May 24, 2011

Is Your Birth Control as Safe as You Think?

Since NuvaRing hit the market, more than 700 women have filed lawsuits, claiming it has caused potentially life-threatening blood clots. The battle may change the way millions of women prevent pregnancy.

By Laura Beil

Christen Childs woke up on September 12, 2009, in the pitch dark of early morning with what she thought was a pulled muscle in her leg. She reached down to massage the cramp, trying to fathom how her left calf could be so achingly sore when she hadn’t made it to the gym in weeks. This was a Saturday — by Monday, her leg was swollen and hot, and when she tried to stand, jolts of pain shot up to her spine. She consulted her brother-in-law, a doctor, and he told her to go to the ER immediately. He suspected what an ultrasound would confirm: Childs, 26, had a blood clot in her leg — left untreated, it could kill her. "When the doctor diagnosed me, I started
"crying," she says. "I was stunned by how close I had come to dying."

Death would come closer still. Later that day, the clot broke apart and traveled to her lungs. Straining to breathe, she remained bedridden in the intensive-care unit as blood thinners were injected into her stomach four times a day for six days. By the following weekend, she was released, instructed to return weekly for hematology checks to make sure new clots hadn't formed. Meanwhile, her doctors ran a battery of tests to figure out what exactly went wrong. After all, Childs didn't have any of the risk factors associated with blood clots: She didn't smoke, wasn't overweight, and had no family history of clots. After six months on blood thinners, Childs was finally back to her old self, with one exception: Her doctors wouldn't let her go back on NuvaRing, her birth control, which they determined was the likely culprit behind her near-fatal illness.

NuvaRing is one of the world's most popular forms of non-pill birth control, and recent data indicates that more than 5.5 million prescriptions were written in the U.S. in 2010, according to IMS Health, a health-care information company. But in recent years, serious questions have arisen concerning its safety. To date, almost 1,000 cases of possible NuvaRing-related blood clots have been reported to the FDA, and more than 700 women in the U.S. are currently suing Merck, NuvaRing's manufacturer, for downplaying its health risks. Most of those lawsuits have been consolidated into a massive, multidistrict federal case that's expected to go to trial in Missouri next year. The NuvaRing case is being closely watched by physicians and the pharm industry. If the litigants persuade a jury that Merck undersold the device's risk for blood clots — a big if, to be sure — it could have far-reaching consequences for several contraceptives on the market.

• When it was approved by the FDA in 2001, NuvaRing became the world's first vaginal birth-control ring. Inserted just once a month, it dispenses hormones directly into the bloodstream. Unlike oral contraceptives, which require taking a pill the same time every day, NuvaRing is marketed as a pill-free, no-muss/no-fuss alternative. Just pop it in and forget about it (the ring remains in for three weeks and comes out for a week during your period). That pitch clearly resonated with women. Last year, NuvaRing generated $559 million in international sales for Merck.

It's worth noting that all hormonal birth control with added estrogen carries a risk of blood clots. In the 1960s, the estrogen used in the earliest pills raised the risk of clots more than ninefold. A decade later, a second generation of pills containing a much gentler dose of the hormone, coupled with the synthetic hormone progestin, had been developed. Though these second-generation pills are effective and safe, drugmakers have sought new forms to market as better able to control conditions like facial hair and acne. NuvaRing contains a version of the third-generation progestin desogestrel. There's even a fourth-generation progestin, said to alleviate symptoms of PMS; it's the essential component of Yaz and Yasmin, two top-selling oral contraceptives.

The problem? Some researchers say third- and fourth-generation contraceptives — including those containing desogestrel — raise the risk of blood clots without adding any benefit. In 2007, the consumer watchdog group Public Citizen petitioned the FDA to ban oral contraceptives containing desogestrel. Although NuvaRing wasn't named in that petition because it was still fairly new, the
director of Public Citizen's Health Resource Group, Dr. Sidney Wolfe, reached an unequivocal conclusion: "We've told people not to use these drugs and have advised women that the safest contraceptives are the older, second-generation ones." The FDA didn't act on Public Citizen's claims, even though during its own review process, the agency concluded that NuvaRing's label should "clearly reflect safety concerns about an increased risk" for blood clots.

