



MotherToBaby

---

Medications and More During  
Pregnancy and Breastfeeding

# MotherToBaby California

---

- ❑ Affiliate of MotherToBaby, Organization of Teratology Information Specialist (OTIS)
- ❑ Established over 30 years ago at UC San Diego School Of Medicine; funded by Ca State Dept of Education.
- ❑ Formerly known as CTIS: California Teratogen Information Service (also Pregnancy Risk Information Line, California Teratogen Registry)
- ❑ Federal fund by a Health Resources and Services Administration (HRSA) Cooperative (2 years) – *through OTIS National Office*
- ❑ **FREE** and **confidential telephone and e-Mail** service providing [pregnancy and breastfeeding health information](#) - no insurance or appointment needed! Try *online chat* service
  - ✓ Not just a RESOURCE or HOTLINE
  - ✓ **Should be an key component of prenatal care ~ education!**

# MotherToBaby California

---

- ❑ Before 1<sup>st</sup> prenatal visit(end of 1<sup>st</sup> trimester), searching for ANSWERS:
  - ✓ Dr. Google
  - ✓ Clinic/OB Office
  - ✓ Contact **pregnancy information health specialist** @ MotherToBaby
  
- ❑ Pregnancy health is important: **“EXPOSURE CHECK-UP”**
  - ✓ 50% of pregnancies - unplanned.
  - ✓ All pregnant women are exposed early in pregnancy to medications, chemicals, a cold or flu, second-hand smoke, and a lot of other things – possible **TERATOGENS**
  - ✓ Perfect fit for CPSP
    - ✧ Health Education
    - ✧ Psycho-social
    - ✧ Nutrition
  
- ❑ Sensitive to different birth customs/beliefs

# MotherToBaby – A Benefit to the Public and Healthcare Providers

---

- Reduce calls to clinics
- Support physician care plan
- Clarify misconceptions, allay fears and reduce anxiety
- Discuss appropriate prenatal testing and specialist referrals
- Promote Healthy Behavioral Choices
- Preserve wanted pregnancies

# MotherToBaby Partners

---

- ❑ Health Resource and Services Administration (HRSA)
  - ✓ Poison Control Systems
  - ✓ Healthy Start
  - ✓ Federally Qualified Health Centers
- ❑ Food and Drug Administration (FDA)
  - ✓ Office of Women's Health
- ❑ Centers for Disease Control (CDC)
- ❑ American Congress of OB/GYN (ACOG)
  - ✓ [Committee on Healthcare for Underserved Women](#)
- ❑ March of Dimes
  - ✓ Comenzando Bien/Becoming a Mom Training
- ❑ Planned Parenthood
- ❑ Kaiser
- ❑ Sweet Success Program
- ❑ Text4Babies
- ❑ California Smokers Helpline
- ❑ California Breastfeeding Coalition
- ❑ California Department of Public Health
  - ✓ WIC
  - ✓ Black Infant Health
  - ✓ Breastfeeding Program
  - ✓ California Diabetes and Pregnancy Program
  - ✓ [Comprehensive Perinatal Services Program](#)
  - ✓ Nurse-Family Partnership
  - ✓ Regional Perinatal Programs of California

# Background Information

---

502,023 (in 2011) California – not including spontaneous and therapeutic abortions

- ❑ Prescription and OTC medications: Food and Drug Administration (FDA)
  - ✓ No Pregnancy Data (>90% of medications on FDA list)
  - ✓ No Clinical Studies performed on Pregnant Women
  - ✓ Average number of prescriptions for a pregnant woman is 3
  - ✓ Average number of prescriptions for a pregnant woman (over 35 years old) is 6

- ❑ Greater than 90% of women reported using at least one Rx or OTC meds during pregnancy
  - ✓ >80% reported use during the first trimester – organogenesis

*Mitchell AA, Gilboa SM, Werler MM, et al. Medication use during pregnancy, with particular focus on prescription drugs: 1976–2008. Am J Obstet Gynecol 2011;205(1): 51.e1–51.e8.*

- ❑ Teratogen Information Services - positioned to prospectively ascertain/conduct post-marketing surveillance for the safety of medications taken during pregnancy

*Felix RJ, Jones KL, Johnson KA, McCloskey CA, Chambers CD; Organization of Teratology Information Services Collaborative Research Group. Postmarketing surveillance for drug safety in pregnancy: the Organization of Teratology Information Services project. Birth Defects Res A Clin Mol Teratol. 2004 Dec;70(12):944-7.*

# Causes of Birth Defects

---

## Teratogens

5-10 %

A substance a mother is exposed to **during** pregnancy

- ✓ that can interfere with the normal development of her baby;
- ✓ causes a pattern of minor and major malformations

