

**THE MOTHERS ACT
(S. 1375)**

INFORMED CONSENT REPRESENTS THE SINGLE MOST IMPORTANT ISSUE IN THE DELIVERY OF HEALTH CARE. INFORMED CONSENT EXISTS ONLY WHEN THERE IS FULL DISCLOSURE OF KNOWN RELEVANT INFORMATION, RISKS AND ALTERNATIVES TO A RECOMMENDED MEDICAL TREATMENT. ONLY IN THIS MANNER CAN PATIENTS MAKE INFORMED DECISIONS. AS DOCUMENTED IN THIS REPORT, THE **MOTHERS ACT** VIOLATES THE PRINCIPLES OF INFORMED CONSENT AND SHOULD NOT BE ENACTED.

EXECUTIVE SUMMARY

I. Background: “The Melanie Blocker-Stokes Postpartum Depression Research and Care Act,” which later became known as the “MOTHERS Act” (S. 1375), is a federal bill that states its purpose is “*To ensure that new mothers and their families are educated about postpartum depression, screened for symptoms, and provided with essential services, and to increase research at the National Institutes of Health on postpartum depression.*” However, a closer look at the bill reveals that it is aimed toward benefiting pharmaceutical/mental health industry interests rather than consumer or patient interests and safety. In fact, the woman for whom the bill was named, Melanie Stokes, was a new mother who was subjected to a full range of psychiatric “treatments” after being diagnosed with postpartum depression, including a cocktail of psychiatric drugs and electroshock. Only after being subjected to brutal treatments and drugs documented by the U.S. Food and Drug Administration (FDA) to cause suicidal ideation, did she commit suicide.

II. Screening Reliability Flawed: The MOTHERS Act calls for using a screening methodology (the Edinburgh Postnatal Depression Scale or EPDS) that has resulted in many women being misdiagnosed—in fact, according to a study published in *Obstetrics & Gynecology*, this method triples the number of women diagnosed with postpartum depression. According to a study in the *Scandinavian Journal of Public Health*, Swedish scientists stated that this particular screening methodology is unethical and should not be used.

III. Expanding Postpartum Depression Treatment to Include Pregnant Women: Despite the definition of “postpartum” being “occurring in or relating to the period immediately after childbirth” (*Encarta College Dictionary*) the MOTHERS Act redefines this by stating “Postpartum depression is a devastating mood disorder which strikes many women *during and after pregnancy.*” This means that, per the language of the bill, not only will women who have just given birth be screened for postpartum depression, but *pregnant women* will also be screened for postpartum depression and referred for treatment, including medication (antidepressants)—the only recommended “medical” treatment mentioned in the bill.

IV. Warnings/Studies Showing Risks Associated with Antidepressants and Pregnant Women or New Mothers: There is ample evidence to support that serious risks are associated with placing pregnant women or new mothers on antidepressant drugs, including miscarriages and birth defects that are sometimes fatal. These include warnings from the Australian Therapeutic Goods Administration, the FDA and Health Canada and studies in the *Archives of General Psychiatry* and the journal *Epidemiology*.

V. FDA’s MedWatch System Already Has Overwhelming Evidence of Spontaneous Abortions, Premature Babies and Birth Defects from Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressants: These figures come from the FDA’s adverse drug reports from 2004-2007 and are only cases where antidepressant use during pregnancy was reported as the *primary suspect drug* in the adverse event:

145 spontaneous abortions; 150 premature babies; 208 babies born with heart disease; 218 babies born with other birth defects. What is particularly alarming is by the FDA's own admission, only 1-10% of side effects to prescription drugs are ever reported to the FDA, so the actual numbers could be 10 times higher than the reported figures.