In 2009, the British Medical Journal published two investigations of desogestrel and fourth-generation progestins that seemed to bolster critics' concerns. Both studies found that women taking third- and fourth-generation pills were almost twice as likely to get a blood clot than those who took second-generation contraceptives. Frits Rosendaal, Ph.D., an epidemiologist at Leiden University Medical Center in the Netherlands who has contributed to more than a dozen scientific papers on desogestrel, coauthored one of the studies that found a higher risk for clots in NuvaRing than in second-generation birth control. "To me, it's incredible that [Merck] used desogestrel and not a second-generation progestin. Why not go for the one with the lowest risk?" says Rosendaal.

But Merck and other scientists dispute claims that NuvaRing poses a higher risk than other contraceptives. In NuvaRing's product information pamphlet, Merck acknowledges the findings, but adds, "Data from additional studies have not shown this twofold increase in risk. It is unknown if NuvaRing has a different risk of [blood clots] than second-generation oral contraceptives." That position infuriates NuvaRing's critics. "Nine years after the product was put on the market, they still say the risk is unknown. To say, 'We just don't know' is not sufficient," says Thomas Lamb, a North Carolina — based attorney whose firm represents more than 50 women around the country who have filed suit against NuvaRing, Yaz, and other third- and fourth-generation contraceptives.

Among those wanting answers is Robert Bozicev, 37, of Tom's River, New Jersey. His 32-year-old wife, Jackie, had begun using NuvaRing shortly after the birth of their daughter in 2007. One Friday morning, as he stood in the kitchen making breakfast for their two kids, he heard her putting about in their second-floor bathroom. As she was about to step into the shower, she called his name. He answered her, preoccupied with their son, 2, who was demanding another waffle. After she cried for him a second time, barely able to get out his name, he dashed upstairs and found her on the floor, unable to breathe. "She was in a lot of pain, rolling around, trying to get onto her stomach," he says. "My son was there, watching the whole thing." To his horror, Jackie started turning blue.

When an ambulance arrived, emergency techs tried to restart her breathing. Bozicev was gripped with terror. Doctors continued to try to revive her in the hospital but eventually had to give up. She died that day. The cause of death: massive pulmonary thromboemboli due to deep vein thrombosis. In other words, she died from a blood clot. Anxious to learn more about what had happened, Bozicev searched online and came upon reports linking NuvaRing to an increased risk of clots. Knowing Jackie had been healthy before she started using the device (she wasn't overweight and didn't smoke), Bozicev concluded that NuvaRing was to blame, and filed a wrongful-death suit against Merck in March 2008. "Even to this day — and this is three and a half years later — I still can't believe it happened," he says. Jackie's clothes remain in her closet. He is too heartbroken to take them out.

NuvaRing isn't the only pill-free contraceptive beset by litigation. When Ortho Evra hit pharmacy shelves in 2002, it was the first birth-control patch of its kind. Its selling point: Simply slap a Band-Aid-like adhesive on your arm, stomach, or back each week. Within two years, sales had swelled to nearly $400 million. But soon after, studies emerged indicating that the blood concentrations of estrogen in Ortho Evra users might be much higher than previously thought, resulting in a greater risk of clots. That's when the lawsuits piled up. In November 2005, Ortho Evra, under an agreement with the FDA, added a black-box warning to its packages stating that patch users are exposed to roughly 60 percent more estrogen than the typical pill user, resulting in a potential "approximate
doubling of risk of serious blood clots." The warning also stated that the risk might not increase at all, but it was still enough to scare off doctors. By year-end 2010, Ortho Evra's sales had fallen 69 percent to $124 million.

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I am one of these women. I had no other risk factors whatsoever. I didn't have any leg pain, but couldn't breathe. I started feeling like an elephant was on my chest at all times. I was out of breath all the time, just from talking, which was not normal obviously. I finally got checked out after a week of not breathing right and so glad that I did. 24 hours later and I would have been like that poor woman in the above scenario who died. I had a massive clot on it's way right to my heart along with 131 other blood clots in my lungs on both sides. I am thankful every day that I am still here. I was put in the ICU with a Heparin drip, the Lovenox shots to the stomach, and after being released was on Coumadin for nine months. I can no longer have any birth control with hormones in it, cannot get pregnant without the risk of death looming, and I get petrified any time that I have chest pains. I urge anyone who is on this medication to watch your body careful and if you see anything or feel anything out of the ordinary, please go get it checked out immediately. Blood clots are a silent killer. I am so relieved that I made the decision to go to the doctor. Someone certainly was looking out for me that day.
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