Experts Spread Message About 'Preventable Birth Defects' On First-Ever World Birth Defects Day

BRENTWOOD, TN – "Many potentially devastating birth defects can be prevented," that's the message leading researchers in the field want the public to know as the world prepares for the inaugural "World Birth Defects Day," which will take place on Tuesday, March 3. The commemorative day is being spearheaded by international maternal and infant health advocates.

MotherToBaby, a service of the international non-profit Organization of Teratology Information Specialists (OTIS), and the Teratology Society, both professional associations hailed as the premier sources for authoritative information related to birth defects research, reproductive science and toxicology, have partnered to help spread the message about alcohol and folic acid fortification – two major issues currently keeping birth defect rates high world-wide. According to the Centers for Disease Control and Prevention (CDC), 1 in 33 babies are born with a birth defect in the U.S. each year.

Some of the most devastating birth defects are associated with alcohol consumption during pregnancy, according to MotherToBaby experts who provide free, evidence-based information through a toll-free hotline about medications, vaccines, drugs, alcohol and other exposures during pregnancy and breastfeeding. "It's thought that Fetal Alcohol Syndrome (FAS) is the most common recognizable cause of mental retardation," said Kenneth Lyons Jones, MD, MotherToBaby past-president and one of two doctors who first identified FAS in 1973. Children with Fetal Alcohol Syndrome are born small, have problems with learning and behavior, and may have other birth defects. "It's totally preventable by avoiding alcohol during pregnancy, yet prenatal alcohol exposure still affects 1 in 100 Americans each year," he added.

"Making sure women have access to folic acid regularly is another major issue around the world that could prevent birth defects," said Mary Alice Smith, PhD, Teratology Society president and professor of developmental and reproductive toxicology at the University of Georgia. At least 400 mcg folic acid daily during pregnancy has been shown to prevent up to 70% of neural tube defects, according to Smith. Neural tube defects are malformations of the spinal cord that are serious and can be life-threatening. Two of the most common neural tube defects are spina bifida and anencephaly, and occur in about 1 in every 1,000 live births.

"Because the neural tube closes in the first month after conception, a time when many women do not yet realize they are pregnant, it is important for women to be taking folic acid supplements before pregnancy, or if they think they might become pregnant," said Smith. She added that while some grains, like bread and pasta, are required to be fortified with folic acid in the U.S., ensuring more foods are fortified, like corn masa flour, could prevent even more neural tube defects. "The bottom line – we could all do more to raise awareness about this vital issue. The health outcome of babies being born today, tomorrow, and for years to come depend on it."

MotherToBaby is a suggested resource by many agencies including the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration's (FDA) Office of Women's Health. The public can be connected with bilingual (English/Spanish) teratogen information specialists at MotherToBaby and receive personalized risk assessments, education and counseling by calling toll-free 1-866-626-6847. The MotherToBaby website also houses a library of fact sheets on medications and other exposures during pregnancy and while breastfeeding located at www.MotherToBaby.org.

The Teratology Society consists of 660 members specializing in cell and molecular biology, developmental biology and toxicology, reproduction and endocrinology, nutritional biochemistry, genetics, and epidemiology, as well as the clinical disciplines of prenatal medicine, pediatrics, obstetrics, neonatology, medical genetics, and teratogen risk counseling. In addition, it publishes the scientific journal, Birth Defects Research, Parts A, B, and C. Scientists interested in becoming a Teratology Society member are encouraged to visit www.Teratology.org.

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Media Contact: Nicole Chavez, 619-368-3259, nchavez@MotherToBaby.org. Interviews in Spanish can also be arranged.

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BRENTWOOD, TN – January 28, 2015

Approximately 50% Of Women Report Taking At Least One Medication During Pregnancy
As January's National Birth Defects Prevention Month comes to a close, the United States' Health Resources and Services Administration's Maternal and Child Health Bureau (HRSA) opens the door for expanded access to pregnancy health education resources by funding the world's leading organization of experts in the field of teratology (the study of exposures that cause birth defects) – the Organization of Teratology Information Specialists (OTIS) MotherToBaby network.

OTIS, an international non-profit, has been awarded a two-year, $2.4 million cooperative agreement from HRSA, establishing a nationwide reproductive and environmental health network. The MotherToBaby network, which consists of 14 affiliate OTIS sites housed at universities and hospitals across the country, provides FREE, evidence-based, personalized risk assessments, education and counseling regarding the effects of exposures like prescription and over-the-counter drugs, alcohol, smoking, illicit substances, vaccines, beauty products, herbal supplements, chemicals and more during pregnancy and while breastfeeding.

