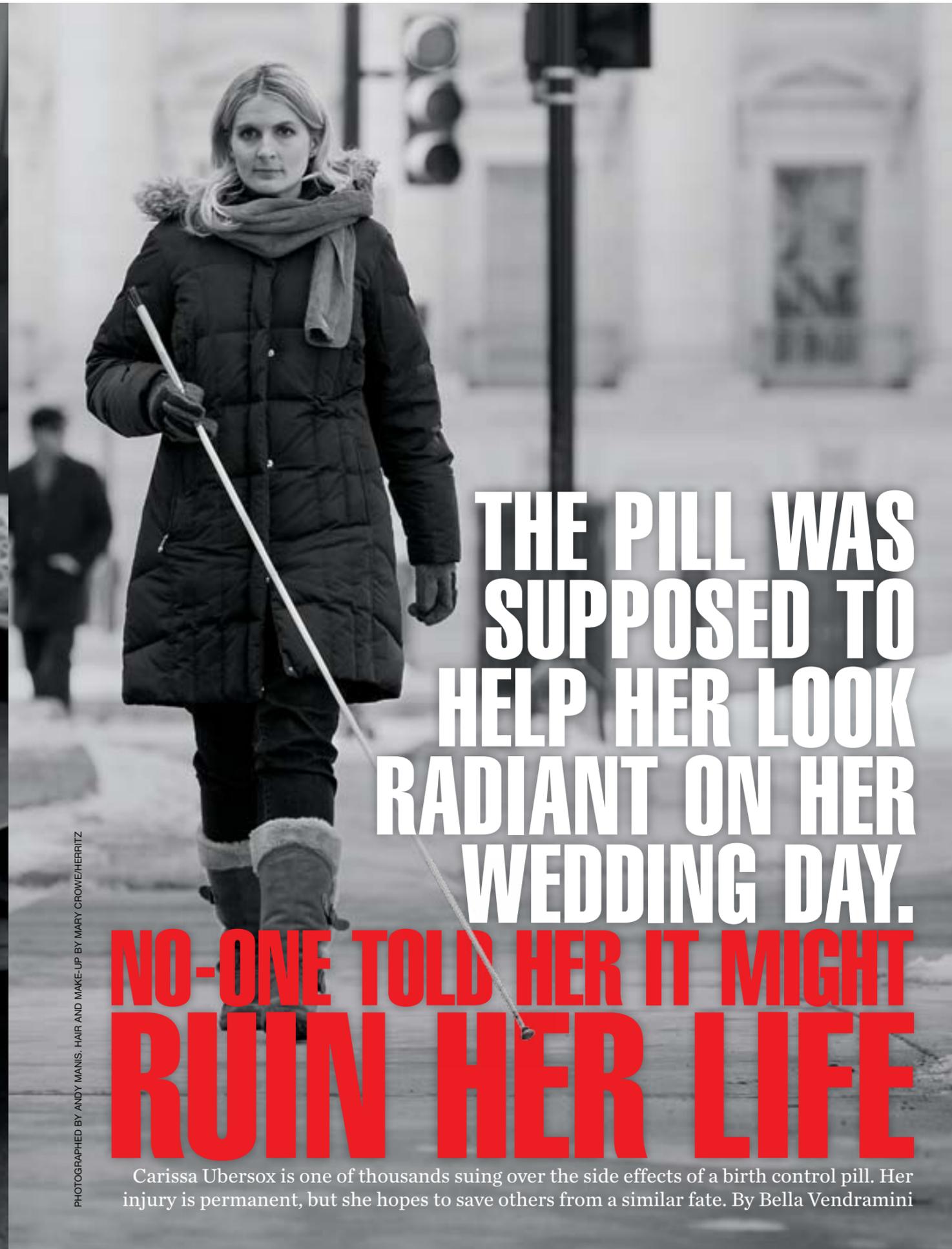




Carissa Ubersox was only 24 when her world was turned upside down. She believes a contraceptive pill was to blame.



