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One Less

A mother wonders whether the sudden death of her nineteen-year-old daughter could be related to the highly marketed Gardasil vaccine

By [Tom Grant](#)

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Photo courtesy of Debra Sonner



Debra Sonner and her daughter, Brooke Petkevicius.

An online ad for Gardasil

Photo courtesy of Breann Kennedy



Breann Kennedy

Photo courtesy of Allie Harvey



Allie Harvey
Tom Grant



Dr. Daron Ferris

Photo courtesy of Debra Sonner



Brooke Petkevicius



The Gardasil vaccine.

In early 2007, as the pharmaceutical giant Merck began promoting its new vaccine Gardasil as protection against cervical cancer, Brooke Petkevicius was a nineteen-year-old freshman at UC Berkeley. She had seen the ads for the vaccine, and discussed getting it with her mother, whose gynecologist also had recommended it. On March 12, Brooke received the

first of three doses. Two weeks later, she dressed to go running with a friend. As they reached the elevator, Brooke suddenly collapsed against the wall and had a seizure.

"She started shaking a lot," recalled the friend, Kristin Bietsch. "And her eyes went glazy a little bit." An ambulance rushed Petkevicius to the hospital, but doctors couldn't save her. Her autopsy indicated that she was killed by a pulmonary embolism, or blood clot, which had blocked the artery between her heart and lungs. "She had a whole bunch of little floating clots in her system," said her mother, Debra Sonner, recalling what doctors told her at the time.

Petkevicius had been healthy and happy, by all accounts. She didn't smoke or use drugs, and was training to run a half marathon. The only unusual thing that Sonner noticed about her daughter's health was that she had just taken Gardasil. When she went to clean out her daughter's dorm room, she encountered the completed insurance paperwork that Brooke was preparing to mail. "Of course, I found it and realized that she had just had the shot." Sonner immediately wondered whether her daughter's death was "some kind of reaction."

Her suspicions prompted health workers to report Brooke's death as one of what are now 4,500 Gardasil-related reports in the federal government's Vaccine Adverse Event Reporting System. About 75 percent of these reports were for minor expected side effects — pain at the injection point, fainting, and nausea, for instance.

But according to researcher Dee Grothe of the Washington foundation Judicial Watch, who read nearly 4,000 of the reports, the remaining 25 percent involved more serious issues, including paralysis, convulsions, and circulatory problems. Grother says the surveillance database now contains eleven Gardasil-related death reports, including the story of a woman who died of a blood clot three hours after getting the vaccine and a healthy twelve-year-old who died in her sleep three weeks later.

Based on the first death reports, including that of Brooke Petkevicius, the federal Centers for Disease Control pointed the finger at birth-control pills, not Gardasil. "Preliminary data indicate that the two women who died of blood clots were taking birth-control pills, and blood clots are a known risk associated with birth-control pills. All four deaths are being fully investigated but none appear to be caused by vaccination," according to the CDC on June 28, 2007. With regard to Gardasil, the CDC wrote, "Since more than 5 million doses have been distributed, some deaths will occur coincidentally following vaccination (but not due to vaccination)."

Gardasil researchers at the Medical College of Georgia and at Dartmouth University believe the vaccine is quite safe and are firmly convinced there's no scientific basis to blame Gardasil for the serious adverse reactions. Merck officials declined a request to comment for this story.

Still, debate is growing. All these reports from health-care workers and individuals have some people worried about the drug's side effects and safety. Meanwhile, the National

Vaccine Information Center, a consumer organization concerned with vaccine safety, has raised concerns about women who have taken Gardasil being subsequently struck by Guillain-Barré Syndrome, a potentially fatal illness. Judicial Watch and the center have publicly questioned whether Gardasil was adequately tested for cross-reactions with other drugs and vaccines.

For her part, Grothe is not convinced that the blood clots and circulatory problems being reported by some Gardasil users are random events unrelated to the vaccine. "Some are pretty hard to discount as being a reaction," Grothe said. "When a patient dies of a blood clot three hours after getting a Gardasil vaccination, that's pretty consistent to me."

I am a 5-4, 120-pound, 17-year-old girl. I am healthy and have never had problems with shots, allergies or fainting. Yesterday (Jan. 3, 2008), I went to the doctor for a routine checkup and was advised by my doctor to receive several shots, including the first Gardasil vaccine.