## Chromosomal Defects

*(i.e. Down's Syndrome = trisomy 21)*

10%

## Single Gene Defects

*(i.e. Tay-sachs, Cystic Fibrosis, achondroplasia)*

20%

## Unknown

Multiple malformations  
Isolated congenital defects

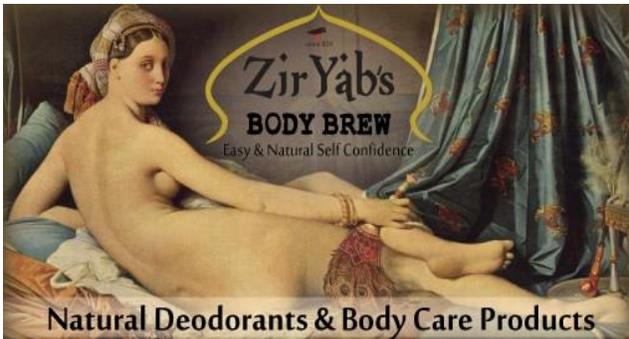
60%

# Dr. GOOGLE is not the answer!



# MotherToBaby.org

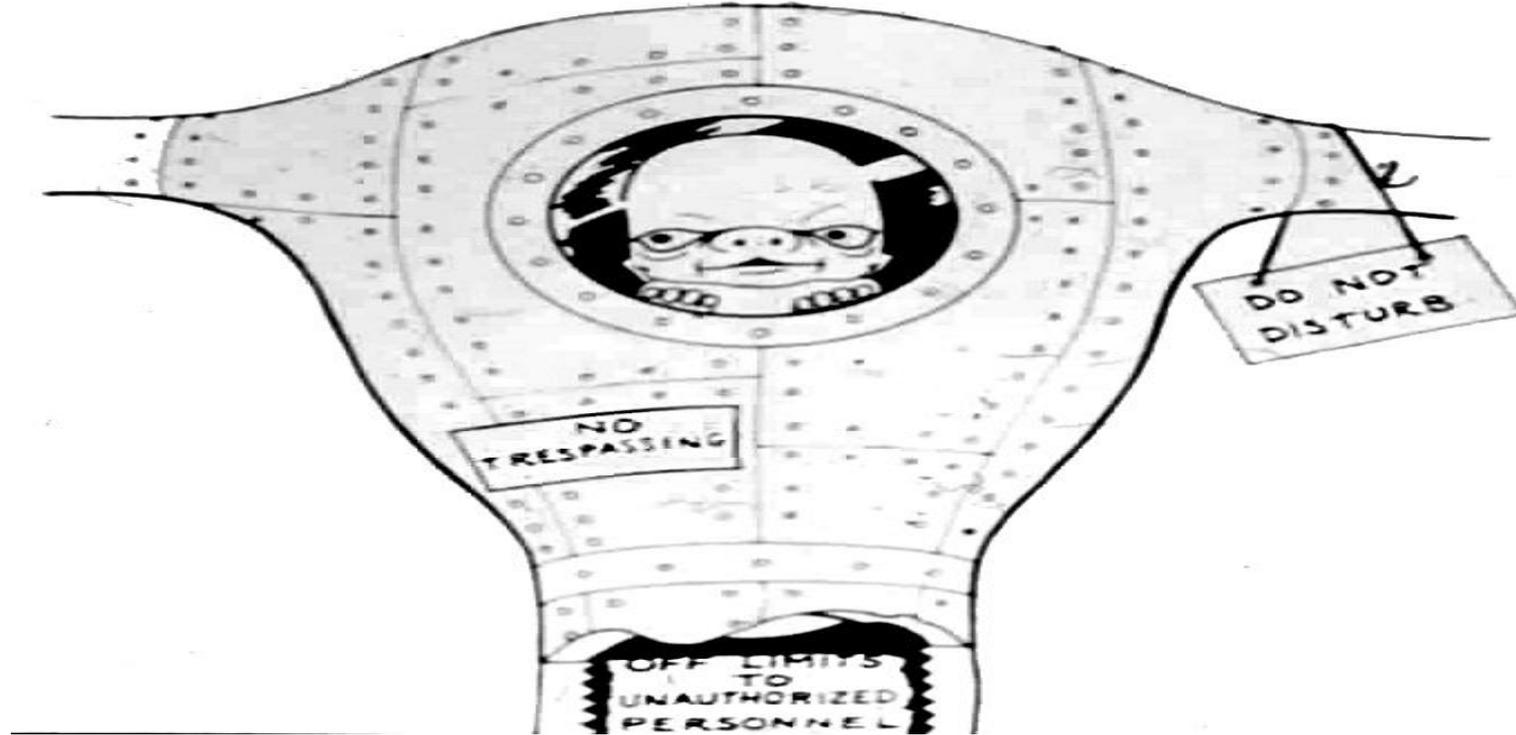
866.626.6847



# Placenta ~ Barrier?

---

Does The Embryo Occupy A Privileged Site  
In An  
IMPREGNABLE UTERUS ?





STEPHANIE KLEIN-DAVIS | The Roanoke Times

Mellisa Williamson, 35, a Bullitt Avenue resident, worries about the effect on her unborn child from the sound of jackhammers.

# MotherToBaby provides **evidence-based** information

---

- ❑ Prescription and Non-Prescription Medications
- ❑ Vaccines, Infections, Diseases and Fever
- ❑ Alcohol, Tobacco, Illicit Drugs
- ❑ Chemical or Occupational Exposures

## *Some commonly asked questions:*

- ✓ When is it safe to drink wine with dinner, after 1st trimester?
- ✓ I want to get an MMR and the Flu vaccine, but how long should I wait before we try?
- ✓ Should I quit taking my antidepressant or switch to a safer drug?
- ✓ I was recently diagnosed with Gestational Diabetes, will my medications cause problems ?

# How does MTB “interact” with callers?

---

## ❑ Reflective Listening/Build Rapport

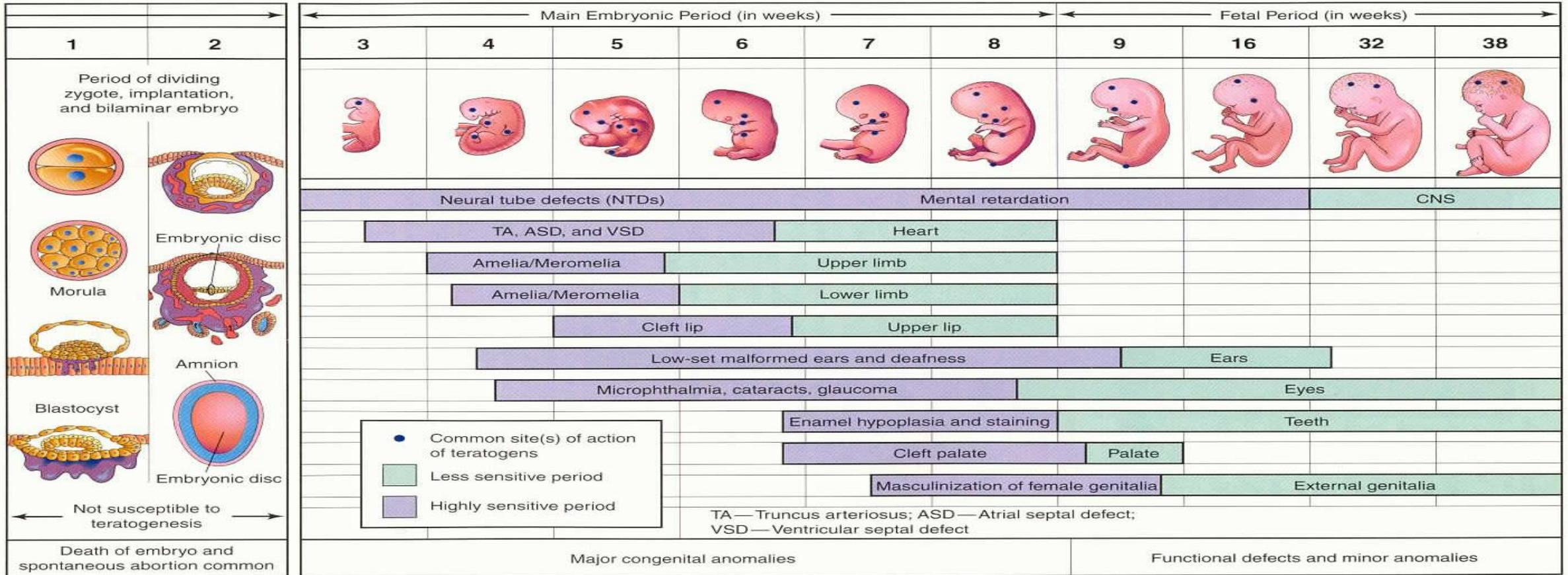
- ✓ Teratogen Information Specialists: *provides non-directive and non-judgmental information*

## ❑ **Comprehensive Pregnancy Exposure Checklist**

## ❑ Conversation/Providing Information/Principles of Teratology

- ✓ **Genetic Susceptibility** *Who 's more sensitive?*
- ✓ **Time of Exposure** *When was it taken?*
- ✓ **Dose-Response Relationship** *How much was taken?*
- ✓ **Bioavailability of Agents** *How much gets to the fetus matters?*
- ✓ **Mechanism/Pathogenesis** *How does it affect the development*
- ✓ **Range of Outcomes** *How severe are the effects?*

# Embryonic and Fetal Development



# FDA Pregnancy Drug Label

---

**Category A:** Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and no evidence of a risk in later trimesters), and possibility of fetal harm appears remote.

