

# LOOKING FOR LOVE.....

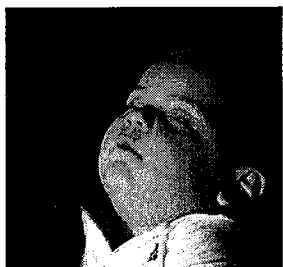
## Baby Blues

Lisa Collins took the Paxil her doctor prescribed. There was supposed to be no problem with her continuing it during her pregnancy. Now, it seems, there was.

By **Todd Spivak**

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Dark blue splotches stained Lisa Collins's newborn son's mouth as if he'd gotten messy with a lollipop.



Daniel Kramer

Mom scrubbed Baby clean in the bathtub, but the blemishes would not go away.

The discoloration soon spread to Chase's tiny fingernail beds -- the sign doctors had warned about.

Midway through her pregnancy, doctors told the 27-year-old Friendswood resident to expect complications.



Daniel Kramer

Chase's daily drug regimen tripled after he had open-heart surgery.

The same ultrasound that revealed she was having a boy also showed the fetus was missing part of his heart. A more detailed X-ray image taken a week later revealed an underdeveloped heart chamber.

Doctors predicted Chase would require surgery within two weeks after delivery, if he survived that long.

Nobody could explain why the baby had congenital heart defects. Neither the mother's nor the father's family had any history with such problems.

Months later Collins caught a TV news segment warning pregnant women against using antidepressants. Studies showed they may cause birth defects in developing fetuses.



Daniel Kramer

Houston attorney Robert Kwok plans to file multiple lawsuits against antidepressant maker GlaxoSmithKline.

Collins doesn't suffer from severe depression or any other mental illness. But six months before becoming pregnant, she complained to her general practitioner in Pearland of irritable bowel syndrome and at times feeling claustrophobic.

Dr. Jackie Lynn Snell prescribed Paxil, a popular antidepressant viewed as a cure-all for all things psychosomatic, from depression to an array of anxiety and compulsive disorders.

After becoming pregnant, Collins asked Snell if she should stop.





Photos courtesy of Cassandra Burdick

Cassandra Burdick holds son Nicholas...



Photos courtesy of Cassandra Burdick

...who died after three months on a ventilator.

"She assured me it was perfectly safe," the mom says. "I trusted my doctor."

Collins popped the oval-shaped pills through the end of her first trimester.

On November 2, 2005, Collins had a cesarean delivery at St. Luke's Hospital. Nurses immediately rushed the baby to the neonatal intensive care unit. For two weeks Chase was hooked to a ventilator and fed through a tube.

"I was tripping over cords trying to hold my baby," Collins recalls.

Able to breathe on his own, he was allowed to go home.

Here he was, nearly three months old, doing fine. A happy, alert infant with a mop of black hair, he ate slowly but rarely fussed and already slept through the night.

Mom held out hope that the doctors were wrong.

Then Baby turned blue.

In March Collins sued GlaxoSmithKline, the pharmaceutical giant that manufactures Paxil. The suit alleges the London-based company concealed studies and manipulated statistics that revealed the drug's risks for pregnant women.

"We cannot discuss pending litigation around our products," says GlaxoSmithKline spokeswoman Gaile Renegar.

Snell is also named in the suit. The 35-year-old general practitioner, currently on sabbatical after giving birth to her own child, contends she did not know about the hazards until the U.S. Food and Drug Administration's advisory late last year.

"The deed was already done by the time the reports came out," says her attorney, Jay Henderson, of the Houston firm Cruse, Scott, Henderson and Allen, LLP.

Since December 2005, the FDA has issued three public health advisories concerning Paxil and the threat of congenital heart defects. The regulatory agency changed Paxil's pregnancy category from C to D, which indicates that there is "positive evidence of fetal risk."

In addition to heart defects, several medical studies published in the last year have shown antidepressants taken during pregnancy significantly increase the risk of potentially fatal lung conditions and abdominal wall defects in newborns.

The FDA has not approved Paxil or other similar drugs for pregnant women, though they are commonly prescribed to treat depression. More than 40,000 pregnant women in the United States take antidepressants, according to the American Medical Association.

Though it remains too early to know how many families may be affected, the potential result is a new generation of deformed children and guilt-ridden mothers not seen since the thousands of thalidomide babies born in the early '60s.

