THE TATIA ODEN FRENCH MEMORIAL FOUNDATION

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SEVERE ADVERSE EVENTS FROM USE OF DRUG IN PREGNANT WOMEN SPURS FOUNDATION TO SUBMIT CITIZEN PETITION TO THE FDA

Foundation petitions FDA to conduct Sentinel Study on drug commonly used to induce labor despite contraindication in pregnancy

Washington, D.C. (April 26, 2017) – The Tatia Oden French Memorial Foundation announced today that it has submitted a Citizen Petition to the U.S. Food and Drug Administration (FDA) for a Sentinel Study on the unapproved use of misoprostol (marketed as Cytotec) for labor induction. Cytotec, a drug approved by the FDA to treat gastric ulcers, is commonly used off-label to induce labor despite being contraindicated for pregnant women. Through this petition, the Foundation ultimately aims to restrict the use of Cytotec in labor induction.

"The U.S. has the most expensive and arguably the most advanced healthcare system in the world and yet we are ranked 50th in the world when it comes to maternal mortality rates. This is unacceptable," said Maddy Oden, Executive Director of the Tatia Oden French Memorial Foundation. "Unnecessary interventions and off-label use of drugs are contributing to our country's abysmal maternity care outcomes. We hope that through this petition, we move one step closer to improving maternity care by driving the FDA to take actions that will help end the unnecessary use of Cytotec for labor induction."

In the United States, Cytotec is approved as an oral tablet indicated for reducing the risk of NSAID-induced gastric ulcers. For nearly two decades, the drug has been used off-label to ripen the cervix and induce labor in pregnant women.[1] While off-label prescribing of drugs is a common and legal practice, the FDA's classification of Cytotec as a Pregnancy Category X drug—meaning the risk of prescribing the drug to pregnant women outweighs the potential benefits—prescribing the drug to pregnant women, we feel, contradicts the healthcare provider's duty to first, do no harm. The use of the drug for this purpose is even more egregious when factoring in that there is currently an FDA-approved medication in the market indicated for cervical ripening.

Since Cytotec is not approved for labor induction or cervical ripening, the FDA does not provide recommended dosage or administration of the drug for these purposes.[2] Therefore, use of the drug can vary greatly from patient to patient, putting those who are sensitive to the drug at a higher risk of a serious reaction if given too high of a dose. Once the drug has been administered there is no way of stopping or reversing its effects. As such, many serious adverse events have resulted from this use of Cytotec, including hyper-stimulation of the uterus, uterine rupture, fetal distress, fetal brain damage and even death to the mother and child.[3]

To date, the FDA has relied on voluntary reporting from healthcare professionals and patients through the Adverse Event Reporting System (FAERS) to monitor the safety of Cytotec. Since healthcare professionals are not required to report on off-label uses of drugs, the Foundation suspects adverse events associated with Cytotec are greatly underreported. The Sentinel System is a nationwide database of over 193 million electronic health records designed to complement FAERS, which can alert the FDA to potential health risks but relies on limited data.[4] The FDA can proactively access Sentinel data to gain a better

understanding of the safety risks of a certain drug in a relevant population. By petitioning the FDA to conduct a Sentinel query, the Foundation hopes that FDA will have the information it needs to take actions to assure patient safety, which can include updates to Cytotec's prescribing information, safety alerts or other action deemed appropriate by the FDA.

"In addition to pushing the FDA to restrict the use of Cytotec for labor induction, we hope to raise awareness among consumers of the dangers of Cytotec," stated Maddy Oden. "As a doula, I encourage my patients to ask their doctors about the risks, benefits and alternatives of any drug or intervention they are given, especially when they are being used off-label. Patients should understand that they have the right to say no to any intervention or drug they do not want to receive."

The Foundation is an educational non-profit organization dedicated to empowering women around the issues of childbirth and pregnancy. It is currently focused on the issues of maternal mortality and the racial disparities in maternal care, fully informed consent and the contraindicated use of Cytotec for labor induction. The Foundation previously submitted a Citizen Petition to the FDA seeking further regulation of Cytotec, prompting the FDA to issue a patient information sheet that outlined the risks associated with the use of Cytotec for cervical ripening and labor induction. The information sheet also stated that no company has sent the FDA scientific proof that the drug is safe and effective for these uses.

The Foundation will be hosting a free educational event focused on improving U.S. maternity care in Washington, DC on May 1, 2017 at the Kaiser Family Foundation's Barbara Jordan Conference Center. For event details and registration, visit: https://usmaternitycare.eventbrite.com

For more information about the Citizen Petition and how to help impact FDA's decision, please visit https://tatia.org/our-work/fda-petition/. To read the petition and/or submit a comment, go to www.regulations.gov and enter **FDA-2017-P-2563-0001** in the search box.

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About the Tatia Oden French Memorial Foundation
The Tatia Oden French Memorial Foundation is a 501(c)(3) non-profit organization dedicated to empowering women around the issues of childbirth and pregnancy. The Foundation aims to address the issue of maternal mortality in the U.S. by educating women about the off-label use of drugs in childbirth and the importance of being fully informed before providing consent to any medical intervention. For more information about the Foundation, visit www.tatia.org.

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[1] Stephenson ML, Wing DA. Misoprostol for induction of labor. *Semin Perinatol*. 2015;39(6):459-462.
[2] FDA Response to Citizen Petition, Docket Nos. FDA-2004-P-0116 and FDA-2000-P-1373.
[3] FDA Postmarket Drug Safety Information for Patients and Providers. Issued 2005, updated July 10, 2015. Available at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111315.htm
[4] FDA's Sentinel Initiative. Last updated 2016, December 14. https://www.fda.gov/safety/fdassentinelinitiative/ucm2007250.htm