**Category B:** Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

**Category C:** Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

**Category D:** There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

**Category X:** Studies in animals or human beings have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

# Retinoids

---



# Retinoids

---

- ❑ **Accutane (isotretinoin) Pregnancy category X** - use during pregnancy increases the incidence of congenital anomalies
- ❑ Retinoids are present in the blood of healthy people, including pregnant women.
- ❑ Produces congenital anomalies in humans - reports of hydrocephalus, microcephaly, ear, face, and limb abnormalities. Increased risks of spontaneous abortion and premature delivery have also been reported. Might also have effects on behavior after intrauterine exposure
- ❑ Current recommendation: discontinue isotretinoin at least one month prior to attempting pregnancy but pharmacokinetic considerations suggest that this time period might be longer than necessary
- ❑ Pregnancy Prevention Program
  - ✓ iPledge
  - ✓ SMART (System to Manage Accutane-Related Teratogenecity)
- ❑ **Retin A (tretinoin)** Controlled studies of **topical** use during pregnancy have not suggested this use with an increased risk of adverse pregnancy outcome; however, there are case reports of birth defects after topical tretinoin that form the basis topical tretinoin avoidance during preg

# Retinoic Acid Embryopathy

---

## Cranio-facial

- ✓ microtia and/or anotia
- ✓ flat depressed nasal bridge
- ✓ ocular hypertension
- ✓ palatal cleft

## Cardiovascular

- ✓ conotruncal malformations including: transposition, Tetralogy of Fallot, Truncus Arteriosus, Interrupted Aortic Arch

## CNS

- ✓ microcephaly
- ✓ hydrocephalus
- ✓ defects of neuronal migration
- ✓ gross malformations of posterior fossa structures, including cerebellar hypoplasia, agenesis of vermis, cerebellar microdysgenesis, and megacisterna

## Thymic

- ✓ defects

# Benzodiazepine

---

**Ativan (C)**  
*lorazepam*

**Restoril (X)**  
*temazepam*

**Klonopin (D)**  
*clonazepam*

**Valium (D)**  
*diazepam*

**Versed (D)**  
*midazolam*

**Xanax (D)**  
*alprazolam*

# Statins

---

## STATINS – 1<sup>st</sup> Trimester

- ❑ **Pregnancy category X** - contraindicated primarily due to the fact that cholesterol is essential for normal fetal development
- ❑ Increase use in women of reproductive age (for obesity or advanced maternal age) or in unplanned pregnancy
- ❑ Initial concern raised from FDA Adverse Event Reports; Review of 31 infants with defects suggested excess of CNS defects (holoprosencephaly), limb reduction defects, and possible VACTERL association *Edison & Muenke, Am J Med Genetics, 2004*
- ❑ Canadian database study identified N=64. Group A (statin), Group B (fibrates or nicotinic acid), and Group C (Rx statin >1 year preconception). **No increase or specific pattern of malformations was seen.** *Ofori et al, British J Clin Pharm 2007*
- ❑ Pharmacovigilance data from Merck; 225 prospective reports. **3.8% rate of major malformations and no specific pattern** or similarities to the FDA case series. *Pollack et al, Birth Defects Research (Part A) 2008*
- ❑ Case series of 22 malformed infants with prenatal statin exposure from National Birth Defects Prevention Study and Slone Epidemiology Birth Defects Study 1997 - 2006. **No VACTERL, holoprosencephaly or limb reduction defects reported.** *Peterson et al, Am J of Med Genet Part A, 2008*

# Statins

---

- ❑ Prevalence of risk factors for cardiovascular disease, including hypercholesterolemia, diabetes, hypertension, and obesity increase as woman's reproductive age increases
- ❑ 2015 Study: 886,996 completed pregnancies (2000-07) cohort study. Women enrolled in Medicaid from 2000-2007. Linked to liveborn infants *Brian T Bateman, Sonia Hernandez-Diaz, Michael A Fischer, Ellen W Seely, Jeffrey L Ecker, Jessica M Franklin, Rishi J Desai, Cora Allen-Coleman, Helen Mogun, Jerry Avorn, Krista F Huybrechts. Statins and congenital malformations: cohort study. [BMJ](#). 2015 Mar 17;350:h1035. doi: 10.1136/bmj.h1035.*
- ❑ Examined the risk of major congenital and organ specific malformations in offspring – maternal 1<sup>st</sup> trimester use
- ❑ Prevalence of malformations in offspring was 6.34 % versus 3.55% in group not exposed in 1<sup>st</sup> trimester
  - ✓ Controlling for confounders accounted for increase
- ❑ Analysis did not find a significant teratogenic effect
  - ✓ Need to Replicate
  - ✓ Evaluate long-term effect
- ❑ Hypertensive disorders specific to pregnancy include gestational hypertension (formerly known as transient hypertension of pregnancy), preeclampsia, and eclampsia
  - ✓ Increase chance of intrauterine growth retardation and stillbirth
  - ✓ Increasing trend in pre-eclampsia
  - ✓ Statins to prevent early pre-eclampsia



## Drugs



Home > Drugs > Development & Approval Process (Drugs) > Development Resources > Labeling

### Development & Approval Process (Drugs)

Development Resources

Labeling

Pregnancy and Lactation Labeling Final

# Pregnancy and Lactation Labeling Final Rule

[12/3/14] The FDA published the *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling*, referred to as the "[Pregnancy and Lactation Labeling Rule](#)" (PLLR or final rule).

## PSYCHIATRIC NEWS alert

The Voice of the American Psychiatric Association and the Psychiatric Community

### CURRENT ISSUE



### NEWS FROM CURRENT ISSUE

- APA Announces Candidates Vying for Board of Trustees Positions
- Child Health Experts Urge Caution on Marijuana Legalization
- FDA Actions on Antidepressants and Suicidality: 10 Years Later

### BLOG ARCHIVE

- ▶ 2015 (17)
- ▼ 2014 (325)
  - ▼ December (21)
    - Teens With and Without Elevated Suicide Risk Have ...
    - Study Finds Olanzapine-Fluoxetine Combo Superior L...
    - FDA Approves New Alzheimer's Medication

FRIDAY, DECEMBER 5, 2014

### FDA to Change Pregnancy and Lactation Labeling Information for Prescription Drugs



On Wednesday, the Food and Drug Administration (FDA) published a [final rule](#) that will set new standards for presentation of information concerning pregnancy and breastfeeding on labels

of prescription drugs and biological products. The rule goes into effect June 15, 2015.