VI. The MOTHERS Act—A Violation of Informed Consent: There is no language in the MOTHERS Act requiring that women get *all* available drug regulatory warnings about the risks of the commonly recommended drugs for postpartum depression: antidepressants. There is no information in the bill requiring women receive information on all available medical treatments—not just drugs—for any pre- or postnatal difficulties thereby violating informed consent procedures. Women need to be provided complete information—including data on viable alternative medical treatments to psychotropic drugs—in order to be able to make a fully informed decision.

THE MOTHERS ACT (S. 1375)

I. Background:

"The Melanie Blocker-Stokes Postpartum Depression Research and Care Act," which later became known as the "MOTHERS Act" (S. 1375), is a federal bill that states its purpose is *"To ensure that new mothers and their families are educated about postpartum depression, screened for symptoms, and provided with essential services, and to increase research at the National Institutes of Health on postpartum depression."*

However, a closer look at the bill reveals that it is aimed toward benefiting pharmaceutical/mental health industry interests instead of consumer or patient safety. The bill is named after Melanie Stokes, who in 2001 was diagnosed with postpartum depression, prescribed a cocktail of extremely dangerous psychiatric drugs including antipsychotic, antianxiety and antidepressant drugs and then was given electroshock treatment. It was only after she received all this standard mental health treatment (including hospitalization) and drugs documented by the FDA to cause worsening depression and suicidal ideation, that she committed suicide.

II. Screening Reliability Flawed:

Incredible as it may seem, the MOTHERS Act uses the Melanie Stokes tragedy not as a warning of the documented risks associated with putting new mothers on antidepressant drugs, but as a federal incentive to get more pregnant women and new mothers on drugs. The language of the bill states that the only "medical" treatment that works to treat postpartum depression is "medication." There are no mentions of any alternative medical treatments, just drugs. Furthermore, the bill calls for using a screening methodology (the Edinburgh Postnatal Depression Scale or EPDS), which, according to a study published in *Obstetrics & Gynecology*, triples the number of women diagnosed with postpartum depression.¹ According to a study in the *Scandinavian Journal of Public Health*, Swedish scientists warned that this particular screening methodology is unethical and should not be used, stating, "...we argue that routine EPDS screening of Swedish postpartum women would lead to considerable ethical problems due to the weak scientific foundation of the screening instrument."²

III. Expanding Postpartum Depression Treatment to Include Pregnant Women:

Despite the definition of "postpartum" being "occurring in or relating to the period immediately after childbirth" (*Encarta College Dictionary*) the MOTHERS Act redefines this by stating "Postpartum depression is a devastating mood disorder which strikes many women *during and after pregnancy.*" This means that not only will women be screened and treated for depression after childbirth, but *while they are still pregnant.*

There is no question that a woman's body can go through many upheavals during pregnancy and/or childbirth. But there are standard, safe medical treatments that can be used instead of drugs—the frontline treatment being offered for women diagnosed with postpartum depression despite the documented risks. Julian Whitaker, M.D., founder of the Whitaker Wellness Institute in California, says, "Add psychiatric drugs to the hormonal imbalance that occurs at birth and you've potentially created a time bomb."

IV. Warnings/Studies Showing Risks Associated with Antidepressants and Pregnant Women or New Mothers:

There is ample evidence to support the risks associated with placing pregnant women or new mothers on antidepressant drugs:

- **September 7, 2005:** The Australian Therapeutic Goods Administration issued an information sheet to health professionals warning that SSRI antidepressant use—especially Paxil—in early pregnancy could cause congenital [defect at birth] heart abnormalities in newborns.³
- **September 27, 2005:** The FDA and GlaxoSmithKline issued a warning that pregnant women taking Paxil or other antidepressants during their first trimester of pregnancy placed their newborns at increased risk of major congenital and cardiovascular [heart] malformations at birth.⁴
- **February 9, 2006:** *The New England Journal of Medicine* found that mothers who took SSRI antidepressants in the second half of their pregnancies were six times more likely to give birth to infants with a lung disorder called persistent pulmonary hypertension (PPHN). The condition occurs when a newborn's circulation system does not adapt to breathing outside the womb and causes high pressure in the blood vessels of the lungs making them unable to get enough oxygen into their bloodstream and can be fatal. Between 10% and 20% of infants with PPHN die even if they receive treatment.⁵
- **March 10, 2006:** Based on *The New England Journal of Medicine* study, Health Canada issued a warning that SSRI antidepressants and other newer antidepressants, when taken by pregnant women, placed newborns at risk of developing PPHN.⁶
- **April 6, 2006:** A Canadian study from the University of Ottawa, published by the *American Journal of Obstetrics and Gynecology*, found pregnant women who used SSRI antidepressants were more likely to have premature and low birth weight babies.⁷
- **July 19, 2006:** The FDA warned of the risk of a fatal lung condition in newborns whose mothers took SSRI antidepressants during pregnancy. The agency added it was seeking more information about persistent pulmonary hypertension in newborns in connection with the drugs. It asked drug makers to list the potential risk on their drug labels.⁸
- **August 2006:** An *Archives of General Psychiatry* study found that women who take antidepressants during pregnancy are at risk of giving birth to children with respiratory problems.⁹
- **November 2006:** The journal *Epidemiology* published a study entitled "Maternal Use of Selective Serotonin Reuptake Inhibitors and Risk of Congenital Malformations." It found that pregnant women who take SSRI antidepressants are more likely to have babies with birth defects than mothers who don't take these drugs.¹⁰
- **August 2007:** *The American Journal of Psychiatry* published a study that determined that antidepressant use during pregnancy was associated with premature births.¹¹
- **September 18, 2007:** A study published in the *Annals of Internal Medicine* of nearly 500,000 women by researchers at the University of Pittsburgh Medical Center found that nearly 50% of women taking a prescription drug that could cause birth defects did not receive warnings to avoid pregnancy.

Moreover, experts say the seriousness of PPHN—found six times more often in infants born to mothers who take *antidepressants* during pregnancy—is not being adequately conveyed to women while they are considering whether to use the drugs.¹²

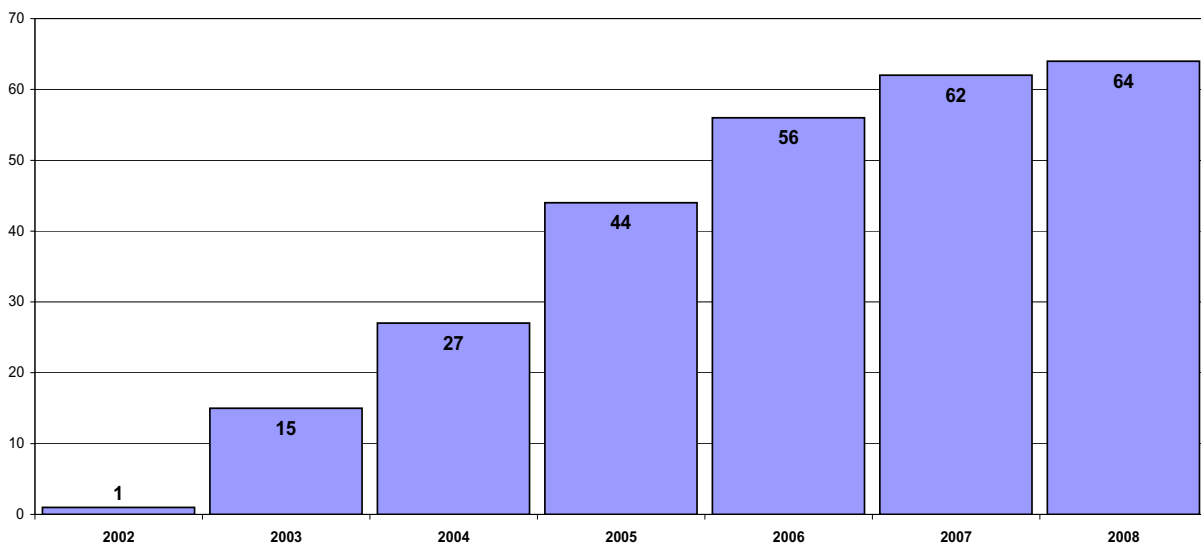
- The *Physicians' Desk Reference* states: "Like many other drugs, paroxetine [chemical name for the antidepressant Paxil] is secreted in human milk, and caution should be exercised when Paxil...is administered to a nursing woman."

