

CYTOTEC - Not Safe for Induction



LAW OFFICES OF
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The jury is returning with a verdict:

Cytotec is NOT safe for induction of labor!

More and more women and their obstetricians or midwives are removing the mystery, not to mention the hurried trip to the hospital, by chemically timing their births. Drugs are used to force birth to happen on a schedule that may be medically necessary, or simply, more convenient. Of the more than 4,000,000 births in the US annually, over 800,000 are now induced each year. These numbers demonstrate more than a doubling of the rates of induced births since 1989, with a sharp increase in the number of elective inductions, i.e., inductions done for convenience without medical indications. In 2002, *Cytotec*® was used in about 5% of those inductions.

BUT how many of those mothers who are induced are "informed," that is, how many really understand that any induction, but especially an induction using *Cytotec*®, places them and their baby at an increased risk for harm and death?

Cytotec® is a drug that was ***not tested in the laboratory*** to determine its safety before doctors starting using it as an agent to induce labor, and its manufacturer recommends ***against its use in inducing labor***. Instead, it was and is tested in real life labor and delivery, and unwitting mothers are the guinea pigs. In some cases, *Cytotec*® imposes risks that far outweigh the benefits of a delivery that takes place at a convenient time. What's worse, it is often impossible to predict whether or when those risks will be realized. Some of the other medications that are used to induce labor, such as Pitocin or Cervadil, can rapidly be discontinued if problems develop. But unlike Pitocin or Cervadil, once *Cytotec*® is given, either in a pill form by mouth, or inserted vaginally, so there is no way to stop its action, ***even if trouble occurs***. The reason *Cytotec*® is used instead of other, safer drugs, is simply that it is cheaper. **[\[Click here to view the A.C.O.G statement.\]](#)**

Cytotec® can cause abnormally strong uterine contractions (hyperstimulation or tetany) so strong that the uterus ruptures, resulting in severe injury or death of the mother and child. It can cause such heavy bleeding that to save the

mother's life, her uterus must be removed (hysterectomy), leaving her incapable of bearing another child, and disrupting her natural hormones. The violent contractions it provokes also increase the risk of amniotic fluid emboli that can result in a stroke or death. The effect of *Cytotec* on later growth, development of a child has not been established. Many, or maybe most doctors and nurses using this drug do not know these risks their patients face.

Following are more facts about Cytotec®:

Cytotec® is the trade name given by pharmaceutical company, Searle (then Pharmacia and now a product of Pfizer), for the drug, Misoprostol or prostaglandin E1. *Cytotec*® is still made by only one manufacturer in the U.S. *Cytotec*® was invented to treat gastric ulcers, and that is the only use that it manufacturer recommends for it.



- *Cytotec*® is **not approved** by the U.S. Food and Drug Administration, nor by its manufacturer, for cervical ripening and labor induction.
- Searle, the original manufacturer of *Cytotec*® sent all physicians a **Drug Alert** (also called a "Dear Doctor letter") in August of 2001, warning that *Cytotec*® may cause uterine rupture, and recommending against its use for induction of labor.
- The FDA then posted Searle's letter, using it as their own "Safety Alert" to interested parties.
- Searle placed warnings on the drug label "not to be used in women who are pregnant." These warnings remain on

* The picture to the right is of Mark R. Bower, a Plaintiff's Attorney, who is committed to representing women and infants who have been harmed by the misuse of *Cytotec* and other drugs and interventions used in Obstetrics.

- Searle placed warnings on the drug label not to be used in women who are pregnant. Those warnings remain on the current package insert. *The silhouette of the pregnant woman with the slash through it at the top of this page actually appears on every Cytotec® box. [Click here to view the entire label and read its warnings, written in unmistakable terms.]*



- The American College of Obstetricians and Gynecologists has declared that Cytotec® should never be used to induce a vaginal delivery following a Cesarean Section, which is also called a "VBAC" (Vaginal Birth After Cesarean).
- Cytotec® occasionally, unpredictably causes uterine ruptures in women who have no identifiable risk factors.

In spite of these problems, rather than falling out of vogue, Cytotec is being used more and more each year. This is not an appropriate response to a drug that has demonstrated such risks to mothers and babies for more than a decade:

- Without clinical research to confirm its safety;
- Used in spite of being "off label";
- Used against the advise of both its manufacturer and the FDA; and
- Resulting in countless medical disasters, deaths of both mothers and fetuses and leaving others disabled to varying degrees for life.
- Real life catastrophic outcomes that resulted from using this drug can be viewed in the following news stories:

CBS News Story <http://www.wsmv.com/video/13210018/index.html>

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