"The [current] letter category system [A, B, D, and X] was overly simplistic and was misinterpreted as a grading system, which gave an oversimplified view of the product risk," said Sandra Kweder, M.D., deputy director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research, in a press statement. "The new labeling rule provides for explanations, based on available information, about the potential benefits and risks for the mother, the fetus, and the breastfeeding child." The information provided under the new labeling requirements will be divided into the following categories:

**Pregnancy:** Containing information such as dosing and potential risks to the developing fetus and will require information about whether there is a registry that collects and maintains data on how pregnant women are affected when they use the drug.

**Lactation:** Containing information about using the drug while breastfeeding, such as the amount of drug in breast milk and potential effects on the breastfed child.

**Females and Males of Reproductive Potential:** Containing information about pregnancy testing, contraception, and infertility as it relates to the drug.

l format for  
isist health c  
id nursing m  
is for them  
also require

ion drug lab



THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

Office of Communications  
tel: 202-484-3321  
communications@acog.org  
www.acog.org

## ACOG Statement on FDA Pregnancy Labeling Final Rule

December 3, 2014

**Washington, DC** – John C. Jennings, MD, President of the American College of Obstetricians and Gynecologists (ACOG), released the following statement addressing the Food and Drug Administration's updated product labeling rule regarding pregnancy and lactation:

"The American College of Obstetricians and Gynecologists applauds the Food and Drug Administration (FDA) for taking needed steps to increase understanding about the effect of prescription medicines on women during pregnancy and lactation. The FDA's updated method of presenting information about both risk and benefit will improve the ability of all physicians to treat their pregnant and breastfeeding patients, as well as women who may become pregnant. It will also help more women to understand and take part in their healthcare decision-making.

"As obstetrician-gynecologists, we understand the importance of keeping women healthy before, during, and after their pregnancies, whether they live with chronic conditions or whether they are confronting new diagnoses. And, we recognize that medications can be vital to maintaining a mother's continued good health when pregnant, a goal of central concern in obstetric care. It is essential that all providers have the information they need to safely, effectively, and reliably treat their female patients. We also want to ensure that medicines will help, and not harm, both mother and child.

"Moreover, ACOG hopes that the inclusion of more information on prescription medicine labeling will provide added incentives for clinical research as well as participation in patient registries, to better capture the impact that prescription medicines have on pregnant and breastfeeding women. It is crucial that healthcare providers have access to as much information as possible, and more research will help lead to better care for women in the future.

"ACOG will review the new rule in detail prior to its implementation in June and will develop physician and patient educational resources as necessary."

# FDA Pregnancy and Lactation Labeling Rule (PLLR)

Prescription Drug Labeling Sections 8.1 – 8.3 USE IN SPECIFIC POPULATIONS

## CURRENT LABELING

8.1 Pregnancy

8.2 Labor and Delivery

8.3 Nursing Mothers

## NEW LABELING

(effective June 30, 2015)

8.1 Pregnancy  
includes Labor and Delivery

8.2 Lactation  
includes Nursing Mothers

**NEW**

8.3 Females and Males of  
Reproductive Potential

# FDA Pregnancy and Lactation Labeling Rule (PLLR)

---

## **Pregnancy Exposure Registry**

- ✓ Contact information

## **Risk Summary**

- ✓ Human, animal & pharmacologic information
- ✓ Background rate of birth defects, by disease if known

## **Clinical Considerations**

- ✓ Disease-associated maternal and/or fetal risk
- ✓ Dose adjustments during pregnancy and postpartum
- ✓ Maternal adverse reactions
- ✓ Fetal/neonatal adverse reactions
- ✓ Labor or delivery

## **Data**

# FDA Pregnancy and Lactation Labeling Rule (PLLR)

---

## IMPLEMENTATION

- ❑ Becomes effective June 30, 2015
- ❑ Drugs approved before June 30, 2001
  - ✓ Must remove pregnancy category within 3 years
  - ✓ Not required to use new labeling
- ❑ Drugs approved between June 30, 2001 and June 30, 2015
  - ✓ 3- to 5-year implementation time
- ❑ NDAs submitted on or after June 30, 2015
  - ✓ Must include new labeling

# FDA Pregnancy and Lactation Labeling Rule (PLLR)

---

## **POTENTIAL WEAKNESSES**

Manufacturers not required to generate new information

- ✓ New drugs are unlikely to have much information

The most information is available on older drugs

- ✓ No requirement to include it if approved before June 30, 2001

Nonprescription drugs are not covered

# Maternal Mental Health

---

- ❑ Onset of mood and anxiety disorders often occurs during the childbearing years:
  - ✓ Up to 30% of pregnant women – affected by prenatal stress, depression, and anxiety  
Kingston DE<sup>1</sup>, Biringer A<sup>2</sup>, McDonald SW<sup>3</sup>, Heaman MI<sup>4</sup>, Lasiuk GC<sup>5</sup>, Hegadoren KM<sup>5</sup>, McDonald SD<sup>6</sup>, van Zanten SV<sup>7</sup>, Sword W<sup>8</sup>, Kingston JJ<sup>5</sup>, Jarema KM<sup>5</sup>, Vermeyden L<sup>5</sup>, Austin MP<sup>9</sup>. *Preferences for Mental Health Screening Among Pregnant Women: A Cross-Sectional Study*. Am J Prev Med. 2015 Jul 2.
  - ✓ Risk factors associated with higher rates of depression during pregnancy: African American, Hispanic, unmarried teens, and pre-existing history of mental illness.
  - ✓ Psychotropic medications for these disorders being taken at conception; medications can cross the placenta,
  - ✓ Discontinuation may lead to relapse, in which case psychiatric symptoms may affect the fetus.
  - ✓ Thoughtful treatment planning presents a dilemma to the clinician

# Maternal Mental Health

---

- ❑ Celexa, Lexapro, Wellbutrin, Paxil, Prozac, Zoloft
- ❑ Risk for major congenital anomalies – conflicting
- ❑ Absolute risk for major anomalies (if any) is small; cardiovascular with Paxil (paroxetine) cannot be excluded
- ❑ Untreated medical condition: a risk for preterm delivery
- ❑ Neonates of mothers treated with SSRIs should be closely followed up after delivery
- ❑ Risks/benefits for mother/child: optimum for both

# Complementary and Alternative Medicine: *For Depressive Disorders*

---

- ❑ Treatments not considered standard or established
- ❑ CAM Meds
  - ✓ SAMe
  - ✓ St John's Wort
  - ✓ Folate
  - ✓ Omega-3 fatty Acids
  - ✓ Bright Light Therapy
  - ✓ Exercise
  - ✓ Accupuncture