Warnings Showing Risks Associated with Antidepressants and the General Public:

- **March 22, 2004:** The FDA warned that SSRI antidepressants could cause "anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia [severe restlessness], hypomania [abnormal excitement] and mania [psychosis characterized by exalted feelings, delusions of grandeur]."
- **October 15, 2004:** The FDA ordered pharmaceutical companies to add a "black box" warning to antidepressant packaging, stating that the drugs could cause suicidal thoughts and actions in children and teenagers. It also directed the manufacturers to print and distribute medication guides with every antidepressant prescription and to inform patients of the risks.¹³
- **June 30, 2005:** The FDA issued a Public Health Advisory entitled "Suicidality in Adults Being Treated with Antidepressant Medications," that there could be an increased risk of suicidal behavior in adults taking antidepressants. It recommended that physicians monitor adults who took antidepressants for suicidal tendencies.¹⁴
- **May 2, 2007:** The FDA officially extended the existing black box warning on all antidepressant medications, about increased risks of suicidal thinking and behavior, from children and adolescents under 18 to young adults ages 18 to 24.¹⁵

There has been a 6,300% increase in the number of government drug regulatory agency warnings and drug company warnings issued between 2002 and 2008.

ANTIDEPRESSANT WARNINGS 2002-2008
THE WARNINGS ON ANTIDEPRESSANT DRUGS CONTINUE TO GROW
(CUMULATIVE)