"Approximately 50% of women report taking at least one medication during pregnancy and may be doing so before they even realize they're pregnant," said Kenneth Lyons Jones, MD, MotherToBaby past president. "Instead of having

to scour unreliable online message boards and websites for information about a medication's risk to a developing baby, they can talk directly to an expert in this topic who will have the most up-to-date research available to them," he explained.

More than 100,000 women and their health care providers seek information about birth defect prevention from MotherToBaby every year already. The new federal support is expected to help increase awareness of the expertise MotherToBaby has to offer among women and health care providers in more hard-to-reach populations.

"Not only is this is a huge step forward for women and children's health, but also the general public's, since it'll allow us to staff increased calls, answer more questions and, ultimately, prevent birth defects, leading to a healthier society," said Jones, who is also one of two doctors who discovered Fetal Alcohol Syndrome (FAS) in 1973. "With a broader presence, we'll also be able to better educate new audiences about dangerous behaviors like drinking alcohol during pregnancy."

Partner organizations, such as Help Me Grow Utah, have applauded HRSA's move to provide funding to the MotherToBaby network. "At Help Me Grow Utah, an affiliate of the Help Me Grow National Network, we understand the challenge of funding. Through a new cooperative agreement with HRSA, all women have been provided access to the MotherToBaby's hotline, with the latest information about risk exposures during pregnancy and breastfeeding. The result is improved health for moms and their babies, which helps put infants on track for reaching optimal development, a goal we wholeheartedly support," said Barbara Leavitt, Program Director of Help Me Grow Utah.

The public can be connected with bilingual (English/Spanish) teratogen information specialists at MotherToBaby and receive personalized risk assessments, education and counseling by calling toll-free 1-866-626-6847. The MotherToBaby website also houses a library of fact sheets on medications and other exposures during pregnancy and while breastfeeding located at https://mothertobaby.org//a>.

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BRENTWOOD, TN – Sonja Rasmussen, MD, MS, current member of the Organization of Teratology Information Specialists (OTIS), the professional society which provides the MotherToBaby service, published a new commentary in the New England Journal of Medicine highlighting the risks pregnant women face if not vaccinated against the flu. She recently sat down with the CDC for a Medscape Q & A article to address common questions about the flu, as well as the vaccine to prevent it, during pregnancy. For the full article click here, or scroll below to read her interview, courtesy of Medscape.

If you have questions about specific vaccines, like the flu shot, during pregnancy or breastfeeding call MotherToBaby toll-FREE at 866-626-6847. You can also read our Fact Sheet on Influenza Vaccine In Pregnancy/Breastfeeding here. MotherToBaby Pregnancy Studies, conducted by OTIS, is also currently following up with women who've recently received the influenza vaccine during pregnancy. To learn more and volunteer for the study, click here.

From Medscape:
Vaccination, Early Flu Treatment Critical for Pregnant Women

Editor's note: What have we learned since the 2009 flu pandemic? That's the focus of a new commentary from CDC experts Sonja Rasmussen, MD, MS, and Denise J. Jamieson, MD, MPH, published October 9th in the New England Journal of Medicine. In the commentary, "2009 H1N1 Influenza and Pregnancy – 5 Years Later," the authors note that during the 2009 pandemic, pregnant women were at substantially higher risk for hospitalization than the general population, and they accounted for approximately 5% of flu-related deaths reported to the CDC.[1]

Dr. Rasmussen, acting director of CDC's Office of Public Health Preparedness and Response, recently spoke with Doug Jordan, MS, CDC Health Communications specialist, about what clinicians can do now to keep pregnant women safe from influenza.

Mr. Jordan: What was your motivation for doing this commentary, and what should pregnant women know about the dangers posed by influenza?

Dr. Rasmussen: Since the 2009 H1N1 pandemic, we have learned a lot about influenza and pregnancy. The results of many studies have provided evidence on the impact of influenza on pregnant women, the benefits of treatment with oseltamivir, the safety of the influenza vaccine, and the steps clinicians can take to increase vaccination rates among pregnant women. We know much more now than we did 5 years ago about how to keep women and their infants safe from influenza. Yet, last year, we heard reports of severe illness, hospitalization, and death among pregnant women, sadly reminiscent of calls we received during the 2009 H1N1 pandemic. The idea for this commentary was in response to those reports. My coauthor, Dr Denise Jamieson, and I wanted to take what we now know about flu and pregnant women and make sure that information was in the hands of the clinicians who care for these women.

Mr. Jordan: What are the most common misconceptions that pregnant women might have about the influenza vaccine?