# Mental Health Co-morbidities

---

- ❑ Smoking
- ❑ Overweight or obesity
- ❑ Poor nutrition, lack of exercise
- ❑ **Substance abuse; Other drug use/alcohol use**
- ❑ Poor uptake/access to adequate prenatal care
- ❑ Failure to take folic acid supplements prior to becoming pregnant and throughout pregnancy

# Drugs of Abuse

---

- ❑ Alcohol
- ❑ Cigarettes (nicotine)
- ❑ Marijuana
- ❑ Cocaine
- ❑ Methamphetamine
- ❑ Ecstasy/MDMA
- ❑ Heroin
- ❑ Oxycodone (Oxycontin)
- ❑ Hydrocodone (Vicodin)
- ❑ Meperidine (Demerol)
- ❑ Diazepam (Valium)
- ❑ Alprazolam (Xanax)
- ❑ Dextroamphetamine (Dexedrine)
- ❑ Methylphenidate (Ritalin)

# Marijuana (*cannabis*)

---

- ❑ One of the most widely used illicit psychoactive drug in the world
  - ✓ Global estimate of 3.9% world population between 15-64 years old (180.6 million people)
  - ✓ Accepted as “relatively” harmless in many parts of the world, BUT there’s evidence of detrimental impact on the adult brain and developing central nervous system
- ❑ Increase in use from 35% up to 72% in last decade
  - ✓ increases to up to 28% among young, urban, socioeconomically disadvantaged women
- ❑ One of the most commonly used illicit drug in pregnancy and breastfeeding
  - ✓ > 60% of marijuana users continue during pregnancy
- ❑ Flowering plant: sativa, indica and ruderalis
  - ✓ Used for fiber (hemp)
  - ✓ Used for medicinal and psychoactive properties (mediated through cannabinoids)
  - ✓ Generally lipophilic and low molecular weight – cross placenta, blood-brain barrier,
- ❑ Nausea and vomiting
  - ✓ Increase in legalization

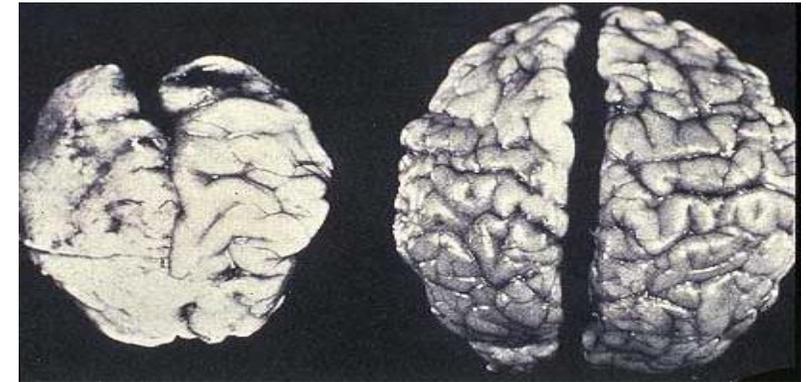
# Fetal Alcohol Syndrome

---

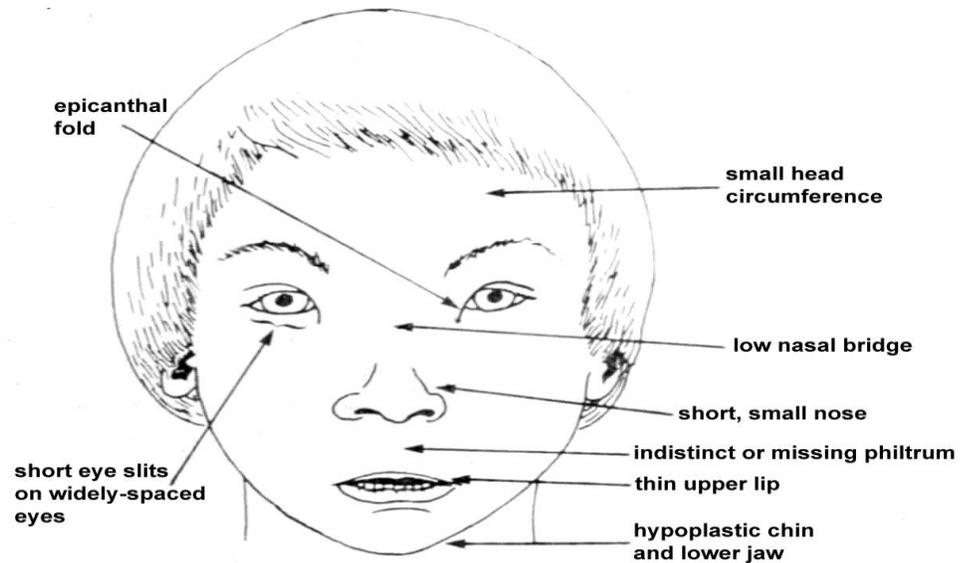
❑ GROWTH: prenatal / postnatal growth deficiency

- ❑ PERFORMANCE (developmental delay):
- ✓ poor attention span & school performance (avg IQ 63)
  - ✓ irritability, hyperactivity,
  - ✓ fine motor dysfunction

❑ FACIES: Microcephaly, short palpebral fissures (eye slits), elongated, smooth philtrum, thin vermilion (lip), maxillary hypoplasia



# Fetal Alcohol Syndrome



Facial Features of Fetal Alcohol Syndrome. After figures by streissguth et al. 1980 and Sulik et al. 1981.



# Marijuana (*cannabis*)

---

- ❑ Current evidence – during pregnancy
  - ✓ No pattern of structural malformations have been identified
  - ✓ Potential adverse health consequences of continued use during pregnancy
  - ✓ Reports of decreased/impaired fetal growth
  - ✓ Reports of increased tremulousness, altered visual response patterns to light stimulus, and withdrawal-like crying
  - ✓ Impacts neuropsychiatric, behavioral and executive functioning
- ❑ Effects of marijuana use as serious as cigarette smoking or alcohol consumption,
  - ✓ Encourage moms to AVOID USE during pregnancy and/or breastfeeding or, at least, decrease use
- ❑ Current evidence – during lactation:
  - ✓ Cannabis and metabolites readily pass in breastmilk
  - ✓ THC concentration may be up to 8-fold mom's plasma concentration
  - ✓ THC (delta 9) – inhibits gonadotropin, prolactin, growth hormones, thyroid-stimulating hormone release affecting quantity/quality of milk
- ❑ Long-term follow-up: VERY CRUCIAL
  - ✓ Neurocognitive and behavioral problems benefit from early intervention - reduces potential difficulties such as delinquency, depression and substance use

