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The SSRI Pushers

Drug Companies Want Women of Childbearing Years

By EVELYN PRINGLE

Drug makers are hell-bent on recovering the antidepressant customer base represented by women of childbearing years. With doctors now reluctant to prescribe the drugs to pregnant women, a new recruitment scheme has cropped up. Screening programs are being set up all over the country to screen every pregnant woman for mental disorders.

The name-brand selective serotonin reuptake inhibitor antidepressants, or SSRIs, with a stake in this controversy, include Paxil, by GlaxoSmithKline; Zoloft, from Pfizer; Prozac by Eli Lilly; Celexa and Lexapro, from Forest Laboratories; and Luvox, from Solvay.

According to one of the world's leading experts on SSRIs, Dr David Healy, a professor at the University of Wales College of Medicine, "there is quite a movement at the moment to say all pregnant women are depressed."

Every pregnant woman, he explains, can have depressive symptoms such as fatigue, disturbed sleep, and anxiety at times, along with loss of interest in sex. "But," he says, "having depressive symptoms and being depressed are two different things."

"When people get the flu," he points out, "they have a full house of depressive symptoms but doctors would not prescribe antidepressants to people with the flu."

The Advocate Good Samaritan Hospital in Downers Grove, Illinois continues to recommend that SSRIs be used to treat pregnant women even despite recent warnings concerning birth defects and other life-threatening disorders in children born to mothers who took antidepressants during pregnancy. "Any woman," the Hospital warns, "who is thinking about becoming pregnant, is pregnant, or had a baby within the past year can be affected by depression or other mood disorders."

Good Samaritan screens all new mothers, according to a March 1, 2007 Naperville Sun article, and universal screening may soon become state law in Illinois through legislation called the, Postpartum Mood Disorders Prevention Act, that was introduced in February 2007. Similar legislation has been adopted or introduced in several other states.

According to the Sun, if the new legislation introduced in Illinois becomes law, it will require health care professionals to:

"Assess women for mood disorders at least four times: at a prenatal checkup in the third trimester of pregnancy, prior to discharge from the place where they give birth,

at the initial postnatal checkup and at every postnatal checkup until the child's first birthday."

And the new potential customer base for SSRIs is no longer limited to postpartum depression, it has now been expanded to include, "mood disorders."

The Good Samaritan Hospital website also instructs women to "check your symptoms for a variety of postpartum mood disorders."

"They are trying to talk women into believing they have a mental illness, says Karen Barth Menzies of Baum, Hedlund, Aristei, Goldman & Menzies, one of the attorneys leading the charge against the antidepressant manufacturers for failing to warn about birth defects. "But the symptoms they are being told to check for are no different than what any person may feel on a bad day or when they are under the weather. By their definition, everyone is mentally ill and should pop a psychotropic pill, continued Menzies.

Talk about market expansion, even in the best of cases, the odds are fairly good that a new mother may be in a bad mood on at least one of those 4 days, leading to a label of "mental illness requiring medication.

For its article, the Sun interviewed a first-time mom named, Jami. Shortly after she gave birth at Good Samaritan, a nurse psychotherapist had Jami fill out a 15-question test. And surprise, surprise, Jami flunked the test, started seeing a shrink and is now on an SSRI.

"I learned I had anxiety before," she told the Sun. "(People like me are) overachievers, our resumes look like we're 40 or 50, but when we have a baby, it can come out very intense."

So Jami agreed to take Lexapro for 6 months for anxiety, something she did not originally want to do, according to the Sun.

The old line that there,s no difference between taking insulin for diabetes and taking SSRIs for whatever, has apparently been replaced with an equally overly simplistic line as Jami explained, "People get glasses, people get braces, and now there's something for anxiety."

Some experts view it differently. "Drug makers have been trying to get a better deal with pregnant women for ages," Dr Healy says, "by saying they are under a lot more stress than most people realize, so this is now the easiest of marketing for drug companies."

"The trouble is," Dr Healy points out, "it,s almost too easy for drug companies here because lots of people are cooperative."

But it gets worse. The SSRI pushers in Illinois, have convinced Jami to start taking an SSRI the moment she even thinks of becoming pregnant again. "My psychiatrist said when my husband and I want to have another baby," she told the Sun, "it might not be a bad idea to get on something low-dosage before we even start trying."

"And I'm OK with that," says Jami. Apparently Jami,s psychiatrist didn,t tell her that she could be placing her unborn child at risk for birth defects, persistent pulmonary

hypertension (PPHN), neonatal withdrawal syndrome and other potential life threatening defects and disorders.