THE PILL WAS SUPPOSED TO HELP HER LOOK RADIANT ON HER WEDDING DAY.

NO-ONE TOLD HER IT MIGHT RUIN HER LIFE

PHOTOGRAPHED BY ANDY MANIS. HAIR AND MAKE-UP BY MARY CROWE/HERRITZ

Carissa Ubersox is one of thousands suing over the side effects of a birth control pill. Her injury is permanent, but she hopes to save others from a similar fate. By Bella Vendramini



Clockwise from above: after graduation Carissa landed her dream job as a nurse; she has had to relearn how to do common household tasks and read braille.



Carissa Ubersox didn't think it was very classy to meet the love of her life in a student bar, but that's where it happened – a damp, barely lit tavern in Madison, Wisconsin, where a jukebox played and drinks were poured into plastic cups. Meeting the broad-shouldered and dark-haired Tyson was, Carissa believed, the beginning of the rest of her life. And so it seemed. Overnight, Carissa, then 20, and Tyson became a popular couple around Madison, both of them attractive and full of enthusiasm: they'd throw fancy dress parties for their friends or hit Hawaii for mini breaks. Life got even better when Carissa graduated from university and landed her dream job as a paediatric nurse at the local hospital. A tireless supporter of her hopes and ambitions, Tyson held her in his arms and told her he was proud of her.

"I wanted to marry him so badly," remembers Carissa. "I'd always hoped to get engaged on Christmas Day." It seemed Tyson was a man who could take a hint. On December 25, 2007, he fought his way through the melting snow to the hospital where Carissa was working the holiday shift. He produced roses, a sparkling diamond ring, a bended knee and a proposal to be with him for the rest of their lives. She said yes in a heartbeat. But a heartbeat of a different sort would be all it would take for Carissa's life to come crashing down around her.

Watching television over breakfast one morning soon after the engagement, Carissa spotted a commercial spruiking a contraceptive pill called Yaz. It promised to halt symptoms of PMS like mood changes and, as a bonus, give her a clear, smooth complexion. Excited to look and feel her best for her upcoming wedding, Carissa jumped at it. "It sounded wonderful," she recalls thinking.

Although the US Food and Drug Administration (FDA) would later rule the commercials were misleading (and order Bayer, the manufacturer of Yaz and Yasmin, to pay \$20 million to correct them), it would be too late for Carissa. Just a few weeks after starting Yaz, she would be fighting for her life.

Yaz is a bestselling new-generation oral contraceptive taken by millions of American women. Bayer launched an earlier version called Yasmin in 2001 (Yasmin is a "sister" contraceptive with the same ingredients as Yaz, notably drospirenone, a synthetic hormone, but with a slightly higher dose of oestradiol, a form of oestrogen). Yaz followed in 2006 and, since then, sales for the two drugs have skyrocketed past \$8 billion worldwide. Commercials like the one Carissa watched – prescription pharmaceuticals can be advertised in the US – help drive Yaz's popularity. But what the ads didn't tell Carissa, or the 200,000 Australian women who take Yaz and Yasmin, is that the so-called "miracle" contraceptive is a potential time bomb.

All drugs have side effects, but, according to some experts, Yaz is in a class of its own. Figures vary, but a 2011 FDA study of more than 835,000 women found that the risk of blood clots with this type of drug is up to three times that of other contraceptives. A 2011 Danish study of 1.3 million women, conducted over nine years and published in the *British Medical Journal*, found that a woman's risk of blood clots is a staggering six times higher when taking either Yaz or Yasmin.

Blood clots can kill in one of three ways: they shoot straight to the heart and cause a heart attack; travel through the arteries to the brain and trigger a stroke; or travel to the lungs and stop you breathing. They can also discharge into the artery behind the eyes and cause blindness.