Antidepressants such as Paxil were widely touted as wonder drugs with no serious side effects when

they entered the market nearly two decades ago. "Sunshine in a bottle," proponents called them. They have since become increasingly controversial, prompting thousands of lawsuits.

These suits have fallen into two main camps. One alleges the drugs are addictive and can produce severe withdrawal symptoms including hallucinations, extreme mania and electric-shock sensations. The other claims they may actually cause depression and trigger suicidal and homicidal behavior.

Collins's case is among the first of its kind and marks the start of a new trend in litigation against antidepressant makers.

Dallas-area residents Anthony and Matilda Vasquez have filed the only other similar lawsuit in Texas. Their two-year-old son, Adrian, has undergone three open-heart surgeries and has a pacemaker. The mom took Paxil during her entire pregnancy.

These cases may attract international attention; the Collins suit is the first in the country to already have a trial date, set for next summer.

The FDA approved Paxil to treat depression in 1992 as part of a new class of antidepressants called selective serotonin reuptake inhibitors, or SSRIs.

It has long been believed that SSRIs work by boosting serotonin levels, the brain chemical most closely associated with depression. Drug makers and several leading scientists say this helps normalize cell-to-cell communication in the brain, stabilizing the chemical imbalance thought to cause depression.

Recent studies cast doubt on this theory, suggesting that scientists have never understood the drugs' effects on the brain.

A growing number of medical researchers say while increasing serotonin retention, SSRIs also indirectly inhibit the neurotransmitter dopamine, causing a chemical imbalance in some users. This has been linked to serious side effects such as akathisia, a severe inner restlessness associated with violent behavior.

Illegal hallucinogens such as ecstasy, LSD and PCP similarly increase serotonin levels and decrease serotonin metabolism.

SSRIs were considered a vast improvement over previous generations of antidepressants, developed in the '50s and '70s, which were found to elevate moods but later deemed acutely toxic with a high risk of overdose.

The first SSRI introduced in the United States was Eli Lilly's Prozac in 1988. Its immediate popularity led to a host of brand-name imitators, from Paxil to Pfizer's Zoloft, Forest Laboratories' Celexa, Solvay Pharmaceuticals' Luvox, Wyeth Pharmaceuticals' Effexor and many others.

All are marketed to treat a range of mental illnesses, including severe depression, post-traumatic stress disorder, social anxiety and obsessive-compulsive disorder. Doctors prescribe them for everything from eating disorders to bed wetting, low self-esteem, nail biting and shyness.

More than 20 million Americans take antidepressants. Last year doctors dispensed 150 million prescriptions in the United States, according to IMS Health, a Connecticut-based health care information company. As much as 70 percent of the drugs are prescribed not by psychiatrists but by general practitioners with no special training in complex mental disorders.

The overall market for antidepressants in the United States exceeds \$12.5 billion annually. Sales of Paxil earn GlaxoSmithKline \$3 billion a year worldwide.

The debate over SSRIs has raged for 20 years. Drug companies and countless patients who swear by them have been quick to dismiss any suggestion that they may be harmful. Then there are doctors and attorneys who blame the drugs for virtually every seemingly unexplainable violent rampage.

Harvard Medical School psychiatrists were the first to identify a link between SSRIs and aggressive behavior, reporting in 1990 that six adults experienced "intense, violent suicidal preoccupation" within a couple of months of starting Prozac.

An FDA panel dismissed the study. It took 15 years for the agency -- which some criticize as more lapdog than watchdog -- to change its thinking.

FDA drug-safety analyst Andrew Mosholder in 2003 discovered several suicide attempts reported in Paxil trials under the euphemistic heading "emotional liability." Mosholder conducted his own analysis of Paxil and other antidepressants. He found they doubled the risk of suicidal thoughts or behavior in children and adolescents compared to a placebo. Several trials further showed they performed no better than a sugar pill.

The FDA blocked Mosholder from going public, claiming that his study had not been finalized. But his findings were soon leaked to the media.

Based on these revelations, the FDA in the summer of 2003 issued a public health advisory warning that Paxil and other SSRIs may worsen depression and cause suicidal tendencies in kids under 18.