Dr. Rasmussen: We find that pregnant women do not always know that they are at higher risk of developing influenza-related complications. In fact, changes in the immune system, heart, and lungs during pregnancy make pregnant women more prone to severe illness, hospitalization, and even death from influenza. Infants born to women severely ill with influenza also have an increased risk for adverse birth outcomes, including preterm birth and small size for gestational age.

We also find that pregnant women often are unaware of the benefits of influenza vaccination for their baby. Flu shots during pregnancy protect not only the pregnant woman, but also her unborn baby and even her infant during the first 6 months of life. Studies have also shown that vaccinating the mother during pregnancy may reduce the occurrence of adverse outcomes like small size for gestational age and preterm birth in infants.

Mr. Jordan: What do you anticipate this season in terms of flu activity and severity?

Dr. Rasmussen: We can't predict what kind of influenza season we will experience in the United States this year. Every flu season is different, and influenza infection can affect people differently. Similarly, we cannot know which viruses will circulate over the season. Influenza viruses can change from one season to the next or they can even change within the course of the same season. But we know that influenza vaccination during pregnancy can reduce the risk for influenza in the mother and her baby. And we know that pregnant women suspected of having influenza should receive prompt antiviral treatment, regardless of risk factors, severity of illness, history, or diagnostic testing.

Mr. Jordan: Which flu viruses does this season's vaccine protect against?

Dr. Rasmussen: For the 2014-2015 flu season, trivalent influenza vaccines are made to protect against three influenza viruses: two influenza A viruses (H1N1 and H3N2) and an influenza B virus. In addition, the quadrivalent influenza vaccines, which are made to protect against four flu viruses, protect against the same viruses, and an additional B virus, as the trivalent vaccine. Yearly seasonal influenza vaccination is the best way to prevent influenza.

Mr. Jordan: What are the current influenza vaccine recommendations during pregnancy?

Dr. Rasmussen: CDC recommends that everyone 6 months of age or older get vaccinated against influenza each year. Getting an influenza vaccination is the best way to prevent influenza infection. Inactivated influenza vaccine is safe for pregnant women and can be administered during any trimester. Live attenuated influenza vaccine (LAIV) is not recommended for use during pregnancy. Postpartum women can receive either LAIV or inactivated flu vaccine.

Mr. Jordan: What are some important points to remember when educating pregnant women about influenza vaccine safety?

Dr. Rasmussen: Recommendations from healthcare providers are a critical motivator for pregnant women to be vaccinated. Clinicians should remind pregnant women of their increased risk of developing influenza-related complications, and emphasize that influenza vaccination is safe for pregnant women and has been recommended for many years by both the Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists. Influenza vaccination is the best way to prevent influenza and influenza-related complications like hospitalization and death in pregnant women and their babies.

Mr. Jordan: What is the best way to raise influenza vaccination rates among pregnant patients?

Dr. Rasmussen: Influenza vaccination benefits the pregnant mother, the unborn child, and even the baby after birth, and we know that pregnant women are motivated to do what they can to ensure the health of their baby. When they learn that influenza vaccination can benefit their child before and after birth, they are more likely to get vaccinated. Clinicians play a vital role in sharing this information.

We also know that the best way to increase influenza vaccination rates in pregnant women is by recommending the influenza vaccine and offering it in your office. Women who reported that their doctor recommended and offered the vaccine were much more likely to get vaccinated than women whose doctors recommended the vaccine but did not offer the vaccine in their office.

Mr. Jordan: What treatment options are available for pregnant women with confirmed influenza?

Dr. Rasmussen: Pregnant women with confirmed or suspected influenza should be treated with oseltamivir as soon as possible, and they can be treated during any trimester. Your decision to treat should be based on clinical evaluation rather than on diagnostic testing because of the limited sensitivity of rapid influenza diagnostic tests and the time required to complete more definitive testing. If a pregnant patient is exhibiting the signs and symptoms of influenza, treatment should be started. Ideally, influenza antiviral treatment should begin less than 48 hours after onset of symptoms. However, there is still clinical benefit when treatment is started in a pregnant woman who is ill with influenza, even if 48 hours have already passed. There is no "48-hour rule" that prohibits later treatment.

Mr. Jordan: What else can pregnant women do to protect themselves and their families from flu?

Dr. Rasmussen: In addition to getting vaccinated, pregnant women should take everyday preventive actions against influenza, like avoiding close contact with sick people, staying home if they are sick, and washing their hands often with soap and water.

It is also important to emphasize that family members and caregivers should get vaccinated. Infants can benefit from added protection when everyone who cares for them gets an influenza vaccine. This includes all members of the household, relatives, and childcare providers.