"About 20 seconds after I received the shots, I felt nauseous and dizzy. I fainted and began to display seizure-like symptoms: My eyes rolled back in my head and I started shaking. After that, I was unconscious for 3-5 minutes. I had a severe headache the entire day and soreness where I received the HPV shot, which I thought was perfectly normal.

"The nurse also reassured me that fainting was normal, and that it was due to me having four shots given in a row; she said it had absolutely nothing to do with the vaccines. Before agreeing to the shots, I asked my doctor what the side effects would be. She told me that there were no serious side effects (just soreness and possibly mild fever) and that it was medically fine for me to have four shots given at once...

"I am sick over the idea that young girls are being recommended this potentially harmful shot, and that very few people seem to be doing anything about it."

— R.B., Madison, Wisconsin, Gardasil user

Gardasil has been shown in clinical studies to be virtually 100 percent effective at preventing the infection of four strains of human papillomavirus (HPV), the sexually transmitted virus that causes genital warts. Two of those strains are believed to be responsible for causing about 70 percent of cervical cancer. The vaccine also has been shown to be about 40 percent

effective at stopping another type of HPV that is the fourth-most-common strain linked to cervical cancer. And there is some evidence that it also offers some protection against vaginal and vulvar cancer.

Nearly everyone gets some form of HPV infection, but most fight off the infection with a natural immune response. However, in some women, the infection develops into an identifiable precancerous condition of the cervix. A woman's chance of getting cervical cancer in her lifetime is about 1 in 142, according to the National Cancer Institute.

For decades, the primary defense against cervical cancer has been the Pap smear. Regular Pap tests allow physicians to identify the precursors to cervical cancer at its early stages, when it's nearly 100 percent treatable. It can take up to ten years for an HPV infection to turn into cervical cancer. In the United States, about 10,000 women will get cervical cancer every year and nearly 4,000 will die from it.

Pap smears have helped reduce the rate of cervical cancer in the United States by 70 percent in the last half-century. The greatest risk for cervical cancer lies with those 11 percent of women who don't see their health-care provider for Pap smears, or who can't afford treatment. That means that the poor and uninsured are at the greatest risk.

That's why most of the world's 250,000 deaths from cervical cancer are in developing countries, where regular health-care screenings are unavailable to most women. The majority of the gains against cervical cancer expected from Gardasil and future HPV vaccines will be in those developing areas of the world, where it will be more cost-effective to treat women with vaccines than to set up ongoing health clinics to examine them on a regular basis.

Yet it's also one of the ironies about Gardasil. At \$360 for a three-shot series (and often more than \$500 when office visits are added in), the vaccine is getting its greatest push in North America, Europe, and Australia, where the health-care gains are lower but the potential financial gains are greatest.

And the financial gains have been significant. One December report from a leading Australian news outlet says 18 million doses have been sold worldwide. [The-Street.com](#) predicts that Merck will make \$4 billion from Gardasil this year.

I am 18 years old. I received my first shot of the three-dosage series in September.

"Shortly after the shot I felt this overwhelming aching heat in my kneecaps and ankles. After 24 hours, it spread to the majority of my bones. About one month after the shot (about the

time for my next dosage) my body practically went through withdrawals from missing the vaccination. I once again had aching bones, only this time there were also cold sweats involved.

"It has been months since my first dosage, and I will not go back. Since the shot my eyesight has been more blurred, I have my first varicose veins all over my thighs and ankles (keep in mind that I just turned 18!) and my bones hurt from even the softest pressure."

— *Breann Kennedy, Sterling, Alaska*

Brooke Petkevicius' favorite book was *The God of Small Things*. She gathered an inspirational quote from author, Arundhati Roy: "There is only one dream worth having ... to live while you are alive, and die only when you are dead."

Her mother, Debra Sonner, asks herself: Why did that death come so soon? The loss of a child is the darkest of times. To Sonner, her daughter's death was the most inexplicable of events.

Sonner was a single mother of two who divorced Brooke's father when the girl was in second grade. Brooke's sister is one year younger.

Brooke was an achiever. She placed fifth in a national speaking contest of Future Farmers of America as a sophomore in high school. She played lacrosse. She was a straight-A student.