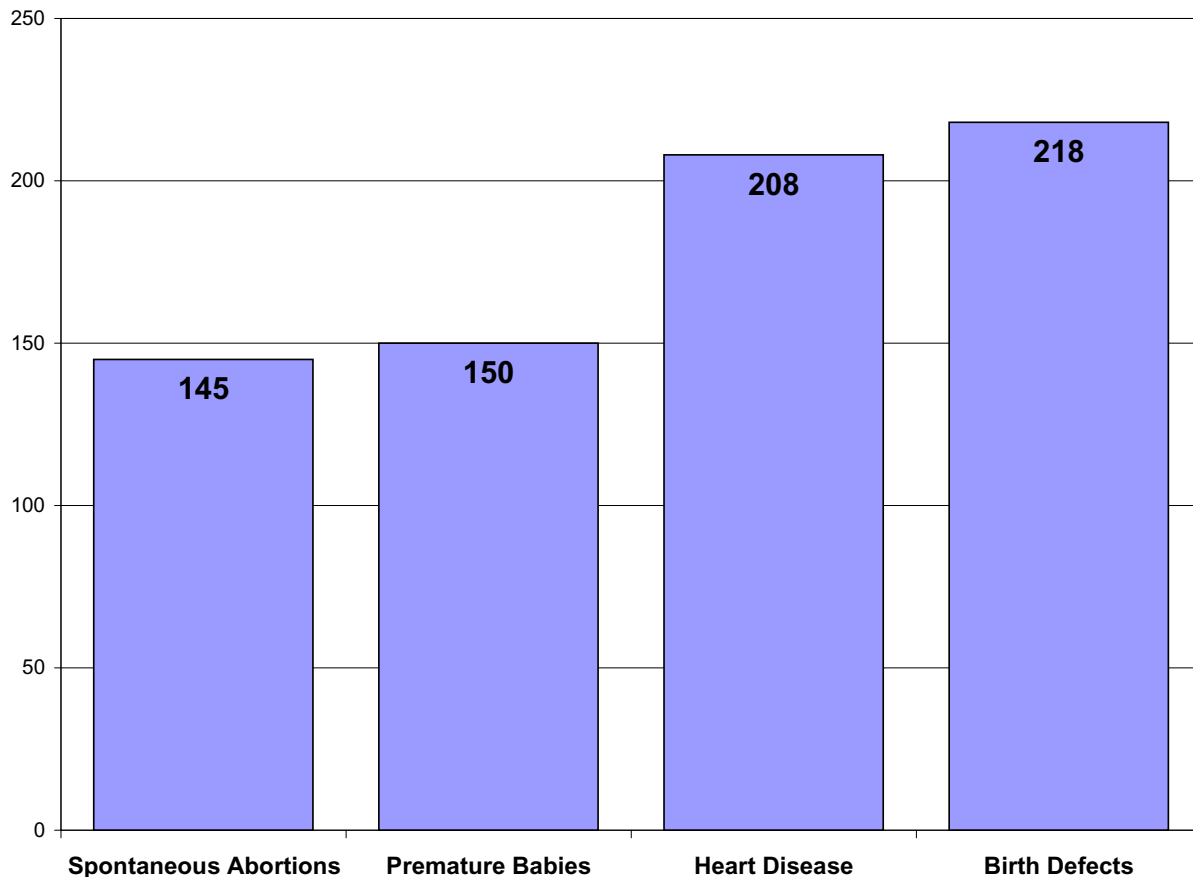


V. FDA's MedWatch System Already Has Overwhelming Evidence of Spontaneous Abortions, Premature Babies and Birth Defects from SSRI Antidepressants:

Doctors, other health care providers, pharmacists, lawyers and consumers filed the following adverse drug reaction reports with the FDA's MedWatch system over a four-year period (2004-2007) concerning pregnant women taking the newer SSRI antidepressants (Prozac, Paxil, Zoloft, Celexa, Lexapro, etc.).

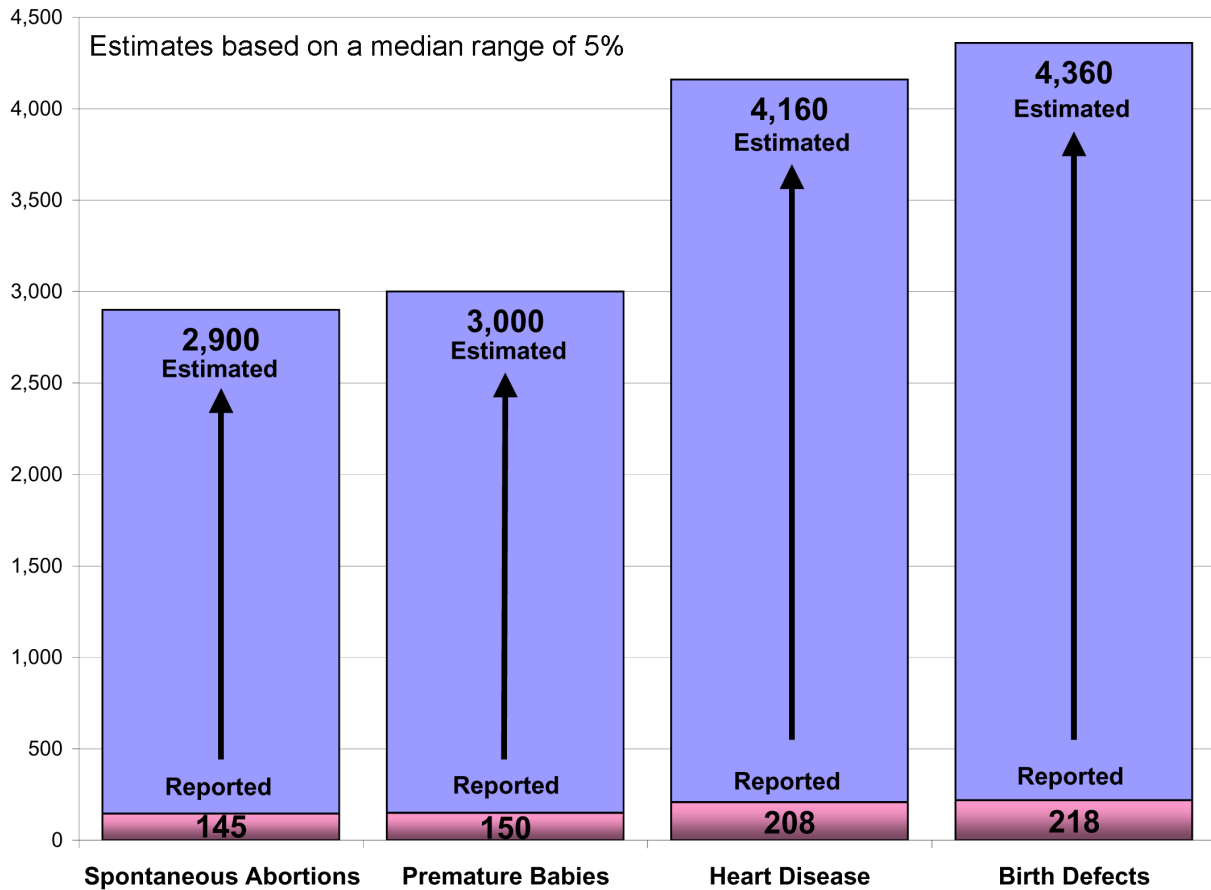
It is important to note that in all these cases, antidepressants were cited as the primary suspected drug to have caused the adverse reaction in pregnant women: 145 spontaneous abortions; 150 premature babies; 208 babies born with heart disease; 218 babies born with defects.