# Opioid Prescription

---

- ❑ New surveillance data suggest an increase in prescription opioid use disorder, frequency of use and related deaths
  - ✓ previously, heroin was more common
- ❑ Prevalence of prescription opioid misuse during pregnancy more than doubled in the U.S. from 1992-2008
- ❑ Opioid misuse
  - ✓ Intoxication, Respiratory Depression, Decreased Oxygen supply
  - ✓ Fetal Hypoxemia
  - ✓ Withdrawal – hypertension, tachycardia, decreased placental perfusion
- ❑ Neonatal Abstinence Syndrome (NAS) has more than tripled in the last decade

# Neonatal Abstinence Syndrome (NAS)

---

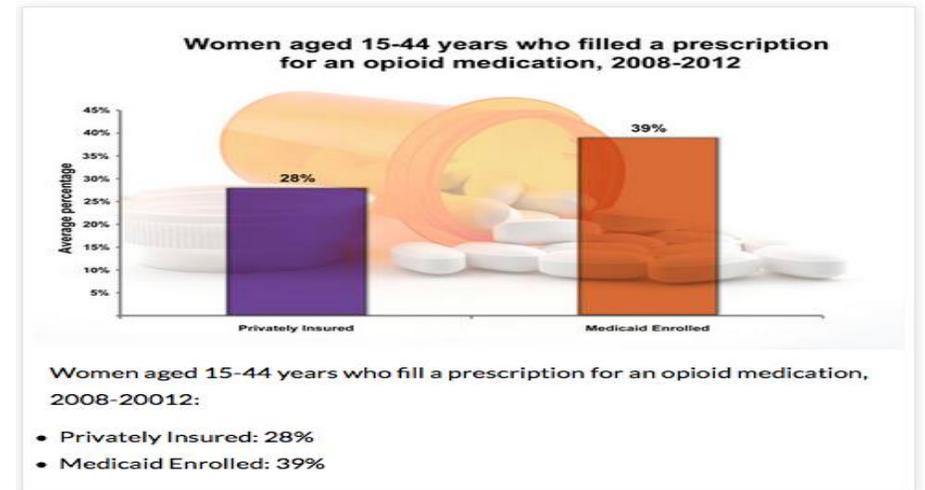
- ❑ Increasing frequency of neonatal abstinence syndrome (NAS)
  - ✓ Can occur with misuse of opioids or taking opioids for chronic pain
  - ✓ About 50% of infants exposed to opioids chronically in utero develop NAS
  - ✓ NAS Typically occurs 48-72 hours post-birth (after prenatal opioid exposure)
  - ✓ CNS hyper-irritability (i.e. increase muscle tone), dysfunction of the autonomic nervous system (sweating), GI tract (vomiting), and respiratory system
  
- ❑ Agency for Healthcare Research and Quality (AHRQ) database
  - ✓ Newborns diagnosed with NAS increased from 1.20 to 3.39 per 1,000 births (2000 and 2009)
  - ✓ Mothers diagnosed as dependent or using opiates at time of delivery increased 1.19 to 5.63 per 1,000 births per year

# Opioid Prescription ~ trends

## Two Insurance Data Sets 2008-12

Centers for Disease Control (CDC)

- ❑ 39 % of Medicaid enrolled women filled an opioid prescription per year
- ❑ 28 % of privately insured women of filled an opioid prescription per year
- ❑ Geographic Distribution
  - ✓ More opioids prescribed to women in the South vs Northeast U.S. (overall)
- ❑ Race-Ethnicity/Medicaid population
  - ✓ 1.5 times higher prescription for white women compared to black and hispanic women



<http://www.cdc.gov/media/releases/2015/p0122-pregnancy-opioids.html>

# Perceptions of Risk (case scenario)

---

- ❑ 30 years old; G2 P0 S0 T1;
- ❑ 8 weeks gestation (6 weeks post-conception)
- ❑ Miconazole (intravaginal)
- ❑ PREGNANCY CHECKLIST:
  - ✓ No tobacco
  - ✓ minimal caffeine,
  - ✓ aspirin prn,
  - ✓ occasional alprazolam,
  - ✓ alcohol



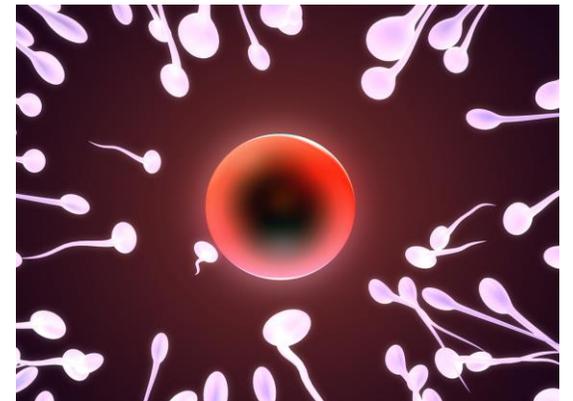
# Paternal (or Male-Mediated) Exposures

---



- ❑ Drugs in seminal fluid
  - ✓ Transported in significant amount (*i.e cocaine*)
- ❑ Drugs, environmental agents, chemicals, radiation, illness or age – induce changes in spermatozoa
  - ✓ Increased Infertility (*i.e. finasteride*)
  - ✓ Increased miscarriages
  - ✓ genetically abnormal children

- ❑ Drugs, environmental agents, chemicals, radiation, illness or age – can these induce epigenetic effects by altering the expression of paternal genes during embryogenesis



# Promote Healthier Babies – *Breastfeed!*

---



# Benefits of Breastfeed for the Infant

---

## **Decreases in risk or severity**

- ✓ diarrhea
- ✓ lower respiratory infections
- ✓ otitis media
- ✓ bacteremia
- ✓ bacterial meningitis
- ✓ botulism
- ✓ Urinary tract infections
- ✓ necrotizing enterocolitis

## **Protects against**

- ✓ SIDS
- ✓ type 1 diabetes mellitus
- ✓ lymphoma
- ✓ allergic diseases
- ✓ ulcerative colitis
- ✓ other chronic digestive diseases