She'd continued her personal achievements even through turmoil in her personal life — moving away from her mom to live with her dad as a fifteen-year-old, falling out with the father during his divorce from her stepmother, and eventually moving in with an aunt and uncle in Portland, Oregon.

Petkevicius earned six merit scholarships to pay for her Berkeley education. And she seemed incredibly happy at her new school. She wrote in an essay about the difficulty she had breaking up with a boy in Portland when she first came to Berkeley.

"Unconsciously, I thought of my relationships as taking place back home, when, really, I should have left that relationship, like the rest of my life, back home," she wrote. "While my clothes had moved here, my academic life had moved, my body had moved here, my social life eventually moved here, too, and I am now fully a California Golden Bear."

Her autopsy report is remarkable for just how "unremarkable" Petkevicius' condition appeared. "The heart (280 gm) is grossly unremarkable," it reads. "There is no significant artery atherosclerosis. The relationship of the cardiac chambers and atrioventricular connections are unremarkable." The final diagnosis: "Pulmonary embolism," a clot blocking

the left artery between the heart and lungs. But why would a healthy nineteen-year-old girl suddenly throw a huge clot?

"Brooke did not smoke," said her school friend, Megan Sadowski. "She was possibly one of the healthiest people I've ever met. She never did drugs and rarely drank alcohol. She worked out daily, and took a lot of classes at the gym. She never complained about anything, really. Certainly not her health. She was an amazing, upbeat, caring, healthy young woman and her death was a complete shock."

She had, however, been on Yasmin birth-control pills for about ten months, her mother said. But Petkevicius had none of the other risk factors associated with blood clots. She had never had any problems with blood clots, nor did her family have any history of clotting problems. Subsequent tests of her younger sister and her mother showed nothing genetic. Petkevicius had no allergies, no tobacco use, and no past substance-abuse problems. Drug tests came back negative.

"She was absolutely clean," her mother said.

Still, birth control is one of the main risk factors associated with pulmonary embolism — along with smoking and genetic predisposition, notes Gardasil researcher Dr. Daron Ferris of the Medical College of Georgia. Sudden death from pulmonary embolism can happen like a lightning strike, said Ferris, who read Petkevicius' autopsy.

"These emboli, that's the way they occur," he said. "They occur out of the blue. Nobody expects them. There's no evidence to date that the vaccines are connected with that type of adverse event."

Dr. Diane Harper, a Gardasil researcher at Dartmouth University, also read Petkevicius' autopsy and said she didn't think it had anything to do with Gardasil. "HPV vaccine is not going to cause hyper clotting," Harper said. "If it had, we would have seen clotting in other places, like away from the heart."

On the other hand, oral birth-control pills *are* known to increase the risk of blood clots. In 2003, *BMJ*, the British Medical Journal, reported on five Dutch cases in which women taking Yasmin had problems with blood clots, including a seventeen-year-old woman who died of a pulmonary embolism. Further research showed about twenty to forty cases of clots within blood vessels per 100,000 women using birth-control pills like Yasmin. That's about four times higher than for women who don't use birth-control pills.

Sonner worries that there may be a drug interaction between Gardasil and birth-control pills. Ferris and Harper say they haven't seen anything to suggest that in the studies, even though thousands of the women they tracked were on birth-control pills.

But at Judicial Watch, Grothe shares Sonner's fears. "I saw enough cardio-related reactions," she said. "So it is a little bit concerning, especially if used with birth control, which also has whole range of side effects."

In late May [2007] at about 9:30 a.m., I was given the first of the three Gardasil injections by the nurses provided by the Australian government. Instantly after the shot I was crying because the shot itself hurt so much, and I was a lot weaker than most of the other girls. I waited five minutes after I received the shot as the nurses suggested and then went back to class.

"An hour later at 10:30 a.m., I was nauseated, very dizzy and weak, so I was taken back down to the sick bay where the nurses were giving the shot. The school nurse took me into a room and told me to lie down and stay there..."

"The kookaburras were flying out of the picture at one point and attacking me, and I couldn't see most of the rainforest animals and the ones I could see were also coming at me.... My friends had told the school nurse I was hallucinating and she then proceeded to get one of the government nurses who were administering the shot to come and have a look at me. The nurse looked straight at me and said, 'Do you have a headache or a rash on your chest?'"