Again, clinicians play a critical role in ensuring that pregnant women and their babies are protected from influenza. By educating women about vaccine safety and the benefits of influenza vaccine, and by offering the influenza vaccine in your office, you can help to ensure that your patients and their loved ones stay safe from influenza this season.

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Brentwood, TN – In a move that was several decades in the making, the U.S. Food and Drug Administration (FDA) has published a final rule that requires prescription drugs and biological products include more detailed labeling about their risks during pregnancy and breastfeeding. The Organization of Teratology Information Specialists (OTIS), the professional society that provides the MotherToBaby service and conducts observational research about exposures during pregnancy and breastfeeding, will provide additional support as health care providers and the public look to understand the new labels.

Up until the ruling announcement today, drug companies were required to use a category system to communicate risk of drugs or biological products during pregnancy. Since the implementation of this category system, the FDA has researched the system’s impact, concluding it to be overly simplistic and confusing. The category system will begin to be phased out and pharmaceutical companies will be required to provide detailed risk information about the drugs, as well as relevant research, specific to pregnancy and breastfeeding.

“We know well that there is a plethora of information out there about these drugs and companies have chosen to not

include that information for whatever reason. Now, they have to," said Sandra Kweder, M.D., deputy director of the FDA's Office of New Drugs in the Center for Drug Evaluation and Research (CDER), during today's announcement.

The impact of a drug on breast milk will also have a dedicated section on the new labels, including whether medication gets into breast milk and whether it might affect the infant or not. In addition, the new labeling will include a section describing a medication's potential impact on fertility, birth control and any relevant pregnancy registry information.

"There will be a steep learning curve for clinicians and patients to feel comfortable with more detailed information as opposed to the simple letter category," said Christina Chambers, PHD, MPH, OTIS member and director of UC San Diego's Center for the Promotion of Maternal Health and Infant Development, the hub of where MotherToBaby pregnancy studies conducted by OTIS is located. "The MotherToBaby toll-free service can help," she added.

According to the FDA, there are 6 million pregnancies in the U.S. each year. In addition, pregnant women take an average of three to five prescription drugs during pregnancy. Those with pre-existing and chronic conditions, such as asthma or autoimmune diseases, often need to continue their medications during pregnancy or while breastfeeding. "Our hope is that the new labeling will help health care providers better understand the risks and benefits of these drugs so they can discuss the options with their pregnant and breastfeeding patients," said Chambers. "This is a huge step forward — and will make even clearer how critical the need is for more human pregnancy data for all medications likely to be used by women of reproductive age."

Chambers has also acted as a consultant for the FDA on issues related to communication of risk both to patients and providers. "Through the MotherToBaby service that OTIS provides, we're hoping to help the public understand the information provided on the new labels, as well as enroll participants into various observational research studies, the results of which will add even more useful information to the data."

Kweder echoed this importance. "Organizations like OTIS need to continue making sure its research gets published," she said.

MotherToBaby and OTIS are also suggested resources by many agencies including the Centers for Disease Control and Prevention (CDC). They are 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. Anyone wishing to receive a personalized risk assessment of drugs or other exposures can be connected with a MotherToBaby expert toll-FREE via its phone counseling service (866) 626-6847 or online at MotherToBaby.org.

MotherToBaby is currently conducting various research studies during pregnancy, including asthma, autoimmune diseases, and vaccines. To learn more, volunteer for a study, or refer a patient, please call (866) 626-6847 or visit the Fact Sheets page.

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PBS – As many parents struggle with decisions about whether or not they should vaccinate their children, diseases that were once nearly eradicated in many parts of the world are making a comeback. Why is whooping cough now an epidemic? Measles and mumps are back with a fury as well. NOVA's "Vaccines- Calling the Shots" gives a historical background about vaccines and the threats the once nearly-extinct diseases are posing in today's society.

Watch the documentary here:

Many pregnant mothers contact MotherToBaby because they are concerned about the risks of flu vaccination to their unborn child. Studies have shown that prenatal exposure to some vaccines, such as the flu shot, is not associated with negative outcome. In fact, diseases like the flu can carry a much greater risk to the mother and her developing fetus than the vaccine that prevents the infection. It is important for mothers and other adults who come in contact with children to be vaccinated against the flu.

If you have questions about specific vaccines during pregnancy or breastfeeding call MotherToBaby toll-FREE at 866-626-6847. You can also browse our Fact Sheets, which cover several common vaccines and their risks during pregnancy/breastfeeding here.

MotherToBaby is recommended by many agencies including the Centers for Disease Control and Prevention (CDC).

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