Attorney Karen Barth Menzies, who represents more than fifty mothers who were taking Paxil and whose babies were born with birth defects, commented, "I wish Jami could talk to any mother who has watched her infant undergo open-heart surgery and then decide if she is willing to take that risk.

According to psychiatrist, Dr Grace Jackson, author of, "Rethinking Psychiatric Drugs: A Guide for Informed Consent," prescribing SSRIs as a preventative measure during pregnancy is a terrible idea. The major reason why preventive use is so dangerous, she says, is that there is research suggesting that the SSRIs exert a direct effect upon the early embryo.

For example, she notes, researchers in France published a paper in 2005 that suggests that serotonin exerts an impact on developmental processes of the embryo much earlier than previously believed. "It was already known in the 1980s and 1990s," Dr Jackson says, "that the administration of SSRIs to embryonic cultures of rats and mice leads to craniofacial and cardiac defects."

Experts critical of SSRI use during pregnancy, all agree that in the absence of any proven effectiveness of treatment with SSRIs, no potential harm to the fetus can be justified.

"Even if women are depressed or anxious during pregnancy," Dr Healy says, "there is no good reason to prescribe antidepressants, because only 1 out of 10 people are likely to respond to the drugs rather than to attention and support."

"So in essence," he notes, "nine out of 10 pregnant women will be subject to the risks of the SSRIs for the one person who might benefit."

Other experts agree. The July 2005, British Medical Journal, published a report on a review of SSRI data by Moncrieff & Kirsch, that said, SSRIs have no clinically meaningful advantage over a placebo and considering the risks, recommendations for prescribing the drugs should be reconsidered.

It's worth noting that there is not a single word in the Sun article that would indicate that Jami is aware of any of the serious birth defects now known to be associated with SSRI use during pregnancy. This concerns Harvard trained psychiatrist, Dr Stefan Kruszewski. "Informed consent," he says, "requires full disclosure."

"In every case in which a doctor writes a prescription for a drug," he explains, "the person receiving the prescription must be fully and understandably provided a statement of the risks associated with treatment."

"This is never more serious," he warns, "than when two lives are potentially at risk, such as the pregnant mom and her fetus.

"Those risks for the pregnant mom," Dr Kruszewski warns, "may include antidepressant withdrawal, akathisia or rapid mood swings."

"For the fetus," he says, "the overwhelming worry is congenital malformations, resulting in complications for both mother and child.

SSRI makers have known about the fetal harm of SSRIs for over a decade. As far back as 1996, the New England Journal of Medicine reported a study that showed higher rates of premature delivery, low birth weight, admissions to intensive care units, and poor neonatal adaptation, including respiratory and feeding difficulties, and jitteriness, in children born to women who took Prozac during pregnancy.

In 2004, the FDA revised SSRI labels to warn that some infants had developed problems requiring prolonged hospitalization, respiratory support, and tube feeding. Three FDA advisories have been issued on Paxil since December 2005, and the drug's pregnancy category has been raised from C to D, meaning there is positive evidence of fetal harm.

In February 2006, the Archives of Pediatrics & Adolescent Medicine, reported that roughly one-third of infants exposed to SSRIs showed signs of withdrawal such as high-pitched crying, tremors, gastrointestinal problems and disturbed sleep, with 13% severe.

The April 2006, American Journal of Obstetrics and Gynecology, reported that taking SSRIs doubled the mother's risk of delivering a stillborn infant and increased the risk of premature delivery, underweight babies, and seizures.

In July 2006, the FDA issued an advisory warning that infants exposed to SSRIs were six times more likely to develop the often fatal lung disorder, persistent pulmonary hypertension (PPH), than infants who were not exposed.

The October 2006 edition of Epidemiology reported that women who took SSRIs during the second or third month of pregnancy had nearly two times the risk of having babies with congenital malformations, with the most common being cardiovascular malformations in 29%, muscle and bone malformations in 31%, and 14% had digestive malformations.

Meanwhile, the Sun reports that Good Samaritan screened 1,262 patients in 2006, and found 18% at risk for postpartum depression. Not a bad catch for SSRI makers and it can only get better when the plan for "universal screening" kicks in.

One of the latest recruitment scams involves expanding the postpartum depression market by 10% simply by including the husbands. According to an August 2006 study in Pediatrics, about 10% of fathers suffer from moderate or severe postpartum depression.

"Postpartum depression in fathers was strikingly high and more than twice as common than in the general adult male population in the U.S.," say researchers including Dr James Paulson, of the Center for Pediatric Research at the Eastern Virginia Medical School.