"I responded with a simple 'No' and she then walked out of the room saying, 'It isn't a reaction to the Gardasil unless it's one of those two symptoms. She is probably just reacting to being given a needle.' I immediately felt like they all thought I was lying now and that I was making it up.

"A few hours had passed by now because my friends had come in at lunch time to check how I was doing. At this point my entire right side had become paralyzed, my hand was clenched into a fist that I couldn't open, I couldn't lift my right leg off the bed and the right side of my face was weak.

"My mum didn't believe that the nurses were glaring at me and that I had gone through such a serious reaction without anyone doing anything so she came down to the school.... She immediately took me to see my family doctor. It was now almost 3:30 in the afternoon and not a single person had admitted it was a reaction to the HPV vaccine. She called a few people to try and find out if it might be a reaction, but kept being told that this wasn't a recorded reaction so it must be something else. I was sent home with orders to rest and see if it goes away. Luckily it did.

"I wasn't upset that I had had a reaction to the vaccine; I was upset that no one would acknowledge it. I still went on to receive the other two injections for the HPV vaccine and each time my reaction was less serious. The second shot only resulted in prolonged weakness and dizziness, and the third shot caused mild weakness and only very slight dizziness. I do stand on the side that the vaccine is a wonderful opportunity for all those who can get it. I don't know why anyone would pass up the chance, and I strongly urge all girls who have had reactions like mine to get the other two shots because would they rather these side effects to a needle or risk the side effect of cervical cancer which is death? I can honestly say I would much rather the side effects of the HPV vaccine."

— Allie Harvey, Adelaide, Australia

Gardasil was fast-tracked for FDA approval because it was the first drug of its kind, a vaccine that could prevent cancer. The vaccine uses the protein shell of HPV to stimulate an immune response. Merck's vaccine was approved in 2006. A second vaccine for HPV has been developed by GlaxoSmithKline, but FDA approval is not expected until late 2008.

Merck used its window of opportunity to urge states to make Gardasil a mandatory vaccine for schoolgirls. Seventeen states have enacted laws to require, fund, or educate the public about the HPV vaccine. And the promotional effort has been worldwide. In Australia, the government made it free to women under the age of 26 and began giving vaccinations in schools.

Oddly, Australia had one of the lowest rates of cervical cancer before this massive inoculation plan began. In a country of 20 million people, only 227 women died of cervical cancer in 2002. Now, about seventeen adverse reactions to the vaccine are reported each week.

According to the Australian television news magazine *Today Tonight*, the reactions include seizures and paralysis. The maker of the vaccine in Australia says the side effects are consistent with other vaccines and mostly minor, such as fainting.

The National Vaccine Information Center has analyzed the adverse event reports in the United States. The center found that 14 percent of them involved some kind of fainting or seizure event with or without neurological symptoms. Another 8 percent involved tingling, numbness, and loss of sensation, facial paralysis, or Guillain-Barré Syndrome.

Guillain-Barré is a disorder in which the body's immune system attacks part of the nervous system and can cause life-threatening paralysis. Scientists do not know what sets the disease in motion. The Vaccine Adverse Event Reporting System now lists 25 cases of patients who received Gardasil and have symptoms of Guillain-Barré. (There may be more cases. At least

one documented case involving a twelve-year-old in Florida who was vaccinated then two weeks later collapsed and lost feeling in her legs is not among the reports.)

The vaccine center has raised concerns that even the relatively minor side effect of fainting could be dangerous. Some girls have collapsed and struck their heads, causing serious injury. And some have reported fainting many hours after getting the vaccine, raising concerns about girls driving after getting the shot.

Because of the fainting problem, the US Advisory Committee on Immunization Practices recommends a fifteen-minute waiting period before patients who have been immunized for HPV are released. The vaccine center says the shots should be given when the patient is lying down.

In August, 2007, my 21-year-old daughter had her third HPV vaccine. Approximately three hours after the vaccine, she had a seizure. I was with her when this happened. She was transported by ambulance to the local ER and was worked up.

"Later she was followed up by a neurologist and had CT scan, MRI, blood work, EEG and X-rays. Luckily, all were negative. But none of the physicians would say it was from the vaccine. My daughter is perfectly healthy, no medical problems, so I know it was from the vaccine..."

