FDA Pregnancy Risk Categories: Going Away for Good

By Lynn Martinez and Julia Robertson, CPM

During the more than 40 years MotherToBaby affiliates have been serving the public with education regarding exposures during pregnancy, many women have called who are very distressed, sometimes in tears, about finding out they were pregnant while taking a drug categorized as an X or D in the Food and Drug Administration (FDA) system. "I've been on birth control pills and I still got pregnant! Does this mean my baby will have birth defects? It's a category X drug for goodness sake!" This kind of hysterical reaction was, unfortunately, a common call. It was not unusual to even hear that some of these women had contemplated terminations of otherwise wanted pregnancies. The FDA realized that these pregnancy categories were not as helpful as they intended and stopped using them in 2014, about ten years ago. Now they use the Pregnancy and Lactation Labeling Rule (PLLR) that has a narrative summary for medications, similar to what you will find here at MotherToBaby.

But first, a little background…

For decades the FDA had been aware of significant problems with the system used to categorize medications for use in pregnancy. In 1992, the Teratology Society (now known as the Society for Birth Defects Research and Prevention), a group of multidisciplinary scientists who study birth defects, expressed concerns and noted that the Category or 'CAT' system led to unnecessary terminations of wanted pregnancies1. The FDA Pregnancy Labeling Initiative recommended elimination of the CAT system, changing the label to include more descriptive risk statements and mandating that drug inserts be updated when human information is known.

Before the labeling rule changed, when a medication was approved for marketing in the U.S., it had to be labeled with one of five pregnancy CATs: A, B, C, D or X. A meant the drug was well-studied and posed no threat to a developing baby; B was a less-studied, but probably still low-risk drug; C was a drug that had not been studied and therefore the risk was unknown; a D-class drug, based on animal or human data, may have posed a risk; and the X classification meant the drug, based on animal or human data, causes birth defects or there was no benefit for its use during pregnancy. Its use was not recommended in pregnancy.

More than 90 percent of new medications were categorized as either CAT C, D or X, the vast majority being C. Drug manufacturers were legally required to update the category if harmful results were reported; however, no such requirement existed for updating the category when studies showed no problems in pregnancy. Most medications on the market in 2014 werelisted as CAT C, when in fact the majority of them should have been labeled as a CAT A or B. Manufacturers knew that no matter a woman's history, all pregnancies carried a 3 percent risk of having a child with a major birth defect. Because of this, many manufacturers may have felt better protected from lawsuits if their drugs were listed as CAT C, D, or X. So, really, why would they move up medications in those categories up to A or B? They really didn't have an incentive.

Moving forward and what it means to mom…

With the FDA rule change in 2014, a new set of requirements was put into place to better inform mom. It now requires the manufacturers to 'upgrade' a medication's labeling when studies show the risk has changed. Also, manufacturers will have to explore various ways of discussing in detail the risks associated with the drug. One expert source that manufacturers could consult is a teratogen information service, like MotherToBaby. More information will help you make more informed choices about your health and pregnancy!

There will still be confusion…

As we see the new labels being implemented, there will still be many drugs on the market with the CAT system since it'll take time to update all of them. MotherToBaby does not recommend the public or providers rely on the old CAT

system for risk assessment. We welcome your questions about the system as well as questions about specific medications in pregnancy and breastfeeding for a complete, personalized risk assessment. Please call us toll-FREE at 866-626-6847.

Lynn Martinez is a retired Teratogen Information Specialist. Lynn has traveled around Utah educating doctors, nurse midwives, pharmacists and others over the past three decades.

Julia Robertson, CPM, now retired, works part-time overseeing quality control efforts for MotherToBaby. In her 25-year career as a teratogen information specialist, sheauthored several peer-reviewed publications focusing on maternal medication consumption and the effect on the developing fetus.

MotherToBaby is a service of the international Organization of Teratology Information Specialists (OTIS), a suggested resource by many agencies, including the Centers for Disease Control and Prevention (CDC). If you have questions about medications, alcohol, diseases, vaccines, or other exposures during pregnancy or breastfeeding, call MotherToBaby toll-FREE at 866-626-6847 or browse a library of **fact sheets**.