In June 2004, New York Attorney General Eliot Spitzer sued GlaxoSmithKline for allegedly burying studies showing Paxil increased suicidal thoughts and behavior in kids. Central to the case was an internal GlaxoSmithKline document showing the company intended to "manage the dissemination of data in order to minimize any potential negative commercial impact." GlaxoSmithKline denied the charges but settled the suit in August 2004 for \$2.5 million and agreed to post its clinical results on the Web.

Later that year the FDA required all antidepressants to carry a black box warning on labels, the agency's strongest kind, to warn of suicide risk in children. Then in May 2006, GlaxoSmithKline issued a statement warning doctors of a heightened risk of suicide in young adults, ages 18 through 30. It marked the first study released by a drug company that showed a connection between antidepressants and suicidal behavior.

This debate has been argued in scores of lawsuits since the late '80s, when Prozac hit the market. Antidepressants have been blamed for prompting the Columbine shootings and countless other killing sprees.

Many of these suits were resolved in 11th-hour settlements, enabling drug companies to avoid the publicity of going to court and nix the risk of confronting a guilty verdict.

One high-profile case pitted the family of Joseph Westbecker against Eli Lilly, claiming the Kentucky man's four-week use of Prozac in 1989 led him to kill eight people. Lilly won the case. But it was later discovered that the drug company doled out huge settlements to all the attack survivors and their attorneys. The judge later changed the official record from a jury verdict in Lilly's favor to dismissal of a settled case.

In 2001 relatives of Donald Schell sued GlaxoSmithKline, claiming the Wyoming man's 48-hour use of

Paxil in 1998 led him to kill his wife, daughter and nine-month-old granddaughter. The jury found Paxil was a "substantial factor" and ordered the drug company to pay \$6.5 million to surviving relatives. It marked the first and only case won by a plaintiff.

Houston trial lawyer Andy Vickery represented the Schell family. He enjoys a national reputation as the lone attorney to stick it to GlaxoSmithKline on the suicide issue.

Vickery and associate Paul Waldner already have consulted with about 70 women who are convinced that taking Paxil during pregnancy caused serious birth defects.

The most commonly reported malformations have been atrial and ventricular septal defects. These are holes in the membrane that separates the chambers of the heart, and often can be surgically repaired.

Vickery and Waldner are in the preliminary stages of filing several lawsuits against GlaxoSmithKline. They are selecting the most extreme and unique cases, all of which required multiple surgeries. In one instance, a baby was born without heart chambers. In another, the aorta and pulmonary artery were conjoined as one vessel.

Vickery points to revelations that GlaxoSmithKline selectively used clinical trial data to play down the risks of violent behavior in Paxil users. He predicts similar information will emerge regarding the dangers to fetuses.

"We gained access to a lot of GlaxoSmithKline documents that are not in the public domain," says Vickery, whose firm is devoted entirely to antidepressant cases. "We're not some wild-eyed crazy lawyers blowing smoke."

Vickery says the first claim linking Paxil with heart defects in fetuses appeared in a 1998 report filed in the FDA's "adverse effects" database.

In 2003 GlaxoSmithKline began the first major study on the subject, performing a retrospective analysis of pregnant women, dating back to 1995, who had taken antidepressants in the first trimester and had given birth to children with major congenital malformations. The analysis showed a more than twofold increase in women taking Paxil compared to other antidepressants.

At about the same time researchers analyzed data from Sweden's birth registry, which collects information on pregnant women and offspring, and found birth defects were twice as common among Paxil users.

Based on these studies, the FDA changed Paxil's labeling.

Meanwhile, new reports continued to surface showing a wider array of health risks for pregnant women taking Paxil and similar antidepressants.

A 2005 study published in *The Teratology Society* reported women who took Paxil were more likely to have infants with birth defects such as omphalocele, in which the intestines or other abdominal organs protrude from the navel, and craniosynostosis, the early closing of one or more of the sutures of an infant's head, resulting in malformation of the skull as well as mental retardation and blindness.

A February 2006 study published in *The Archives of Pediatrics & Adolescent Medicine* examined 60 newborns exposed in utero to SSRIs. Of these, 18 showed mild to severe signs of "neonatal abstinence syndrome," or withdrawal from the drugs at birth. Symptoms included tremors, high-pitched crying

