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FDA to require new information for prescribing medications during pregnancy

By Bonnie Miller Rubin

Chicago Tribune ***contact the reporter***

Laura Wylie, of Oak Park, wrestled with whether she should stop taking antidepressants during her pregnancy with daughter Matilda. (Abel Uribe, Chicago Tribune)

When Laura Wylie became pregnant for the second time, she confronted a vexing dilemma: Stay on the antidepressants that could have adverse effects on her developing baby or risk descending into a deep, black hole that left her feeling numb.

"You can't go through a healthy pregnancy if you're not in a healthy state of mind," said Wylie, 35, of Oak Park. "I finally realized that if I had a broken leg, I wouldn't be expected to fix it myself. ... The same thing is true with depression."

For years, cautious mothers-to-be and their obstetricians thought "just say no" was most the prudent approach to any medication more potent than a cough drop. But

abandoning treatment for chronic health conditions — such as depression, asthma or diabetes — can sometimes affect the baby more than taking a medication while pregnant, experts said.

To help doctors and patients weigh the risks and benefits of taking medications during pregnancy and breast-feeding, the Food and Drug Administration in June will require a new labeling system for prescription drugs.

"Should we let women with epilepsy just have seizures?" said Dr. Katherine Wisner, a professor and psychiatrist at Northwestern University Feinberg School of Medicine, who advised the FDA on the changes. "Pregnant women get sick and sick women get pregnant. But somehow we have created this myth of the medication-free pregnancy."

The revisions to prescription guidelines — the first since 1979 — will provide more up-to-date and specific information to doctors to help them identify the safest treatment options for common conditions during pregnancy, said Wisner, who specializes in maternal mood disorders.

The old system relied on letter grades of A,B,C, D and X — A for the most benign medications to X for off-limits. The new system is designed to give physicians more technical information when prescribing medications, said Sandy Walsh, an FDA spokeswoman.

The updated prescribing guidelines consist of three components. The first gives physicians information on dosing and risks to the fetus. It also indicates whether data has been collected to show the drug's effects — something never required until now. The second offers what is known about the drug's impact on breast-feeding, and the final section addresses how the product may affect fertility.

The letter labels were "confusing and overly simplistic," Wisner said. "But now doctors and patients will have quality data to provide better answers. ... We're moving from a single letter to more practical guidelines."

The change comes at a time when a growing number of women are taking medications during their childbearing years. According to the Centers for Disease Control and Prevention, 90 percent of all women are on at least one prescription or over-the-counter drug, while the use of four or more prescriptions has more than doubled during the past 30 years.

Some drugmakers have already phased in the changes; the deadline is June 30. While consumers won't see new labels on pill bottles or bags, doctors will have more data to discuss with them.

"It's more about laying out the information for health care professionals so they are in a better position to help their patients make these decisions," Walsh said. "That's why the most important thing is for women to still have conversations with their doctors."

Navigating a thicket of often conflicting advice can be daunting. Some medications are off-limits during the first trimester — when a fetus' vital organs are forming — but less problematic later on. Others are OK early in the pregnancy but not in the final months. Dosing, too, can be a moving target. Surging hormones can affect the rate that drugs are metabolized into the bloodstream.

Even when a pregnant woman takes no medication, the overall risk of birth defects is 3 to 5 percent, according to Suzanne Gilboa, an epidemiologist with the CDC's National Center on Birth Defects and Developmental Disabilities. It's often difficult to tease out what is a drug-related defect and what is not. Pregnant women typically are excluded from double-blind, placebo-controlled clinical studies, "so a lot of what we know is from post-marketing surveillance and retrospective studies, which have more limitations," Gilboa said.

Dr. Marsie Hass, who has been a south suburban OB/GYN for more than 30 years, welcomes more relevant prescribing information, she said. But the effect of drugs on the developing fetus should always require case-by-case decision-making, she said.

"Everyone wants a simple yes or no answer, but often it's not so simple," Hass said. "That said, we have to offer patients something more than 'medication is bad.'"

In Wylie's case, she said she desperately needed something to regain her equilibrium in a world turned upside down.

After several rounds of fertility treatment, Wylie and her husband, Sean, received joyous news: They were expecting twins.

But in July 2013, during the second trimester, a severe cervical issue made it impossible to carry them to term. After a premature labor and delivery, the twins lived for an hour but did not survive.

"Making funeral arrangements was the hardest thing I have ever had to do," Wylie said.

She was mired in unbearable pain, which she characterized as "a deep pit that I could not get out of." She struggled to get from one breath to the next, unable to string together more than two hours of sleep a night and crying so much that her tear ducts ached, recalled Wylie, who acknowledged that she probably had undiagnosed depression and anxiety for years.

The couple shut the door on the nursery, with its two cribs.

But her body would not let her forget, and her milk came in.

And then came what mental health experts call intrusive thoughts.

"I wasn't thinking about suicide as much as just wanting to be with the babies. Like if we had a car crash, would it be so horrible? It meant we could see them," she said.

A short time later, Wylie found her way to a psychologist who thought she was grappling with more than grief and referred her to Wisner, who is also director of Northwestern's Asher Center for the Study and Treatment of Depressive Disorders.

Wisner prescribed two antidepressants, Zoloft and Trazodone. Within days, Wylie said she noticed a difference — if for no other reason than she was getting more sleep.

Other small victories followed — making it through a TV show, walking to the end of the block, then getting all the way around the block. Sean still had to make sure the path was stroller-free, but she did it.

The couple took another step forward when they continued to try to conceive. "I didn't know if I could get this miracle again ... but I knew I couldn't get there unless I could level off in some way."

Moreover, untreated psychiatric illnesses can have negative effects on babies in utero, producing higher levels of stress hormones that can reduce fetal growth and increase the risk of premature labor, Wisner said.

And the already risky postpartum period, with an incidence of depression as high as 20 percent, can be even more dangerous if the illness goes untreated during pregnancy, she said, leaving the new mother unable to properly care for or bond with the newborn.

So when Wylie became pregnant again, she wrestled with her options. She weighed the risks of a pregnancy with and without antidepressants. In the end, she decided to remain on her medications.

"After talking to Dr. Wisner and thinking it over, where I landed was that one scenario — not taking medication — was very likely to be a bad experience for me and the baby, whereas taking the medication would enable me to stay more emotionally capable and carried a small chance of something happening," she said.

"As I sadly know, there are no certainties when it comes to pregnancy and childbirth. I think every woman needs to make decisions that take both her and the baby's health into account."

On Sept. 25, 2014, Matilda was born. Today she is a healthy 7-month-old.

"The meds were comforting. I trusted my doctor ... and it worked," Wylie said. "And now I have this amazing, healthy, beautiful baby girl."

The CDC and the Organization of Teratology Information Specialists offer more information on medication use during pregnancy at cdc.gov/treatingfortwo *and*otispregnancy.org.

brubin@Tribpub.com

Twitter @bmrubin