- Friedman, J. Teratology 1993:48:506
- For more information go to: **http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/labeling/ucm093307.htm**

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Sara contacted us on the MotherToBaby live chat service after being referred by her OB/GYN who had told her that the Paxil (drug name paroxetine) she was taking could cause a heart defect. She was 14 weeks along and wanted to learn more, but was confused because all her genetic testing results had come back normal. She asked: “How could my baby have a heart defect if my non-invasive prenatal testing (NIPT) was negative?”

During pregnancy, there are many tests done to check on the health and development of your baby. It can be difficult to keep track of what they are all looking for and why they are important. To understand these tests, it can be helpful to know the differences between a birth defect and a chromosomal abnormality and what they each mean for the health of your baby.

All pregnancies have a background risk for birth defects of 3-5%, but certain exposures can increase the risk of birth defects above this background estimate. Most birth defects occur during the first trimester while the baby is growing and developing. A certain body part – such as the heart, brain, or limbs – might not develop correctly, and the baby's body may look or function differently than it should. You may have heard of a baby being born with a hole in the heart, or with something called a cleft lip. These are two examples of birth defects that can occur during pregnancy. Birth defects can range from mild to severe, and the health of the baby will be dependent on where the birth defect occurs and how severe the problem is.

Certain tests done during pregnancy can look at your baby to see if there are birth defects. For example, most pregnant individuals will go in for an anatomy scan between 18 and 22 weeks where the healthcare provider will look at the baby using an ultrasound. Most people know this as the time when they can learn the gender of the baby, but the ultrasound will also take a detailed look at the baby's organs and body parts, including the heart, brain, face, and stomach, to check for birth defects. While this is an important screening test, it is not perfect, and more minor defects may go unnoticed until birth.

Chromosomal abnormalities are changes in the baby's DNA that happen at the time of conception. The best way to understand DNA is to think of it like a recipe book that holds all the recipes for the growth and development of different body parts. If a certain recipe calls for one stick of butter, but the printed book accidentally says two sticks of butter, the recipe will turn out different. In the same way, sometimes people have extra or missing amounts of DNA that can cause changes in development. For example, people who have a chromosomal abnormality known as Down syndrome have three copies of their 21st chromosome rather than only two. This extra amount of DNA is what causes the developmental differences in individuals with Down syndrome.

During your pregnancy, your healthcare provider may suggest that you meet with a genetic counselor to have non-invasive prenatal testing, or NIPT, performed. This test can be done as early as 10 weeks. During pregnancy, some of the baby's DNA enters the pregnant woman's bloodstream. By taking a small blood sample from mom, a lab can take a look at the baby's DNA and tell if they have certain chromosomal abnormalities, such as Down syndrome. When you meet with a genetic counselor, they will go over all of the pros and cons of this test as well as your family history, and will meet with you again to review the results.

Back on the live chat service, Sara asked: "So because my NIPT results were normal, the baby is unlikely to have a chromosomal abnormality. However, a birth defect still could have happened in the first trimester, and I need to wait until my anatomy scan to get those results, is that right?" That's exactly right, I replied. I then went on to explain that although Paxil (paroxetine) has been shown to increase the risk for heart defects in some studies, other studies do not suggest a risk, so the overall chance of the baby being affected is low.

As we ended our chat, Sara shared that she was feeling much more knowledgeable about the difference between a birth defect and a chromosomal abnormality. She was able to breathe a sigh of relief that her NIPT results came back normal, indicating a low risk for conditions like Down syndrome. She also felt much more confident heading to her anatomy scan in a few weeks knowing that this test, while not perfect, would be the best way to identify birth defects before her baby is born.