"I have read through the ... database on the HPV vaccine. It is shocking how many side effects, including death, that are reported."

— Joanne Venice, Atlantic City, New Jersey

K. Krasnow Waterman keeps a blog that has become a gathering point for many people with concerns about Gardasil. A lawyer, consultant, former law professor, and former fellow at MIT, Waterman maintains a web site at KKrasnowWaterman.com.

About sixty people have described their experiences with Gardasil, and Waterman has compiled their reports into a spreadsheet. The purpose is to create a publicly available site where people can post details and, as the blog says, "Help solve the mystery of HPV vaccine side effects!"

Waterman asked people to specify their age and weight, to say whether they had other vaccinations with the Gardasil, to tell how long it took for the reaction to occur, and to describe the reaction. The idea is to see whether certain reactions happen under specific conditions. One thing that's striking from reading Waterman's data is how many people report seizures or convulsions — roughly one-third. Often, the reaction is immediate.

"My 14-year-old daughter had [her] first Gardasil shot with the meningitis shot," Kristie wrote on October 18. "She immediately fainted and had a seizure. She is very healthy, athletic and had never had any reactions to any of her shots."

Others complain about reactions days or weeks later.

"Less than a month after receiving the Gardasil vaccine I blacked out and had a seizure (or what looked like one)," wrote 24-year-old Julia. She said her doctors can't figure out what's wrong. "I'm still blacking out, dizzy all the time and having minor convulsions. I got the shot six months ago."

In most cases, women are being told that it's not a reaction to the vaccine but rather a reaction to having the shot, which can be more painful than others.

In Biloxi, Miss., Anita Yarborough took her twelve-year-old daughter Olivia to the doctor for a routine visit. The physician's office recommended the Gardasil vaccine, which is being marketed to girls before they become sexually active.

A few minutes after the vaccination, Yarborough watched her daughter walk about fifty steps then go into what she believes was a seizure. Olivia's eyes rolled back in her head, she stiffened up and had irregular spasms, also known as clonic jerks. Yarborough is familiar with seizures because her husband has survived brain cancer and she's seen them before.

Olivia was placed on a stretcher and rushed to the emergency room. But doctors told her mother later that it was merely a case of vaso-vagal syncope caused because Olivia was scared from the shot. Vaso-vagal syncope is described as a paradoxical reflex that causes a fall in blood pressure and a loss of consciousness.

"It was very scary," Yarborough said, "and I'm not settled about the 'why' they gave me."

Dr. Harper has a different theory for why all the fainting. "We think it's needle phobia," she said. During vaccine trials, she and her colleagues discovered that many of the young women they were dealing with hadn't eaten very much during the day and had lots of hormones running in their blood. When they get the shot, they get woozy. "I don't think it's the vaccine that's causing them to faint."

The National Vaccine Information Center says there may be reporting confusion between fainting and actual seizures. About 30 percent of the Vaccine Adverse Event Reporting System reports involve fainting and 6 percent involve convulsions. Yet some reports

supposedly describe fainting but actually talk of seizure activity. "Tonic/clonic seizures are also known as 'grand mal' seizures," the center writes on its web site. A report from the center suggests that one-quarter of the adverse reports were for "neurological adverse events."

Even Brooke Petkevicius' death began not with shortness of breath, as doctors would expect in the case of a pulmonary embolism, but with a seizure. (One doctor, who did not want to be quoted, raised the question of whether such seizures could lead to an embolism.) The National Vaccine Information Center has asked the federal Food and Drug Administration for further investigation of Gardasil's neurological effects.

The center advises against taking Gardasil in combination with other vaccines, particularly the anti-Meningitis vaccine Menactra, because it found a significant increase in adverse events when women get multiple vaccinations including Gardasil. The center found that reports of Guillain-Barré were ten times higher when Menactra and Gardasil were given together.

Both of my daughters received the Gardasil shot on Nov. 6, 2007. Three weeks after the shot my oldest daughter (16 years old), woke up to not being able to walk or feel her legs.

"We took her to the hospital and [she] was then admitted with Guillain-Barré Syndrome and for four days was paralyzed from the top of her knees down. It has been a month and a half, and now my youngest daughter age 13 is experiencing the same symptoms. They are both very tired all the time, [with] passing out episodes [and] not feeling well. Both girls are having these symptoms.

