaecologists of Canada and the Motherisk program at Toronto's Hospital for Sick Children are calling on women to step up those levels. They say women planning pregnancy should take a multivitamin containing between 0.4 and 1.0 milligram of folic acid at least two to three months before conception, throughout pregnancy and keep taking it as long as breastfeeding continues. Women who are smokers, obese, diabetic or with a previous history of spina bifida in the family should be taking a multivitamin containing 5.0 milligrams of folic acid, three months prior to and up to 12 weeks following conception. The panel of experts says new research suggests that folic acid can do more than cut the risk of neural birth defects; it can also reduce the rates of other birth defects such as congenital heart disease and some early pediatric cancers.

***Novartis' Myfortic poses fetal risks - FDA***  
**Baertlein L, Hill G**  
***Reuters.com, 2007; November 27***

The FDA announced that Novartis AG's organ rejection drug Myfortic increases the risk of first-trimester miscarriage and birth defects. Data collected from the United States National

Transplantation Pregnancy Registry and postmarketing data collected from women who took the drug during pregnancy revealed increased miscarriage risk, malformations of the external ear and the face (such as cleft lip and palate), and anomalies of distal limbs (which include fingers and toes), heart, esophagus and kidney. Novartis said the drug will carry a new safety warning which will describe the risks. The FDA recommends that women who are planning a pregnancy should not use Myfortic unless she cannot be successfully treated with other immunosuppressant drugs. Female patients who are taking Myfortic must receive contraceptive counseling and must use effective contraception.

***28 women miscarry after receiving HPV vaccine Gardasil; FDA says no reason to re-examine approval***

***FOXnews.com, 2007; December 6***

The FDA has announced that the cervical cancer vaccine Gardasil is safe even though 28 U.S. women who received the vaccine had miscarriages. According to the FDA, clinical trials show that the vaccine's miscarriage rate is consistent with that of the general population who were given placebos and most of the miscarriages reported cannot be directly linked to Gardasil. The FDA and the U.S. Centers for Disease Control and Prevention have concluded most side effects are minor and there is no reason to re-examine the drug's approval.

***American College of Gastroenterology Offers Updated Clinical Guidance for Managing Pregnant Patients***

***PR Newswire (U.S.), 2007; December 7***

Physician experts from the American College of Gastroenterology have released a seven chapter monograph entitled "Pregnancy in Gastrointestinal Disorders", which provides up-to-date clinical recommendations on managing common gastrointestinal disorders and challenges during pregnancy. An important focus of the monograph addresses the challenges encountered in the treatment and management of chronic digestive disorders in pregnancy. It includes a discussion of pharmacologic and alternative therapies available to treat GI symptoms in pregnancy and, importantly, identifies which medications are safe for use in pregnant women and those which should be avoided. "The major risk to the fetus is encountered during the first trimester of pregnancy," says Dr. Foxx-Orenstein. "It is important for physicians and expectant mothers to maintain a high level of concern for the use of prescription and over-the-counter drugs to treat GI symptoms during pregnancy."

***Health Canada News Release: One year after launch, Canada's Chemicals Management Plan is on track and delivering results***

***www.hc-sc.gc.ca, 2007; November 20***

The Government of Canada today announced a \$3.9 million investment in Canada's largest study of the environmental chemicals in pregnant women and their babies. The study is being funded by Health Canada, the Canadian Institutes of Health Research and the Ontario Ministry of the Environment, which is contributing an additional \$200,000. The study, known as the Maternal-Infant Research on Environmental Chemicals (MIREC), is recruiting about 2,000 women during the first trimester of pregnancy and following them through the birth of their child and up to eight weeks after birth. MIREC is a collaborative effort among Health Canada scientists, the Sainte-Justine Hospital in Montreal, and clinical researchers from Vancouver, Calgary, Winnipeg, Sudbury, Ottawa, Kingston, Hamilton, Toronto and Halifax.