If you have any questions about birth defects or exposures during pregnancy, speak with a MotherToBaby specialist via phone, text, live chat, or email. For any questions regarding genetic testing in pregnancy, or to find a genetic counselor in your area, visit the Find a Genetic Counselor page on the National Society of Genetic Counselors

website: https://findageneticcounselor.nsgc.org/

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FDA Pregnancy Risk Categories: Going Away for Good

By Lauren Kozlowski, MSW, MPH, MotherToBaby Georgia

"I didn't even know I should ask my OB about that!" It's a reaction I hear almost daily as a teratogen information specialist (a fancy way of saying I've been trained in evaluating and communicating risks of exposures, like medications, during pregnancy). This particular caller's reaction was like so many women going into their first appointment after finding out they were pregnant – she really didn't know how to be her own best advocate. I don't blame her by any stretch. How are women supposed to just know this? What questions should they be asking? Why should they be asking them? I thought, not only did I want to help her, but all of the pregnant women out there, to have a positive, empowering experience once they've found their pregnancy care provider team.

The Importance of the HCP Match

Finding the right health care provider (HCP) for you is essential because doctors, physician's assistants, nurse practitioners, and midwives are people just like you and me. They come with a wide range of personalities and styles of care. Sometimes they will match your own and sometimes they won't. You want to be sure that the people that you entrust with your health and your baby's health are going to help you make the right decisions about your care. Plus it is worth thinking about how you can reduce any stress you may have about sitting down with the person who will care for you and be a source of support during your pregnancy. In this blog I'd like to suggest some ways that you can plan for the most successful experience during pregnancy with your HCP. In this case, success means finding a provider who listens to you, makes you feel comfortable and discusses all of your concerns and options openly and respectfully.

Getting the Most Out of Your Appointments

The good news is there are some ways to empower yourself in these situations and be more likely to get what you

need! Below I have a list of some ways you can get the most out of appointments with your pregnancy care provider:

- You should be able to ask your provider anything you'd like to know about their experience and philosophy around pregnancy and child birth. You can even ask to make a non-clinical appointment to sit down with her or him and discuss this if you'd like to.
- Be prepared for a short visit with the provider at regular appointments throughout your pregnancy. Write down your most important questions and make sure to ask them first.
- If you'd like to research some topics before your HCP visit, choose your sources wisely. The internet is full of a lot of misinformation, but there are reputable organizations from whom you can get evidence-based information about pregnancy. Just a few examples include the American College of Obstetricians and Gynecologists (ACOG, the professional society for HCPs specializing in women's health); the Centers for Disease Control and Prevention (CDC); the Food and Drug Administration (FDA); and our own service, MotherToBaby. Pull information from your sources and bring it with you to your appointment to drive your conversation with your HCP.
- Bring a trusted family member or friend who can bring up anything you forget to – or that can step into the conversation to help make sure you are being heard correctly. This is particularly important at the first visit or when you are worried about something.
- If you routinely take any medications, bring them up as soon as you find out you are pregnant (and when possible, even ***before*** you become pregnant); this will allow you and your HCP to talk about whether there are any alternative medications or therapies better suited for pregnancy and/or breastfeeding. And remember that our specialists at MotherToBaby are available to provide you with up-to-date information on the safety/risk during pregnancy and breastfeeding of any medications you may be taking.
- If you see a specialist for other medical conditions (such as asthma, diabetes, arthritis, lupus, psoriasis, etc.), tell your OB provider who you are seeing and authorize them to communicate with one another about your care. When you are living with a chronic health condition, connecting your pregnancy care provider with your other health providers is important to ensure your disease is well-managed throughout your pregnancy and when you are breastfeeding.
- Even if they don't ask about it, tell your HCP about your use of alcohol, tobacco, or any recreational drugs (like marijuana, heroin, meth, etc.). Some of these substances can affect your pregnancy or your baby's development, so it's important for you and your HCP to talk about it even if you are just an occasional user. Recreational drugs are another type of exposure where MotherToBaby experts can provide you with confidential, up-to-date information on the safety/risk of use during pregnancy and breastfeeding. Importantly, talk to your HCP if you need help quitting any of these substances; there are ways to treat substance use disorders during pregnancy. You also have a chance of being screened for substances at birth – meaning they may test both you and your baby at the hospital. Being prepared for this is important so you know what to expect.
- Ask questions about the hospital at which you will be delivering. Do they have any specific policies or practices you would want to know about in advance? Your HCP will be connected to a specific hospital(s); if you do not want to deliver at that hospital and your insurance allows for other options, you may need to find another prenatal care provider. It is best to ask these questions before you become pregnant or as soon as you start your prenatal care visits.
- If for any reason you do not feel like your HCP listens to you or is able to create a welcoming, safe environment, change providers! If it's a requirement of your insurance, get a list of providers in your network. Then ask friends or family if they have someone they'd recommend. You can further whittle down your list by other things that may be important to you, such as a male vs. female provider or office location. Pregnancy is such an important time in a woman's life, so it's critical that you are under the care of a health provider that you trust. Depending on where you live and what insurance you have, it may not be possible to find another provider – but if you are able and want to, the sooner you do so in your pregnancy the better. You deserve to feel comfortable and cared for!

