

## CDC Takes Closer Look at Gardasil and Paralysis

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Phil Tetlock and Barbara Mellers were in a race against time to save their 15-year-old daughter, Jenny. As I reported last summer, Jenny developed a degenerative muscle disease nearly two years ago, soon after being vaccinated against the cervical-cancer-causing HPV. She became nearly completely paralyzed, though her mind was perfectly intact and she could still enjoy her pet parakeet, Hannah Montana, and Twilight.

I've been E-mailing Phil regularly over the past year, and up until our last E-mail, one week ago, he had been holding out hope that they would be able to find a cure for his daughter—or to at least determine if the human papillomavirus vaccine called Gardasil had caused his daughter's illness, most likely a juvenile form of amyotrophic lateral sclerosis (aka Lou Gehrig's disease). Sadly, the clock ran out last Sunday, and Jenny passed away.

Through their efforts to publicize Jenny's case on their blog, Jenny's parents have connected with two other sets of parents whose daughters developed what appears to be ALS after being injected with Gardasil. One was 22-year-old Whitney Baird, who died last August, just 13 months after receiving Gardasil. Another is Alicia Olund, a 12-year-old who began having trouble walking after getting her third shot last September. She now uses leg braces and a walker at home as her muscles continue to deteriorate. After ruling out other conditions, her specialists at the University of California-San Francisco Medical Center—who also treated Jenny—suspect that Alicia may have the same condition. "They don't know what she has," her mother, Barbara, tells me through tears, "but it's destroying her nerves and muscles, and none of the treatments they've given her are working. Before the vaccine, she was a perfectly healthy child, going for her brown belt in karate." (They're awaiting the results of the ALS test.)

I should point out that juvenile ALS is extremely rare, affecting just 1 in 2 million young people. It's impossible to say at this point whether these girls would have developed the condition regardless of whether they received Gardasil, but government officials—who still strongly maintain that the vaccine is perfectly safe and potentially lifesaving—are now starting to investigate. Scientists from the Food and Drug Administration met recently with Jenny's neurologists at UCSF to discuss whether it's scientifically plausible for a vaccine to trigger ALS. And the [Centers for Disease Control and Prevention](#) is planning to scour its adverse-event database, called VAERS, to see whether other vaccinations have led to reports of ALS or other severe neurological complications.

Turns out, warnings concerning ALS and vaccines have been raised before. John Iskander, the CDC's associate director for immunization safety, tells me the agency previously has received reports of ALS following the anthrax vaccine. This, in addition to the deaths of Jenny and Whitney, "kind of tells us that we need to look more broadly at this issue," he says. He's quick to add that "we're doing just an initial review at this point; we don't have suspicions that these are casually related."

[Merck](#), the manufacturer of Gardasil, maintains that its vaccine is extremely safe and points out that it could potentially save women from dying of cervical cancer. "There are unusual and rare diseases that occur in girls and women in this age group whether they're vaccinated or not," says Rick Haupt, Merck's head of the clinical program for Gardasil. "These patterns don't indicate any causality." He says no cases of ALS occurred in Merck's clinical trials but also admits that the trials—**which included thousands, not millions—weren't large enough to detect such rare diseases.**

Barbara Shapiro, an ALS expert and associate professor of neurology at Case Western Reserve University School of Medicine who was enlisted by a mutual friend to help the Tetlocks do their research, isn't ready to dismiss the cases as pure coincidence. She's pored over the medical records of Jenny, Whitney, and Alicia and sees a striking similarity. "Juvenile ALS tends to progress very slowly over years or even decades, but these girls all seemed to have a more rapid, progressive form." She also has uncovered another VAERS report in the CDC database that could be similar, but since it was filed by a pharmacist, the

CDC told her it doesn't have details on the girl's identity. Shapiro worries that there may be more cases out there that the CDC doesn't know about.

After all, she tells me, both Whitney and Alicia came to the CDC's attention only after their parents discovered Jenny's blog and Phil Tetlock urged them to file a VAERS report. This system of voluntary reporting of adverse events related to vaccines by doctors and patients is notoriously crude. All too often, adverse events go unreported, whereas many reports that are filed turn out not to be related at all to the vaccines. When I point this out to Iskander, he tells me that while VAERS certainly isn't perfect, it's pretty good at catching rare events.

But what if doctors wouldn't think to link the onset of ALS with a vaccination? I press him. "Reports in the media, such as the one you're doing, are a good trigger to get doctors to file reports," he responds. In fact, largely because of media attention, reports of adverse events for Gardasil are about five times as high as the overall average for any vaccine, he adds. So I suppose he's hoping that if there are other girls out there who developed severe physical disabilities after receiving Gardasil, they'll soon be entered into the VAERS database.

Still, I'm troubled by the complexities of all of this. How will the CDC ever be able to know whether there's a true connection between Gardasil and ALS if this disease is so rare? And just how much evidence is needed? Iskander tells me he doesn't make that decision but passes on all the information he has to the government's vaccine working group, which makes recommendations about the national immunization schedule. "They are aware of these cases and that we've started discussions with neurologists and immunologists to determine if there are mechanisms that could explain how a vaccine could cause ALS," Iskander says, adding that "I haven't heard a good answer yet from these experts" when it comes to explaining a mechanism.

Shapiro says her suspicions are raised enough that she's decided not to give her own 11-year-old daughter the Gardasil vaccine. "Let's say it causes just one or two cases of ALS every year out of a million doses that are given. What if your daughter is the one?"

I haven't decided yet whether I want to have my own teenage daughter vaccinated. The arguments for Gardasil are compelling: It protects against viruses responsible for 70 percent of cervical cancers, which still kill many women in this country. Since the vaccine is so new, until more evidence emerges I think it may be prudent for concerned parents to consider holding off until their daughters reach the verge of sexual activity.