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Vaccine Makers Enjoy Immunity

By AVERY JOHNSON

One of the little-noticed reasons that Wyeth was attractive enough to command a \$68 billion price for rival Pfizer Inc.'s planned takeover sits in a building catty-corner from the White House across Pennsylvania Avenue. That is where a special "vaccines court" hears cases brought by parents who claim their children have been harmed by routine vaccinations.

The court -- and the law that established it more than two decades ago -- buffers Wyeth and other makers of childhood-disease vaccines from much of the litigation risk that dogs traditional pill manufacturers and is an important reason why the vaccine business has been transformed from a risky, low-profit venture in the 1970s to one of the pharmaceutical industry's most attractive product lines today.

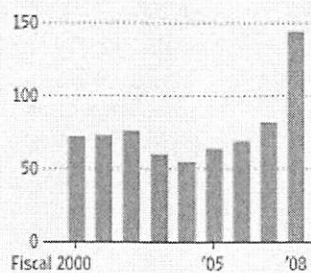
The legal shield, known as the National Childhood Vaccine Injury Compensation Program, was put into place in 1986 to encourage the development of vaccines, a mainstay of the nation's public-health policy. A spate of lawsuits against vaccine makers in the 1970s and 1980s had caused dozens of companies to get out of the low-profit business, creating a public-health scare.

The strategy worked and the public-health implications have been sizable. Vaccines have driven huge reductions -- and in the case of smallpox, for instance, complete eradications -- of major childhood diseases. Paul Offit, chief of infectious diseases at the Children's Hospital of Philadelphia, who developed a vaccine for rotavirus with Merck & Co., says, "If that Act didn't happen, I think American children would have been at risk."

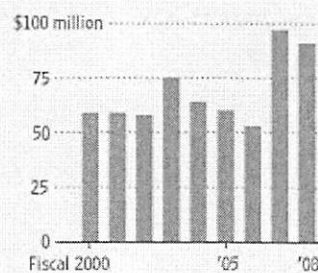
Vaccine Court Victories

The court has paid damages on 2,260 cases in two decades

Number of awards



Total payments



Source: Health Resources and Services Administration

Vaccines have also become big business. They are poised to generate \$21.5 billion in annual sales for their makers by 2012, according to France's Sanofi-Aventis SA, a leading producer of inoculations.

At a time when pharmaceutical companies are being battered by generic competition to their best-selling drugs, vaccines offer an appealing alternative because they are biologic products that can't yet be copied. Another big draw is the partial protection from liability risk offered by the vaccines court, officially known as the Office of Special Masters at the U.S. Court of Federal Claims.

Such immunity makes a product like Wyeth's Prevnar enormously attractive. Designed to protect children against seven strains of pneumococcal disease, Prevnar had sales of \$2.7 billion last year that are projected to grow to \$5.5 billion in 2015, according to Sanford C. Bernstein & Co.

Pfizer spokesman Ray Kerins acknowledges that Wyeth's strength in vaccines was an important factor behind Pfizer's interest in the company, but he adds that the deal made sense for a number of other reasons.

Vaccines' transformation into a lucrative business has some observers questioning whether the shield law is still appropriate. Critics say the vaccine court's ruling this month that routine childhood immunizations aren't linked to autism underscored the limited recourse families have in claiming injury from vaccines.

"When you've got a monopoly and can dictate price in a way that you couldn't before, I'm not sure you need the liability protection," said Lars Noah, a specialist in medical technology at the University of Florida's law school who has written about vaccines.

Many plaintiffs' lawyers would prefer to take their lawsuits directly to civil court because the vaccine court limits compensation in death cases to \$250,000. They also think that juries could give them a more sympathetic hearing.

Kevin Conway, an attorney at Boston law firm Conway, Homer & Chin-Caplan PC, which specializes in vaccine cases and brought one of the recent autism suits, says the lack of liability for the pharmaceutical industry compromises safety.

"The dire straits of the 1980s do not exist anymore and it calls into question the need for the program, since the ability to sue the pharmaceutical companies would provide a different level of oversight," Mr. Conway says.

Even if they had won their cases, the families of autistic children wouldn't have been paid by the companies that make the vaccines, as is common in other pharmaceutical-liability cases. Instead, the government would have footed the bill, using the funds from a tax levied on inoculations.

The pharmaceutical industry, for its part, argues that the vaccine shield is still necessary. "The Act remains an important and relevant protection against baseless litigation that may dissuade parents from having their kids receive important vaccines," says Wyeth's outside counsel for vaccine litigation, Daniel Thomasch, of Orrick, Herrington & Sutcliffe LLC.

Mark Feinberg, vice president for medical affairs and policy at Merck's vaccine division, says companies need the government's protection to shoulder the risk of pricey clinical trials. "Today, there are a number of important infectious diseases that don't have vaccines," he says. "The program does provide clarity for manufacturers as they go forward with new development."

To be sure, the vaccine court has been friendly to some plaintiffs. About \$970 million has been awarded in its two decades of existence, and 12,890 cases have been filed. The court has relaxed standards about which witnesses and evidence can be admitted, because its judges -- called special masters -- are better equipped to navigate dubious science than a jury.

And injured parties can still sue vaccine makers in civil court if they reject the vaccine court's decision, if the court dismisses the claim or if the claim is stalled in the court for more than 240 days. Rep. Henry Waxman, who introduced the 1986 bill, hails those limits to the liability shield. "Vaccines are products that are completely different from any others. We need to encourage companies to develop vaccines in order to protect the public health," he says. "The manufacturers have long fought for total immunity from lawsuits, but I have fought back hard to ensure that the law preserves access to courts in cases of true negligence or misconduct."


But vaccine suits, when they do get to civil court, face restrictions there on punitive damages and failure-to-warn arguments.

Barbara Loe Fisher, the co-founder of a nonprofit parents' group called the National Vaccine Information Center, says the inclusion of high-priced new vaccines, like Merck's Gardasil, which aren't vital to preventing pandemics, runs counter to the spirit of the original law, which she worked on in the 1980s.

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