A lot of these tips apply to any type of HCP, but pregnancy is a perfect time to flex your self-advocacy muscles and find the provider that is best suited for you. You and baby deserve wonderful and respectful care, and the reality is that sometimes it takes a bit of seeing what's out there to find the right fit. Finding the right HCP can feel a lot like dating,

but don't be discouraged! If you don't like the care you are getting, move on to another HCP – with so many exceptional ones out there you can find the best match for you and your pregnancy.

Although not specific to a pregnancy visit, ACOG also offers some tips to help you make the most out of your health care visit: https://www.acog.org/Patients/FAQs/Making-the-Most-of-Your-Health-Care-Visit

If you want to read more about advocating for yourself as a patient, some other resources are below:

Your Best Birth: Providers, Plans and Being Proactive

https://bloomlife.com/wp-content/uploads/2018/11/Best-Birth-Bloomlife-ebook-1.pdf

At the end this includes a great acronym BRAIN (**B**enefits, **R**isks, **A**lternatives, **I**ntuition, Do **N**othing) that can be used whenever you are making decisions or have questions about receiving medical care.

A Doctor's Guide: How To Be A Patient Advocacy Rockstar (For You or a Loved One)

https://www.acsh.org/news/2018/06/21/doctors-guide-how-be-patient-advocacy-rock-star-you-or-loved-one-13106

Health Care Self-Advocacy: Be the Squeaky Wheel

https://www.care2.com/causes/health-care-self-advocacy-be-the-squeaky-wheel.html

The Complete Guide to Becoming Your Own Medical Advocate

https://betterhumans.coach.me/the-complete-guide-to-becoming-your-own-medical-advocate-ddc658a10a57

Lauren Kozlowski, MSW, MPH is serving as the Program Coordinator for MotherToBaby Georgia. She graduated from Boston University with both a Masters of Social Work and a Masters of Public Health. She has experience working with families in both an educational setting, as well as in housing and health, allowing her to recognize the multiple factors contributing to the ability of women and children to thrive. She enjoys living in Atlanta and exploring what the city has to offer.

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FDA Pregnancy Risk Categories: Going Away for Good

By Ginger Nichols, Licensed Certified Genetic Counselor at MotherToBaby Connecticut

With Birth Defects Prevention Month in full swing, it's time to focus on **Tip #2 for Preventing Birth Defects: Booking a visit with your health care provider before stopping or starting any medicine.**

Callers to MotherToBaby often wonder why it's important to talk with their health care provider before stopping or starting a medication. My most recent caller to MotherToBaby asked this very question.

Maria contacted us at MotherToBaby telling us that she and her partner had decided that they would like to start a family. Like many women, Maria was taking medications for a health condition, and she wanted to learn if it would be OK to use them while trying to get pregnant and during pregnancy. She was planning to stop taking them because she was worried that they could be harmful for her baby. She told me that she felt alone as she faced this decision.

In fact, Maria is not alone; 70 percent of women need to take prescription medication during pregnancy to treat a wide variety of health conditions, like depression, asthma, diabetes, nausea and vomiting of pregnancy and inflammatory bowel disease.. And most women (90 percent) report using over-the-counter medication, vitamins or supplements for overall health or for specific health concerns, such as acne, allergies, colds, constipation, headaches and lice .

Why should you talk with you health care provider before starting or stopping taking medication?

