Government program tapped to pay for COVID-19 vaccine injuries rarely sides with consumers

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In March, Health and Human Services Secretary Alex Azar declared that all claims of injury from COVID-19 vaccines would be handled through a program run by his agency.

Because the vaccine is for a once-in-a-century virus and hasn't been approved for routine use, anyone who seeks compensation for a serious side effect will be directed to a little-known federal program that rarely sides with consumers.

That program, the Countermeasures Injury Compensation Program, has rejected 90% of vaccine-injury claims over the last decade.

In contrast, the federal government's "vaccine court," which handles claims mainly involving routine childhood vaccines, has paid about 70% of claims from 2006 through 2018.

As COVID-19 vaccines are being shipped to millions of Americans, some attorneys and consumer advocates question whether people will get a fair review in the rare cases of alleged harm.

"We are going to have hundreds of millions of people that will be getting the COVID vaccine," said David Carney, a Philadelphia lawyer who handles vaccine-injury claims. "The recourse available if and likely when people suffer side effects is going to be pretty limited."

Consider this: How to persuade someone to take the COVID-19 vaccine

Serious side effects can occur even with safe vaccines

With more than 325,000 COVID-19 deaths in the U.S. and as hospitals struggle to handle the winter surge of patients, public health experts say vaccines will play a critical role in slowing the pandemic.
The federal government has granted emergency authorization for two vaccines, saying they're safe and effective. Two more could be approved by February.

Clinical studies with tens of thousands of patients concluded vaccines from Pfizer/BioNTech and Moderna are highly effective and safe, with minor side effects such as soreness, redness and swelling.

**Two COVID-19 vaccines are authorized in the US:** Here's what we know about them

But when millions of people are injected, attorneys and consumer advocates say, even the safest vaccines can cause side effects in a small number of people.

"When you have a brand-new vaccine coming out, you want people to take it," Carney said. "No matter what vaccines are given out, you are always going to have this rare percentage of people whose immune systems just get triggered in the wrong way, revved up in the wrong way, and they have adverse events."

Six Americans and at least two people in Great Britain have had strong allergic reactions to the Pfizer/BioNTech vaccine, according to the Centers for Disease Control and Prevention. Although the federal government is studying these reactions, the vaccine appears to be safe for anyone who has not had an allergic reaction to one of its ingredients.

Even if COVID-19 vaccines generate just one claim for every million people who get a shot, it could vastly increase the workload of the countermeasures program, authorized by the 2005 federal Public Readiness and Emergency Preparedness Act to deal with threats from pandemics and bioterrorism.

The program, run by the Health Resources and Services Administration, has reviewed an average of fewer than five claims per month since 2010. Four people are on staff.

“It could essentially break the countermeasures program,” said Anne Carrión Toale, a Sarasota, Florida, attorney whose firm handles hundreds of vaccine injury cases.

The agency plans to hire more staff and contractors to handle the workload from COVID-19 vaccine claims, a spokesman said.

Since 2010 the countermeasures program has rejected 450 of 499 injury claims. It has paid 29 claims, totaling more than $6 million. Ten cases were eligible for compensation but had no expenses to pay, and 10 cases are currently under review.
More: Side effects from the COVID-19 vaccine means 'your body responded the way it's supposed to,' experts say

'Vaccine court' usually rules in favor of patients

Lawyers and consumer advocates say another program, one with a track record of ruling in favor of consumers, would be better suited to handle COVID-19 cases.

Vaccine court, formally called the Vaccine Injury Program, conducts hearings before independent "special masters." Their decisions about injury claims are public, but they protect patient confidentiality. Consumers have three years to file a claim, and the court pays for attorneys and expert medical opinions.

The vaccine court paid 5,297 of 7,565 petitions from 2006 to 2018, a rate of 70% in favor of patients. But cases are still rare. For every 1 million doses of vaccine, one person is compensated for a claim, according to the Health Resources and Services Administration.

The program that will be used for the COVID-19 vaccine, however, limits claims to one year after a person gets a vaccine, doesn't pay attorneys' fees and does not conduct hearings.

Unlike vaccine court, the countermeasures program doesn't pay for pain, suffering and rehabilitation, and it offers only partial compensation for lost income, attorneys say.