They have done two MRIs and many blood tests and now [health workers] want to say it is stress and put my daughter on Prozac. This was bothering me a lot until I [began] researching this shot. Now at least I know what it is.

The question now is how long are these things that are happening to my girls going to last so, please, anybody out there thinking about getting this shot, I would think twice about it."

— Terri, Utah

The ads for Gardasil have a theme. "I want to be one less," says a young woman on horseback. "One less. I want to be one less woman who will battle cervical cancer. Because now there's Gardasil. The only vaccine that may help protect you from the four types of human papillomavirus that may cause cervical cancer."

The ad goes on to say it doesn't prevent all cervical cancer. It doesn't protect everyone. And women still need routine health screening for cervical cancer. Despite the warnings and repeated use of the word "may," the clear implication of the television ad is that if mothers give their daughters Gardasil, their daughters won't have to battle cervical cancer.

But even as stout a supporter as Dr. Harper worries that the vaccine may not actually protect against cervical cancer if given to young girls who are still five years or more from the time they're most likely to be sexually active — around ages 17 to 23. Dr. Harper believes that the rate of cervical cancer could actually see an increase if Gardasil continues to push the vaccine to girls as young as nine.

"I would not vaccinate a twelve-year-old with Gardasil," she said. "I'm not convinced Gardasil is going to last through the college years."

Harper points to data indicating that the antibody levels in women vaccinated with Gardasil decline after a few years. She believes further research is needed to determine if a booster shot would be needed five or ten years after the first vaccination.

She's concerned that if a child gets a vaccine at twelve but, as is normal, becomes most sexually active between the ages of seventeen and 23, she may not have the protection she thinks she has when she needs it most.

Harper also worries that girls who are vaccinated may believe they don't need regular Pap smears. "If they're vaccinated and have the assumption that they're protected from cervical cancer for life, and choose not to get a Pap smear because they believe they are protected, the rate of cervical cancer will actually increase," Harper said.

She recommends waiting to inoculate girls with Gardasil until they are fifteen or sixteen, and she favors the new GlaxoSmithKline vaccine because research suggests to her that it will last longer. Still, she believes Gardasil is a great vaccine for women fifteen or older. "This is not a virgin vaccine," she said. She added that she might choose to wait for the GlaxoSmithKline vaccine if she had a twelve-year-old, but for women who are entering the most sexually active years of their lives, she believes Gardasil can be a lifesaver. She sees few risks that can't be avoided by simply giving the vaccine to women when they're lying down and watching them carefully for fifteen minutes afterward.

At the Medical College of Georgia, Dr. Daron Ferris disagrees with Harper. He says that studies so far indicate that once someone has been vaccinated, that woman's immune system

will quickly respond to knock out new infections, even many years after the initial vaccination.

Studies going on in Scandinavia and other parts of the world could help to resolve this debate within a few years. But the heavy promotion of Gardasil continues. And women are being asked to make informed decisions today — not in a few years.

Ferris comes down clearly on the side of giving Gardasil to girls age twelve and up, inoculating them before they become sexually active. And while he still advises women to get regular Pap smears and tests for HPV, he thinks Gardasil will last a lifetime. He believes it's so safe and effective that he urges members of his own family to have their teenage daughters inoculated with Gardasil at the earliest opportunity.

But in the wake of tragedies like the death of Brooke Petkevicius, there is another point of view. "I'm not sure if her death was related to Gardasil or not, but my friend and I were in the process of taking it (she had two of the three shots, I had one), but we both stopped, just in case," wrote friend Megan Sadowski.

In the opinions of Harper and Ferris, that would be an irrational response to the random event of Petkevicius' death. Any time millions of young women are given a drug, a few will experience negative outcomes completely unrelated to the drug itself.

Harper suggests that people take the 30,000-foot view of these presumed drug reactions. "The rate is no greater than in the general population," she says, whether talking about Guillain-Barré or pulmonary embolism. "The woman has a health condition, but it's probably not related to receiving the vaccine."

But to Debra Sonner, who lost her daughter, the vaccine and the loss will be linked forever. And those "One Less" ads have a tearfully different meaning.