ADVERSE DRUG REACTIONS REPORTED TO THE U.S. FDA'S MEDWATCH REPORTING SYSTEM CONCERNING PREGNANT WOMEN TAKING SSRI ANTIDEPRESSANTS FROM 2004-2007



By the FDA's own admission, only 1-10% of adverse drug reactions are ever reported to the FDA. Using a median range of 5% being reported, the actual number of pregnant women experiencing adverse reactions to antidepressant drugs is estimated below:

**ESTIMATED SSRI SIDE EFFECTS BASED ON FDA STATEMENT
THAT ONLY 1-10% OF SIDE EFFECTS ARE REPORTED**



The MOTHERS Act, under the guise of helping women during pregnancy or birth by treating their emotional upheavals with antidepressants, could factually result in thousands of spontaneous abortions and tens of thousands of babies being born with birth defects or being born prematurely each year in the U.S.

"Informed consent not only ensures the protection of the patient against unwanted medical treatment, but it also makes possible the active involvement of the patient in her medical planning and care."

- The Committee on Ethics of the American College of Obstetricians and Gynecologists

VI. The MOTHERS Act—A Violation of Informed Consent:

There is no language in the MOTHERS Act requiring that women get all available drug regulatory warnings about the risks of the drugs. There is no information in the bill requiring women receive information on all available medical treatment for any pre- or postnatal difficulties—not just drugs—thereby violating informed consent procedures. There is no guarantee this information will be given to pregnant women and new mothers so they can make a safe decision for themselves and their children.

Informed consent is a legal doctrine that has been developed by the courts over a number of years. It requires that medical doctors provide a patient with all relevant information about a proposed procedure or treatment prior to obtaining the consent of the patient to carry out the procedure or treatment. Informed consent protects the patient by providing him/her with complete information on which to make an informed decision.

The American Medical Association defines informed consent as follows:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

The MOTHERS Act violates informed consent as it will not ensure that patients are given the above information. It is a pharmaceutical friendly bill, not a consumer friendly bill, intended to broaden the base of women being prescribed antidepressants despite the potential risks involved to mothers and newborns.