At press time, more than 13,500 lawsuits had been served or were pending against Bayer in the US. So far, only Americans are able to sue, despite Yaz and Yasmin being available in Australia and around the world. A corporate affairs manager with Bayer Australia told *marie claire* he didn't anticipate

lawsuits here: "Australians are so culturally different from Americans."

In the US, Bayer has already settled about 3500 cases, paying out \$720 million to those affected by blood clots, and on the basis of inadequate warnings. They have put aside a further \$250 million for future claims.

For Carissa, a young woman blissfully poised on the brink of marriage, the alarm bells didn't sound soon enough. "I was going about my business, getting ready for work, so everything seemed normal," she recalls of that day in February 2008. "My legs felt achy, but I disregarded it because as a nurse I often had to be on my feet for 12 hours at a time. I remember telling one of the doctors at work, 'Oh, my calves hurt,' and he was like, 'Stop being a hypochondriac. You're 24 years old, you're healthy, there's nothing that could possibly cause that.' I'm thin, I'm athletic, I look nothing like the overweight smoker who a doctor might think was a potential candidate for a blood clot."

It was while she was taking a shower that multiple clots dislodged from her legs, travelled to Carissa's lungs and caused a massive double pulmonary embolism. "I wasn't able to breathe," recounts Carissa with a quavering voice. Tyson was with her and called an ambulance. "But on the way down in the elevator, my heart stopped."

Carissa was clinically dead for four minutes before paramedics revived her. She then fell into a coma for 14 days. As



SUFFERED YAZ'S SIDE EFFECTS

From left: Professor Kerryn Phelps, Eva Fritz, Helena Mathis and Michelle Green experienced severe reactions to Yaz.

soon as she awoke, she knew something was drastically wrong. She could hear her mother's voice breaking with tears and the doctor instructing her to wriggle her toes, but she couldn't see anything. The once healthy, happy woman had woken up blind. The blood clot attacked Carissa's eyes so savagely that she remains almost completely blind to this day, without hope of recovery. "I don't want another 20-something woman to have to learn how to tie their shoelaces, or talk, or learn how to wash clothes," she reasons. "It's horribly difficult, an unimaginable thing to have to do."

Carissa not only lost her sight, but also her job – and her beloved Tyson. "I just kept looking at him and thinking, 'He can't take the ring back without looking heartless.' I had

A spokesperson for Bayer Australia told *marie claire* that Yaz or Yasmin did not pose any greater risk of blood clots than other oral contraceptives, and the risk was less than that of pregnancy. Bayer maintains post-marketing monitoring has found the "adverse event profile" to be consistent with other combined oral contraceptive pills – in other words, no worse. Two large studies on blood clot risks, funded by Bayer in the US, reported no increased danger.

Within the company, however, it seems to have been a different story. In a 2004 internal Bayer document, uncovered by David Kessler, a former FDA commissioner and an expert witness in litigation against the company, Bayer employees had written that "Yasmin has a several-fold increase in the

patented that the FDA would pull the two drugs off the shelves, but, to the surprise of many, the panel of medical experts voted 15–11 that the benefits outweighed the risks. Sales would continue.

The decision was controversial. A not-for-profit organisation called the Project On Government Oversight found that each of the four deciding votes came from panel members who had either worked for Bayer in the past or received research funding from the company. And while the experts had apparently declared these interests to the FDA, the FDA had not made public the commercial ties.

The panel did, however, recommend Bayer change its warning labels to reflect the concerns over blood clots. It's a move Australia's Therapeutic Goods Administration (TGA) agrees is vital, although it has no plans to restrict sale of the drugs in Australia. A spokesperson says all contraceptives carry risk of thromboembolism and that all products here provide warnings.

Most women *marie claire* spoke to who took Yaz or Yasmin were unaware of the dangers. Nor did they know that one of the other most common side effects – not featured in Yaz commercials – is depression.