People denied compensation by the countermeasures program have virtually no legal recourse. If they were to sue in civil court, they'd need to prove drugmakers acted with "willful misconduct" — an extremely high legal standard meant to protect those who manufacture, distribute and administer vaccines and treatments to counter a deadly public health threat such as COVID-19.

Call to move COVID-19 vaccine claims to vaccine court

Peter Meyers, former director of George Washington University Law School's Vaccine Injury Clinic, said public confidence depends on a fair compensation program for rare side effects. He wants Congress and the administration of President-elect Joe Biden to replace the countermeasures program with a new one that borrows elements of the vaccine court and the Sept. 11 Victim Compensation Fund.

In an essay published Nov. 26 on the website of the Journal of Law and the Biosciences, Meyers argues if the countermeasures program is not improved or replaced, it "will give ammunition to anti-vaxxers and undermine the widespread use of these vaccines."
So far, Americans' acceptance of the coronavirus vaccine appears to be growing as health care workers and nursing home residents get their first doses. In a recent USA TODAY/Suffolk University Poll, 46% said they will take the vaccine as soon as they can – nearly double the 26% who said so in late October. Another 32% will wait for others to get shots first.

“Trust is essential here,” said Meyers, a professor emeritus at George Washington University Law School. “It’s very important to get the message out to people: We have a good program that will look after you if you’re one of those very rare people who have an adverse reaction.”

**Program denied claim from teenager paralyzed after getting H1N1 vaccine**

In March, Azar invoked the 2005 PREP Act and declared COVID-19 vaccines and treatments would be handled by the countermeasures program. It handled injury claims for the 2009 H1N1 flu vaccine and seldom-used vaccines such as anthrax and smallpox.

Although the government does not publicly release figures on types of claims, a Freedom of Information Act request by Meyers revealed the agency rejected 372 of 407 claims for the 2009 H1N1 vaccine. All 18 anthrax vaccine claims and eight of 11 smallpox vaccine claims were rejected.

Robert Beckham of Conowingo, Maryland, was a high school student in 2009 when he received the H1N1 vaccine. About a month later, he was hospitalized and eventually diagnosed with transverse myelitis, a neurological disorder that can causes pain, weakness and paralysis.

He’s been paralyzed from the chest down ever since.

His attorney filed a claim with the vaccine court, but it was moved to the countermeasures program. Although his attorney submitted extensive medical records and his neurologist submitted a letter saying the vaccine was more than likely the cause, his claim was rejected. There was no hearing and no chance for appeal.

Beckham, now 26 and a Baltimore County resident, remains in a wheelchair. He has been in and out of the hospital with complications.

"I was just trying to make sure I was healthy and safe from the flu and boom – I end up basically losing my life," Beckham told USA TODAY. "Everything changed on a drop of a dime."
Had his injury occurred a year later, he could have taken his case to vaccine court. In 2010, the H1N1 vaccine was added to the annual flu vaccine for children and adults. Routine flu vaccine claims are handled in vaccine court.

In the countermeasures program, people claiming an injury from a vaccine must provide “compelling, reliable, valid, medical and scientific evidence," according to Health Resources and Services Administration spokesman David Bowman.

Because the program does not pay for attorneys or medical experts, it’s challenging for people to prove cases on their own, said Toale, the Sarasota attorney who handles vaccine injury claims.

"If any defense, problem or issue is raised, how is that person going to have access to medical experts or be able to front the money?" Toale asked.

That’s one reason attorneys and consumer advocates want the COVID-19 vaccine moved to vaccine court.

That won’t happen now, if at all. In order to be eligible for vaccine court, the CDC must recommend a vaccine for routine use by children or pregnant women. None of the clinical trials for vaccines have included pregnant women, nursing mothers or children.

Without clinical data, obstetricians and gynecologists say pregnant women should decide whether to get vaccinated based in part on how widely the virus is spreading in their community. Doctors and public health experts say the benefits of the vaccine likely outweigh the risks.

Vaccines also must include a nominal excise tax to be eligible for vaccine court. If a vaccine is routine and taxed, the Health and Human Services Secretary can make it eligible for vaccine court.

Kim Witczak, a consumer representative on an advisory committee for the Food and Drug Administration, said the widespread distribution of the coronavirus vaccine means stronger protections are needed for people who experience rare but serious side effects.

"People need to be able to get compensated — or at least have a fair trial," Witczak said. "They have to have a fair and due process to be able to be compensated for any injuries."

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