Here's why it's important to check with your providers about taking medications and supplements before and during pregnancy:

- Some medications or herbal products can make it harder to get pregnant. And some medications can help you get pregnant.
- In some cases, stopping a medication and having an untreated medical condition may be more of a concern for pregnancy than the medications used to treat it. If a medicine can be harmful during pregnancy, your provider may want to switch you to one that's safer for your baby. But some medications are necessary, even if they may be risky for your baby. You and your provider can talk about all your treatment options to make the best decision for you and your baby. Some medications can cause you to go through withdrawal (have unpleasant physical and/or mental symptoms) if you stop suddenly (also called "cold turkey"). If you and your provider decide to stop a treatment, you may need to stop taking the medicine slowly over time rather than stopping all at once.

- Some medications may need to be increased or decreased during pregnancy in order to continue working properly.
- Some vitamins and supplements may have too much or too little of the nutrients that you need during pregnancy. You may need to adjust the amount you take.
- Supplements and herbal products are not regulated by the Food and Drug Administration. There are no standards for ingredients and strength, and most have been poorly studied regarding their safety for use in a pregnancy.

Now that you know why it's important to check on the safety of medication before and during pregnancy, what's next?

- Whether you are planning a pregnancy or currently pregnant, talk to your health care providers before starting any medication (prescription or over-the-counter), vitamins or herbal products.
- Don't stop taking your prescription medication unless your health care provider says that it is OK.
- Make appointments with your health care providers to review medications they prescribe, and make an appointment with your prenatal provider. If you are planning a pregnancy, talk with your providers before you get pregnant; and talk with them again as soon as you find out that you are pregnant.
- Tell your provider about any medicine you take, including medications that you only use once in a while, like seasonal allergy medication or rescue inhalers. Tell them about over-the-counter medicines, supplements and herbal products, too. A product may be made from herbs if it has word on the label like indigenous or tribal medicine, traditional Chinese medicine, natural remedies, herbal supplements, nutritional shakes, essential oils and tinctures.
- Start taking a prenatal vitamin as soon as you stop your birth control. Talk to your provider about which prenatal vitamin to take.

How can you get ready to talk to your providers about medication and pregnancy?

- Prepare and bring with you a list of all the medications and supplements that you take, including the ones you may only take occasionally.
    - Bring all pill bottles/boxes with you to the appointment so your provider can check on the active ingredients.
    - For each medication/supplement on your list, include information on:
        - Dosage (how much you take),
        - Frequency (how often you take it), and
        - Indication (why you are taking it).
- Some medications can stay in the body for a long time. If your treatment plan includes stopping a medication before getting pregnant, discuss the timing of when you should stop.
- There may be alternative treatments that work just as well for you and are better options during pregnancy and breastfeeding.
    - Ask about alternative treatments. Find out if you can try them out before pregnancy to see if they will work for you.
- Talk about the right prenatal vitamins with the right amount of folic acid for you.
    - Some medications can affect how your body uses folic acid, which is important for pregnancy.
    - Ask your prenatal provider to prescribe you a prenatal vitamin to make the choice easier.

After our call, Maria felt more comfortable in learning about her medications and questions she should have ready to

discuss with her providers about the best way to treat her medical condition throughout her pregnancy.

Remember, just like Maria, you are not alone. MotherToBaby is here to help you and your providers work together to make informed decisions about your medication options for pregnancy and breastfeeding.

Ginger Nichols is a licensed certified genetic counselor based in Farmington, Connecticut. She currently works for MotherToBaby CT, which is housed at UCONN Health in the Division of Human Genetics, Department of Genetics and Genome Sciences. She obtained her Bachelor of Science degree in Biology and Sociology from Juniata College and her Master's Degree in Medical Genetics from the University of Cincinnati. She has a special interest in occupational and environmental exposures.

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FDA Pregnancy Risk Categories: Going Away for Good

By Lori Wolfe, Certified Genetic Counselor and Teratogen Information Specialist, MotherToBaby North Texas

It's pretty much a fact – ALL pregnant women worry…about what they eat, what they do, what they breathe. Basically, they worry about everything. That's simply because every expectant mother wants to do the very best she can for her developing baby. As a genetic counselor who runs the North Texas affiliate of MotherToBaby, I get calls every day from pregnant woman who want to know what to do and what not to do in order to have the best chance of having a heathy baby without birth defects.