In an ongoing study, Professor Jayashri Kulkarni, director of the Monash Alfred Psychiatry Research Centre at Victoria's Monash University, has found that it is the specific combination of drospirenone and low-dose oestrogen that places women at risk of depression. It can strike at any time. "The onset of depression can happen within a day of taking it or within a year of taking it," she points out. ▶

A 2011 STUDY FOUND THAT THE RISK OF BLOOD CLOTS WITH YAZ IS UP TO THREE TIMES THAT OF OTHER CONTRACEPTIVES

to break it off. I told him, 'We'll see.' Then, when I came back from blind school, he was dating a doctor."

Professor Kerryn Phelps, former federal president of the Australian Medical Association, GP and popular TV host, knows too well the risks of Yaz. In 2003, she went through her own personal nightmare with it. "I hate this drug," she tells *marie claire*. Like millions lured by Yaz's claims, she took the drug to regulate her periods. It took just three weeks to strike her down.

April 6, 2003, started like any other morning for Professor Phelps. She'd worked in her clinic, delivered a lecture, and was about to dash to the airport to take a meeting in Canberra with then Prime Minister John Howard. But by then she was having difficulty walking and couldn't catch her breath. "I knew something was seriously wrong," she describes in her book, *Ultimate Wellness*.

A blood clot in her leg dislodged and travelled straight to her lungs, causing a pulmonary embolism. For 25 hours Professor Phelps battled for her life in intensive care. She was one of the lucky ones: "Even making it to hospital, I had just over 10 per cent chance of surviving, less of surviving without disability."

reporting rates for deep vein thrombosis [blood clots], pulmonary embolism and venous thrombosis. The reporting rate for Yasmin was 10 times higher than that with the other products, which were very similar in magnitude."

In a letter to the FDA, Kessler accused Bayer of selectively presenting data about blood clotting to the authority. "Bayer," he stated, "needlessly exposed large numbers of women to risks of serious or fatal thromboembolic events." (Bayer Australia said it was unable to comment on these claims due to the current legal proceedings.)

On December 8, 2011, the FDA ordered a safety review of Yaz and Yasmin. Concerned observers antici-



Left: former Food and Drug Administration commissioner David Kessler accused Bayer of concealing the truth about the side effects of Yaz and Yasmin. Right: Bayer CEO Dr Marijn E Dekkers.

GETTY IMAGES; GREG HARM/TANGIBLE MEDIA; ANDY MANIS

It's easy to be complacent about a contraceptive pill. Most women feel that taking it is like having a morning cup of coffee. "You just don't think about it," says Eva Fritz, a 39 year-old from Queensland who took Yaz. "Like most women, I was attracted to it because of the vanity aspect: good skin and [the promise of] no PMS!"

As a psychologist, Eva was staggered to find herself plunged into a depression by day three of taking Yaz, without any external factors that could have influenced her mood. "I began yelling at my children. I was so freaked out by the intensity of it," she reveals. It was so crippling, she was often unable to get out of bed for hours on end. By day eight she realised that what she was experiencing wasn't just a "bad mood".

She suspected Yaz was the culprit. Two days after she stopped taking it, Eva's anger and tears vanished. "I feel lucky to have escaped so quickly, but what about all those women who have been on Yaz for years?"

Professor Kulkarni says that women often tend to blame themselves for feeling depressed and forget to consider the effect of the daily hormone they are taking.

A post-marketing study last November by eHealthMe (which analysed data from the FDA and women who take the pills) found that 42 per cent of Yasmin users experienced severe anxiety and emotional distress. Of those taking Yaz, 60 per cent suffered anxiety and/or emotional distress.

Helena Mathis, a 32-year-old Swedish woman who lives in Philadelphia in the US, began taking Yasmin while at university and almost immediately developed anxiety. "The heart palpitations would wake me up in the middle of the night. I was unable to sleep and even afraid of falling asleep in case I wouldn't wake up," she recalls.