REFERENCES

1. Georgiopoulos, *et al.*, "Population-Based Screening for Postpartum Depression," *Obstetrics & Gynecology*, Vol. 93, 1999, pp. 653-657.
2. Frantz, *et al.*, "Screening for postpartum depression with the Edinburgh Postnatal Depression Scale (EPDS): An ethical analysis," *Scandinavian Journal of Public Health*, Vol. 36, No. 2, 2008, pp. 211-216.
3. "Information for health professionals concerning the use of SSRI antidepressants in pregnant women," Australian Therapeutic Goods Administration, 7 Sept. 2005.
4. "Important Prescribing Information," Letter to health care professionals by GlaxoSmithKline, Sept. 2005; Miranda Hitti, "New Study Links Paxil to Twice as Many Birth Defects as Other Antidepressants," *WebMD Medical News*, 27 Sept. 2005.
5. Christina D. Chambers, Ph.D., M.P.H., Sonia Hernandez-Diaz, M.D., Dr.P.H., Linda J. Van Marter, M.D., M.P.H., Martha M. Werler, Sc.D., Carol Louik, Sc.D., Kenneth Lyons Jones, M.D. and Allen A. Mitchell, M.D., "Selective Serotonin-Reuptake Inhibitors and Risk of Persistent Pulmonary Hypertension of the Newborn," *The New England Journal of Medicine*, Vol. 354, 2006, pp. 579-587.
6. "Newer antidepressants linked to serious lung disorder in newborns," Health Canada Advisory, 10 Mar. 2006.
7. Shi Wu Wen, MB, Ph.D., Qiuying Yang, M.D., Ph.D., Peter Garner, M.D., *et al.*, "Selective serotonin reuptake inhibitors and adverse pregnancy outcomes," *American Journal of Obstetrics and Gynecology*, Vol. 194, 2006, pp. 961-966.
8. "Antidepressants should list new risks: FDA," *Reuters*, 19 July 2006.
9. Tim F. Oberlander, M.D., FRCPC; William Warburton, Ph.D.; Shaila Misri, M.D., FRCPC; Jaafar Aghajanian, B.Sc.; Clyde Hertzman, M.Sc., M.D., FRCPC, "Neonatal Outcomes After Prenatal Exposure to Selective Serotonin Reuptake Inhibitor Antidepressants and Maternal Depression Using Population-Based Linked Health Data," *Archives of General Psychiatry*, Vol. 63, Aug. 2006, pp. 898-906.
10. Pia Wogelius, Mette Nørgaard, Mette Gislum, Lars Pedersen, Estrid Munk, *et al.*, "Maternal Use of Selective Serotonin Reuptake Inhibitors and Risk of Congenital Malformations," *Epidemiology*, Vol. 17, No. 6, Nov. 2006.
11. Rita Suri, M.D., Lori Altshuler, M.D., Gerhard Helleman, Ph.D., Vivien K. Burt, M.D., Ph.D., Ana Aquino, B.S., Jim Mintz, Ph.D., "Effects of Antenatal Depression and Antidepressant Treatment on Gestational Age at Birth and Risk of Preterm Birth," *American Journal of Psychiatry*, Vol. 164, Aug. 2007, pp. 1206-1213.
12. Eleanor Bimla Schwarz, M.D., M.S.; Debbie A. Postlethwaite, RNP, M.P.H.; Yun-Yi Hung, Ph.D., and Mary Anne Armstrong, M.A., "Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women," *Annals of Internal Medicine*, Vol. 147, Iss. 6, 18 Sept. 2007, pp. 370-376.
13. "Suicidality in Children and Adolescents Being Treated With Antidepressant Medications," FDA Public Health Advisory, 15 Oct. 2004.
14. "Suicidality in Adults Being Treated with Antidepressant Medications," FDA Public Health Advisory, 30 June 2004.
15. "FDA Proposes New Warnings About Suicidal Thinking, Behavior in Young Adults Who Take Antidepressant Medications," FDA News, 2 May 2007.

