

## THE TATIA ODEN FRENCH MEMORIAL FOUNDATION

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LIVES OF THOSE GIVING LIFE TO OTHERS

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Acting Commissioner  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Dear Commissioner,

The Tatia M. French Oden Foundation is organizing a consumer group which is petitioning the FDA because of adverse events with the use of G.D. Searle's (now Pharmacia) drug Cytotec, (Misoprostol) for cervical ripening or labor induction. The Board and employees of this Foundation as well as signatories to this petition are: people who are related to or have friends (as well as their babies) who died because of the misuse of this product, and some of them were given the drug, with no warning information about its use.

The action that we are requesting of the FDA is the establishment of a much better regulation of this product in its off-label use in obstetrics for cervical ripening and induction of labor. We recognize that the drug may well have a legitimate use in the prevention of stomach ulcers in people taking daily aspirin (the use for which the FDA approved it), as well as its use in combination with RU-486 for abortion, for treatment of postpartum hemorrhage (but only if the mother hasn't already been given the drug to induce labor), and for the comparatively rare need to induce labor in the case of a dead fetus when labor fails to start within 2-3 weeks. In the two latter cases, the life of the mother may already be in danger from the real or potential loss of blood, so the risk may be warranted. We also recognize the right to early pregnancy termination.

Specifically, we request the FDA to revisit the issue of drug labeling of Pharmacia's drug, Cytotec. G.D. Searle, the original manufacturer of the product included a "Black Box" warning to pregnant women in its packaging for the first several years of its obstetrical use. On August 23, 2000, the company took an even stronger step and issued a statement sent to 200,000 health care providers throughout the U.S. We quote from this statement:

"The uterotonic effect of Cytotec is an inherent property of prostaglandin E1 (PGE1), of which Cytotec is a stable, orally active, analog. Searle has become aware of some instances where Cytotec, outside of its approved indication, was used as a cervical ripening agent prior to termination of pregnancy, or for induction of labor, in spite of the specific contraindications to its use during pregnancy.

Serious adverse events reported following off-label use of Cytotec in pregnant women include *maternal or fetal death, uterine hyper-stimulation, rupture or perforation requiring uterine surgical repair, hysterectomy or salpingo-oophorectomy, amniotic fluid embolism, severe vaginal bleeding, retained placenta, shock, fetal bradycardia and pelvic pain.* (Our italics)

On May 31, 2002, the American College of Obstetricians and Gynecologists announced that the FDA had announced on April 17, 2002, a revision in the drug labeling of Pharmacia's drug, Cytotec. The label change acknowledged the

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widespread off-label use of Cytotec by obstetricians for cervical ripening to induce labor and "removed the previous contraindication for use in pregnant women for this purpose."

We ask that the original labeling be restored and that the FDA make publicly known the adverse event reports that have been associated with this drug. People all across this great country assume that is what the FDA is for. You are supposed to be the early warning system and protect the public from unwarranted use of dangerous drugs. If the manufacturer itself warns of death as a possibility for both mother and child, the FDA should make this known.

Tatia Malika Oden French and her daughter are only two of the people who would be alive today had the FDA made the Searle announcement available to consumers via its website. They both died because of the amniotic fluid embolism that Tatia experienced, shortly after being administered her second dose of Cytotec on December 27, 2001. That is a fact. If her health care provider, an obstetrician, had informed her of the August 23 letter that her office received from G.D. Searle, she would never have taken the drug. But her obstetrician chose not to share this information with her.

*You, the FDA, have a duty to publish, at the very least, all of the possible adverse events that have been reported to the manufacturer, including those published by the original manufacturer when it is bought by a larger company.*

This is a lesson that many of the U. S. public assume was learned after 2 million women were given DES during the 1950s and 1960s, leading to adenosis, high cancer rates as adolescents and young adults, genital abnormalities, higher incidences of infertility, as well as higher rates of ectopic pregnancy, miscarriage and premature dilation. The lesson of this monumental tragedy should not be lost to the current staff of the FDA and the generation of childbearing women and their babies whose lives depend upon the information disseminated by the FDA.

Your website instructs petitioners to include information "known to the petitioner that may be unfavorable to the petitioner's position." Accordingly:

1. Cytotec is effective at inducing labor, even in women whose cervixes aren't ripe and ready for birth.
2. The safe use of Cytotec for induction is questionable because there have NOT been significant approved and documented trials on women to test its safety when used to induce labor. Therefore it is very cheap.
3. Women have been taught to demand Cytotec, unaware of its adverse effects.
4. Cytotec is easy to administer.
5. Cytotec allows physicians and women more control over the time of birth.

The FDA has an even more important role in play than it would bear if the U.S. were a country with reliable data on maternal mortality and morbidity or with mandatory mortality and morbidity reporting. The Centers for Disease Control itself says that its data on maternal mortality are "grossly underreported." (1-8)

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**SUMMARY OF FDA PETITION**

**Tatia Malika Oden French and her daughter Zorah Allie Mae both died during childbirth, after being given the "off label drug", CYTOTEC to induce her labor. Cytotec is NOT approved by the FDA for use in inducing labor.**

The Tatia Oden French Memorial Foundation is petitioning the FDA to establish better regulations of CYTOTEC. Specifically, we want the FDA to let the public know ALL the side effects of Cytotec when used to induce labor , upto and including maternal and infant death.

The FDA is supposed to be an early warning system for the public regarding drugs. This petition asks them to fulfill that responsibility.

Please help us in this effort by signing.

Thank you.