Mathis's anxiety eventually developed into depression; she found herself bursting into tears for no apparent

reason. "There I was with an open, exciting future ahead of me, yet I felt like I was dying." It took seven years and visits to three separate doctors (none of whom made the connection with Yasmin) before Mathis Googled "Yasmin side effects". "I found story after story about Yasmin where my own experience was told over and over again," she says. "I cried for days. I felt robbed of my life and youth. I felt like a human guinea pig, but most of all I felt that I had been lied to all of these years."

One of the more disturbing threads in the growing number of online forums is the depressive effects experienced after *stopping* Yaz or Yasmin. Michelle Green, a cheerful 41-year-old IT manager from Brisbane, took Yaz for a year until her migraines became so

I FELT LIKE A HUMAN GUINEA PIG ... THAT I HAD BEEN LIED TO ALL OF THESE YEARS

HELENA MATHIS

debilitating that her doctor ordered her to stop (migraines are a possible side effect of Yaz). Soon afterwards, Michelle unaccountably developed bouts of depression and paranoia. She remembers curling up in bed, hysterical and adamant that she couldn't leave the safety of her doona because of a sense of something sinister that she couldn't quite place. "I felt like I was going crazy, like I needed to be locked away ... I couldn't stop thinking that if I were dead I wouldn't have to feel the way I did," she remembers. The only thing that stopped her killing herself was the fate of her two children.

Seeing a therapist who drew the connection with Yaz was Michelle's light at the end of the tunnel. She says that now, six months after stopping the pill, she still gets migraines, but her depression has finally lifted. (The TGA told *marie claire* it's aware of the link between depression and Yaz/Yasmin and that it is now in talks with Bayer about a possible need for further warnings on Australian packaging.)

Meanwhile, former Yaz users are sounding warnings. Professor Phelps's near-death experience made her rethink conventional medicines like

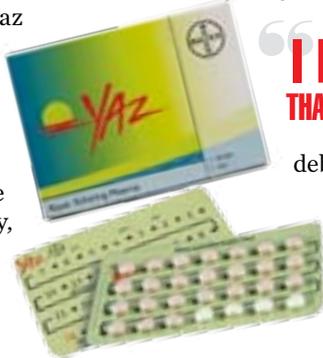
Yaz and she now prefers a holistic approach to health care. Eva Fritz took a job as a high-school guidance counsellor and managed to identify Yaz-induced depression in one of her students. Helena Mathis's experience prompted her to start an online forum, *Yasmin and Yaz Survivors* (yasminandyaz.blogspot.com.au).

For women already affected, it's a matter of picking up the pieces and moving on. Carissa Ubersox has had to learn how to talk again, her legs and arms still shoot out involuntarily, and it's unlikely she'll ever see again. "People can be cruel," she sighs. "I remember one day at blind school, I was walking to a bus stop and some guys shouted, 'Oh, check her out, she's so beautiful. Too bad she's got that cane.'"

She, too, is now intent on warning other women. "I would beg of them, for their own safety and the life that they know, to speak to their physician and get on something different. If one good thing can come out of this thing happening to me, it would be that no other woman in the world would have to wake up and have their entire life change."

Ever the fighter, Carissa plans to work with children again, write a book, and is in a new relationship. She's also taking Bayer to court. "If I could talk to the CEO of Bayer I would say, 'Imagine me as your granddaughter. Would you want your granddaughter on something like this? Knowing that it could do to her what it's done to me?'"

Bayer continues to target Australia. Profits from Yaz "doubled expectations", according to Bayer and, last September, Australia was the first country to sell Yaz Flex – a new version of Yaz that allows women to go months without a period – same pill, same risks, but now available in a digital dispenser. ■



BECOME INVOLVED

To take part in Professor Jayashri Kulkarni's Monash Alfred Psychiatry Research Centre study of the risks of Yaz/Yasmin and depression, visit www.maprc.org.au.

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