As a result, the authors advise, pediatricians must make a greater effort to screen moms *and dads* for postpartum depression.

However, this appears to be a case of the dueling researchers in medical journals because in December 2006, a Danish study in the Journal of American Medical Association, found that first-time mothers were at an increased risk for mental disorders but fathers were not.

This 32-year stdy included more than 2.3 million people, and roughly one out of 1,000 first-time mothers were admitted to a hospital with a mental illness within one year, and most were admitted within the first three months after birth. But among fathers, only 0.37 of 1,000 births resulted in a mental disorder, which the authors noted, was comparable to men without children or men with an older infant.

"This may indicate that the causes of postpartum mental disorders are more strongly linked to an altered physiological process related to pregnancy and childbirth than psychosocial aspects of motherhood," said study author Trine Munk-Olsen of the University of Aarhus, Denmark.

This is indeed the case, according to Dr Jackson. "The third trimester," she says, "is a wild time for the mother, in terms of hormonal changes that occur within her system largely because of the hormones that are produced in the placenta."

In general, she notes, the mother,s hypothalamus-pituitary-adrenal axis is in a state of over-drive, and "the brain itself gets in on the act in terms of Steroids that are made inside the brain."

She says, researchers were very excited in the late 1990s to discover that Prozac, for example, increased levels of the neurosteroid called allopregnanolone.

Neurosteroids, Dr Jackson explains, are made in the brain itself and allopregnanolone is a chemical which acts to modulate mood and anxiety and may account for why most mothers forget the intense pain of labor. "Nature," Dr Jackson says, "has created a way to remove the memory of the most intensely painful experience which a woman can encounter during her lifetime."

Some researchers report that it takes about 90 days for the steroid levels to re-equilibrate. "Although all women experience these hormonal changes," Dr Jackson explains, "some may be more sensitive than others to the fluctuations which occur in the immediate post-partum period - a 90 day phase of steroid, withdrawal."

Giving SSRIs may help relieve this "withdrawal period by boosting the allopregnanolone artificially, she says, but many women will become addicted to the SSRIs, for a hormonal change that would have ended naturally on its own within 90 days.

Then there is the little matter of prescribing SSRIs to nursing mothers. "No one yet knows," Dr Jackson warns, "because no one has studied the long term consequences of administering SSRIs to infants via breast milk."

"It has never been proven," she notes, "that there is no effect, of giving infants these drugs during the first months or years of post-uterine existence."

Furthermore, she says, no one understands how the in utero exposure to SSRIs changes the wiring of the newborn's brain.

In regard to the overall scheme of screening all women before, during and after pregnancy and putting them on SSRIs, Dr Jackson says, "in sum, there could not be a more foolhardy public health practice than this one."

A better use for a post-pregnancy screening survey, may be to screen women who were conned into taking SSRIs during pregnancy whose babies died or were born with birth defects, to see how many of those mothers are depressed for reasons that no pill can cure.

A good place to start would be West Virginia, with the mother of twin daughters who were born with heart birth defects, after she took Paxil during pregnancy. Only one infant survived and the other died at 20-months-old.

Another infant with Paxil related heart defects was born to a mother in Omaha, Nebraska, and the baby lived only 24 days after enduring four surgeries in an attempt to save his life.

A screening should also be conducted on the Toledo, Ohio mother who took Paxil and had a baby born with heart defects who lived only 17 days after undergoing several surgeries.

Another infant was born with Paxil related heart birth defects to a mother in Westerville, Ohio, and the baby required two surgeries in the first nine months after birth and will have to undergo more in the future.

A Texas mother on Paxil also gave birth to an infant with heart birth defects who required multiple open-heart surgeries and had to have a pacemaker implanted.

The Los Angeles-based Baum Hedlund law firm has the longest track-record handling SSRI litigation in the country. The firm currently represents families in dozens of SSRI-related birth defect cases, including Paxil, and has seven attorneys assigned specifically to SSRI litigation.

Attorney, Karen Barth Menzies, has been handling SSRI cases for more than a decade involving Prozac, Paxil and Zoloft and now leads the team, along with Baum Hedlund attorney Jennifer Liakos, representing families in Paxil birth defect cases.

In addition to birth defects, SSRIs have been linked to suicidality, violence and homicide, abnormal gastrointestinal and uterine bleeding, a decrease in bone density, fertility problems, sexual dysfunction, and a severe withdrawal syndrome.

However, almost without exception, every time the FDA issues a warning about a new adverse event associated with SSRIs, the drug companies send out their paid shills to present industry-funded studies to downplay the seriousness of the warning.