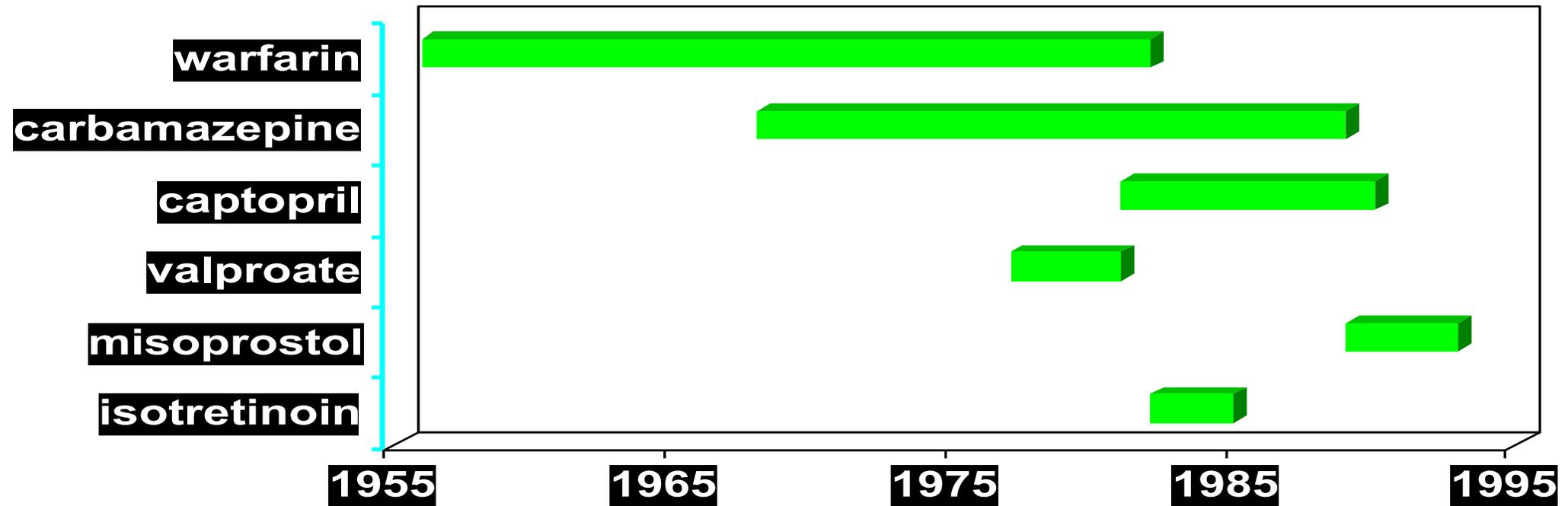
## **Enhances intelligence**

# Benefits of Breastfeeding for the Mother

---

- ❑ Decreased postpartum blood loss
- ❑ More rapid uterine involution
- ❑ Earlier return to pre-pregnancy weight
- ❑ Fertility reduction
- ❑ Lowered risks of breast & uterine cancer
- ❑ Lowered risk of osteoporosis
- ❑ Protection against obesity & type 2 DM
- ❑ Enhanced bonding with infant
- ❑ Increased self-esteem

# How can we improve the *RECOGNITION* of *NEW TERATOGENS*”



*Year drug first marketed to year first recognized as a human teratogen*

# Mom-Baby Follow-up Program

---

- ❑ Prospective observational follow-up; **NOT A CLINICAL TRIAL!**
- ❑ Information collected
  - ✓ Name of Exposure/agent
  - ✓ Exposure Dose and when taken in pregnancy
  - ✓ Potential Confounders
- ❑ Relatively low lost to follow-up (LTFU)
- ❑ Evaluation of a Range of Outcomes
  - ✓ Pattern of major and minor malformation (**Home Visit**)
  - ✓ Adverse Pregnancy Outcome (i.e. Growth Deficiency, Miscarriages)
  - ✓ Neurodevelopmental evaluation (California residents)

# Mom-Baby Follow-up Program

**Experts Call Unhealthy Behaviors Among Pregnant Teens 'Huge' Problem**  
MAY 12, 2015 0 COMMENTS  
May 13, 2015 MotherToBaby Aims To Curb Trend Through New Partnership With 'Healthy Teen Network'  
BRENTWOOD, TN – Drug and alcohol abuse during pregnancy that leads to serious birth defects is something health care providers have often warned the general public about, but the message often struggles to reach pregnant teens – until now. MotherToBaby, [...]  
[Read more](#) [Like](#) 0 [Tweet](#) 0  
News slider

**Is It Normal To Be Anxious During Pregnancy?**  
MAY 7, 2015 0 COMMENTS  
\*May is Maternal Mental Health Awareness Month\* By Elizabeth Salas, MPH, Teratology Information Specialist, MotherToBaby California If you are feeling anxious during your pregnancy, you're not alone. It seems every year there are more articles and news stories on the latest health hazards. Whether you read it online or in a medical journal, hear it [...]  
[Read more](#) [Like](#) 0 [Tweet](#) 0  
Baby Blog slider

**AH-CHOOsing the Best Way to Stifle Seasonal Allergies During**

**Search**  
Enter keywords... [Search](#)

**Videos**  
MotherToBaby CA Specialized Pediatric...  
VIDEO: MotherToBaby CA Offers Specialized Pediatric Exams For Study Participants  
MotherToBaby CA: Who We Are  
Crohn's/Colitis & Pregnancy

**Welcome Baby**  
Cohen Joel Magnan was welcomed to this world by his parents Christine and ... Magnan. He was born on December 21, 2014 at 7:30 am, weighing 7lb 10oz, measuring 19 1/2 inches. MotherToBaby...