Recently I was having lunch with my friend, Amber, who is expecting her first babies…Yes… plural! In seven short months, she'll become the mother of twins! As a first time mom-to-be, Amber is always full of questions when we get together. Nothing like having a friend who is an expert in the pregnancy exposure field, right?! "Lori, is it true that since I eat lots of dark green veggies, and breads and cereals, that my babies will not have spina bifida? I remember hearing something about how good folic acid is for developing babies. Is that true?" asked Amber. "Yes!" I enthusiastically replied. "Having enough folic acid in the first two months of your pregnancy is very important to help prevent birth defects in your developing babies. In fact, studies have shown that if you are getting at least 400 mcg of folic acid during your early pregnancy through the foods you eat, as well as your prenatal vitamin, then your babies have up to a 70% less chance of having a spinal cord defect such as spina bifida." The look on her face was priceless…pure shock! "70%? Really?! Wow, I had no idea it could be so effective," Amber answered. "Yes, I have been taking a daily prenatal vitamin since before I became pregnant. I am always careful to take one every day. So what else can I do to help my babies be born without birth defects?"

Let me break it down for all of the "Ambers" out there. What's thought to be the most common preventable cause of mental retardation in a baby? The answer – drinking alcohol during pregnancy. "And what is so crazy is that women do not need to drink alcohol when they are trying to become pregnant, and definitely not once they have a confirmed pregnancy," I explained. About one in every 100 babies born in America is affected by prenatal alcohol exposure and it is totally preventable by simply avoiding alcohol during pregnancy. "Amazing!" replied Amber. "I never realized so many kids were affected by their moms' drinking alcohol during pregnancy. That is sad. But I am good on this count as I have not had any alcohol at all during the last few months," Amber said.

"So is there anything else I can or can't eat or drink, or something else I can avoid that could make a difference in my babies not having birth defects?" she went on to say. "You are about eight weeks pregnant now, right Amber?" I asked her. "Yes. I am now about eight and one half weeks. Why?" she asked. "Well, another thing we worry about is hyperthermia," I told her. "Hyperthermia means increasing your internal or core body temperature up to 102 degrees Fahrenheit or more. When you become that hot, the baby inside of you becomes hot too. When the baby's temperature becomes too hot, especially in weeks five and six of a pregnancy, there is an increased chance that the spinal cord will not close, and your baby can be born with an open spinal cord defect like spina bifida. So we always caution pregnant women not to sit in hot tubs that are heated over 100 degrees, or to be careful to watch their temperature if they become ill with a fever during early pregnancy," I said.
"All of this is really good to know," Amber answered, as we wrapped up lunch. "I'm lucky I have you as a friend!"

I love making sure women have someone to turn to for answers when they have questions about exposures while pregnant or breastfeeding. In fact, during March when the world will commemorate the first-ever World Birth Defects Awareness Day, my lunch with Amber serves as a great reminder that my colleagues and I are there for all pregnant and breastfeeding women across North America.
If you have a question during pregnancy and breastfeeding about something you ate, drank or medication you took, call MotherToBaby at 866-626-6847. I may not be able to meet you for lunch, but a main course of free expertise over the phone, followed by a huge helping of cutting edge research to support that expertise, will certainly be exactly what you ordered in your search for answers. And who knows? Your kids might even thank you for having such an appetite for knowledge one day!

Lori Wolfe is a board certified Genetic Counselor and the Director of MotherToBaby's North Texas affiliate.
MotherToBaby aims to educate women about medications and more during pregnancy and breastfeeding. Along with answering women's and health professionals' questions regarding exposures during pregnancy/breastfeeding via MotherToBaby's toll-free number and by email, Wolfe also teaches at the University of North Texas, provides educational talks regarding pregnancy health in community clinics and high schools, and counsels adoptive parents. MotherToBaby is a service of the international non-profit Organization of Teratology Information Specialists (OTIS), a suggested resource by many agencies includingthe Centers for Disease Control and Prevention (CDC). If you have questions about vaccines, medications or other exposures, call MotherToBaby toll-FREE at 866-626-6847 or visit **MotherToBaby.org** to browse a library of fact sheets and find your nearest affiliate

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