***Thalidomide resurfaces as treatment for multiple myeloma: drug derivative may prolong life of people battling incurable type of bone marrow cancer***  
***CBC.ca, 2007; November 23***

A study published in the New England Journal of Medicine has found that a derivative of thalidomide may prolong life in people with a type of bone marrow cancer called multiple myeloma - if taken with a steroid. Lenalidomide, in combination with the steroid dexamethasone, can slow the progress of incurable bone marrow cancer and extend the lives of patients with the condition by an average of 10 months. The research was funded by Celgene, the manufacturer of thalidomide, which this week announced a \$2.9-billion buyout of Pharmion, a biopharmaceutical manufacturer that has been working with Celgene in marketing thalidomide as a cancer treatment. Between 1957 and 1962, thalidomide was prescribed to treat morning sickness in pregnant women. Worldwide, 10,000 people were born with missing or shrunken limbs, and came to be known as "thalidomide babies." In Canada alone, it's estimated that about 100 babies were born with severe deformities after their mothers took the drug during their pregnancies. The drug was pulled from Canadian pharmacies in 1962. In the case of multiple myeloma, lenalidomide is welcome news. Midway through the study, the clinical trial was halted to allow those participants on placebos to be administered the drug. Dr. Darrell White, a hematologist with the Queen Elizabeth II Health Sciences Centre in Halifax and one of the Canadian investigators in the study, told CBC News that multiple myeloma patients typically have relapses as their treatments become ineffective over time. "So for these patients with this incurable malignancy, this means they have another effective treatment that they can move onto," he said. While the U.S. FDA approved lenalidomide and dexamethasone in 2006, the drug is not yet approved for use in Canada. Health Canada is currently reviewing an application from the manufacturer. If it is approved, it will cost thousands of dollars a month and will be tightly controlled due to serious and potentially toxic side effects.

***In Depth Health: Thalidomide***  
***CBC.ca, 2007; November 22***

On their website, the CBC examines the drug Thalidomide. The history of Thalidomide's use in Canada, the deformities it caused in babies and the new indications for the drug are discussed.

***FDA Official says legislation could foster lactation studies***  
***FDA Week, 2007; December 7***

An FDA official says legislation that allows the FDA to require drug makers to study mothers who nurse as part of the drug approval process would foster more lactation research. Currently, there is little scientific information on the extent to which drugs seep into breast milk or whether they affect infants. Karen Feibus, medical team leader at FDA's Maternal Health Team, says the FDA has no mechanism to force companies to submit lactation clinical trial data as part of new drug or supplemental applications. Companies are often reluctant to do the studies because of ethical concerns and potential lawsuits in the event children are hurt during clinical research. "It would be wonderful" to have legislation, she says. "This sort of data would help practitioners make good risk/benefit decisions for their patients." Recently passed FDA legislation may give the agency expanded powers to request lactation studies if a serious drug safety signal arises, but the signal would have to be well-defined. Feibus spoke at a Pediatric Advisory Committee meeting last week that discussed issues surrounding the enrollment of lactating mothers and their infants in clinical trials. The agency is proposing revisions to its 2005 draft guidance on clinical lactation studies. The FDA asked the panel about the use of data from clinical lactation studies, the timing of study enrollment for mother/infant pairs, labeling, and ethical issues related to

studying breastfeeding mother/infant pairs. The FDA expects to issue final lactation guidance by the middle of next year.

***FDA slightly eases access to birth defect-causing acne drug***  
***Associated Press Newswires, 2007; December 5***

The FDA announced that they have now implemented the changes to the iPledge program which will ease access to Accutane, the acne medication which can cause severe birth defects. Women of childbearing age who don't fill a prescription within seven days of a pregnancy test will be allowed to get another test and then fill the prescription - with the exception of the initial prescription. Until now, women who didn't act within seven days were frozen out of the program for the next 23 days. These women will have to fill the prescription within seven days of a pregnancy test rather than within seven days of first seeing their doctor.

***Anti-depressants make babies smaller***  
***AAP Bulletins, 2007; December 1***

Melbourne researchers tracked 34 women taking antidepressant medication during their pregnancy and the same number of women who did not. The babies born to women on antidepressants are smaller and more likely to suffer tremor and irritability, but the symptoms were not long lasting. According to lead researcher Dr. Megan Galbally, the symptoms were minor and were gone within a month. They did not find any major complications such as deformations and the level of symptoms seemed to correlate to the amount of medication taken by the mothers. Dr. Galbally believes that antidepressant medication should be prescribed to pregnant women on a case-by-case basis and women should discuss this issue with their doctors.

***Questions pile up on birth drug trial***  
***The Sydney Morning Herald, 2007; November 20***

As part of a drug trial at Wagga Wagga Base Hospital in NSW, a number of women were administered the drug misoprostol (marketed as Cytotec) to induce labour - regardless of the safety warning against its use in pregnant women. One woman has settled a claim over a child born with cerebral palsy and others may now sue. Cytotec is known to cause strong uterine contractions which, if used in pregnant women, can cause catastrophic results. The case raises many questions, but with the hospital and the relevant area health service ducking for cover, there are as yet no answers.