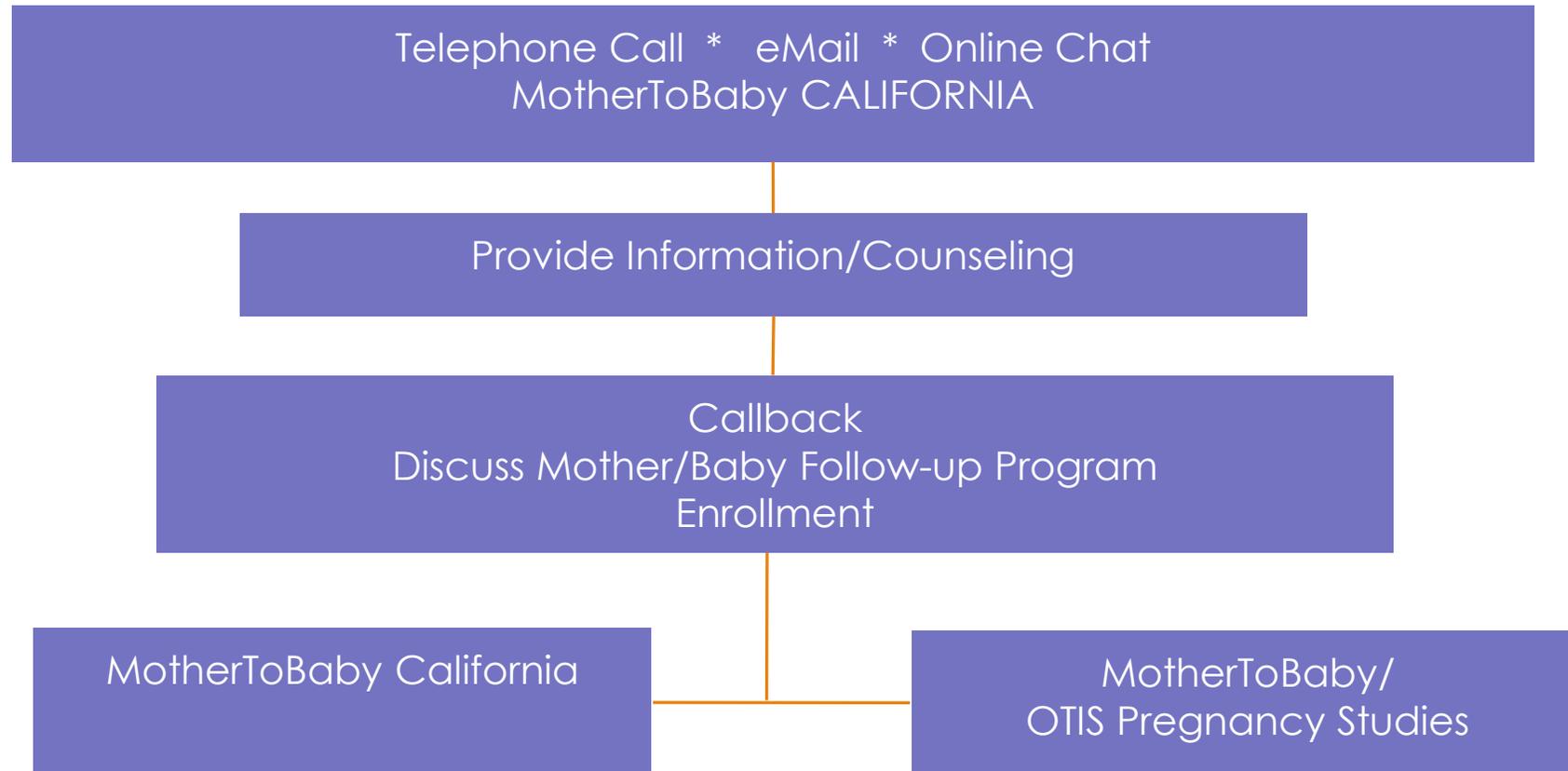


Watch video!

# MotherToBaby California

*Working Conceptual Model – prospective ascertainment of pregnant women*

---



# Vaccines and Medications in Pregnancy Surveillance Systems (VAMPSS)

---

- ❑ New Network To Track Drugs and Vaccines in Pregnancy
- ❑ American Academy of Allergy, Asthma and Immunology
  - ✓ **Organization of Teratology Information Specialist (OTIS)**
  - ✓ Slone Epidemiology Center
- ❑ Federal Fund
  - ✓ Agency for Healthcare Research and Quality (AHRQ)
  - ✓ Biomedical Advanced Research and Developmental Authority (BARDA)
- ❑ Advisory Committee
  - ✓ Center for Disease Control (CDC)
  - ✓ Obstetrics and Pediatric Groups

# MotherToBaby – Benefit to the Public and Healthcare Providers

---

- Reduce calls to clinics
- Support physician care plan
- Clarify misconceptions, allay fears and reduce anxiety
- Discuss appropriate prenatal testing and specialist referrals
- Promote Healthy Behavioral Choices
- Preserve wanted pregnancies

Friendly, expert information about exposures during pregnancy and breastfeeding.

 Call Us Toll Free  
**866-626-6847**  
¡Hablamos Español!

 [Email An Expert](#)

 [Live Chat: Coming Soon](#)

- [Welcome](#)
- [Fact Sheets](#)
- [Pregnancy Studies](#)
- [Find A Service Near You](#)

### Welcome To MotherToBaby

MotherToBaby, a service of the non-profit Organization of Teratology Information Specialists, is dedicated to providing evidence-based information to mothers, health care professionals, and the general public about medications and other exposures during pregnancy and while breastfeeding. Talk directly to the experts behind the most up-to-date research!

- [Health Professionals](#)
- [Fact Sheets](#)
- [F.A.Q's](#)

[Testimonials](#)

You have questions. We have answers.



Call Us Toll Free  
**866-626-6847**  
¡Hablamos Español!



[Email An Expert](#)



[Live Chat: Coming Soon](#)

## Fact Sheets

The experts behind MotherToBaby have created fact sheets that answer frequently asked questions about exposures during pregnancy and breastfeeding. MotherToBaby Fact Sheets are available in both English and Spanish and can be downloaded for free. Currently available fact sheets are listed below by category of exposure. All medications are listed by generic name. The generic name can be found on your prescription or medication packaging listed as the Active Ingredient, or in parentheses after the medication's brand name.

MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. If you have additional questions, or if you do not see your topic of interest listed below, please call us toll-FREE at 1-866-626-6847 to speak with a MotherToBaby expert.

[Health Professionals](#)



[Fact Sheets](#)



[F.A.Q's](#)



[Testimonials](#)

Search for:

[Find Results](#)



**MotherToBaby**

Medications & More During Pregnancy & Breastfeeding  
Ask The Experts

## Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**  
For more information about us or to find a service in your area,  
call **(866) 626-6847**. Visit us online at **www.MotherToBaby.org**.  
Find us! Facebook.com/MotherToBaby or @MotherToBaby on Twitter

### **ACE Inhibitors and Pregnancy**

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to ACE Inhibitors may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

#### ***What is an ACE Inhibitor?***

Angiotensin-converting-enzyme inhibitor (ACE Inhibitor) is the name used to describe a group of medications used to treat high blood pressure. They have also been used for treating problems with the heart and kidneys.

ACE Inhibitors are sold under many names, such as: benazepril (Lotensin®), captopril (Capoten®), cilazapril (Inhibace®), enalapril (Vasotec®, Renitec®), fosinopril, imidapril (Tanatril®), lisinopril (Listril®, Lopril®, Novatec®, Prinivil®, Zestril®), moexipril (Univasc®), perindopril (Aceon®), quinapril (Accupril®), ramipril (Altace®, Prilace®, Ramace®, Ramiwin®, Triatec®, Tritace®), trandolapril (Gopten®, Mavik®, Odrik®) and zofenopril.

#### ***How long do ace inhibitors stay in the body? Should I stop taking it before I try to get pregnant?***

Some of the ACE inhibitor medications are cleared from the body faster than others. The amount of time will vary with each particular medication and might also vary from person to person. Kidney disease can affect the amount of time it takes for your body to clear medication. Your health care provider or pharmacist may be able

# Another *Healthy Baby!*

---



# MotherToBaby ~ A Provider's Resource for *Pregnancy and Lactation*

---

## ❑ MotherToBaby

- ✓ PubMed
- ✓ Micromedex – Reprotox, TERIS, Shepards
- ✓ Brigg's Drugs Pregnancy and Lactation
- ✓ LactMed, Hale, Brigg's, etc.

## ❑ Intergrate available information with your expertise

- ✓ Promote/Support better outcomes for Pregnant women
- ✓ Encourage continued breastfeeding
- ✓ **MotherToBaby \* [mothertobaby.org](http://mothertobaby.org) \* 866.626.6847**