Vaccine’s a lifesaver---and a hazard

Sandra Tomkins, Fresno Bee, DPT report 1984

A vaccination required of all U.S. schoolchildren has been linked to thousands of adverse reactions ranging from fever toseizures, brain damage and death.

U.S. Public Health officials say permanent brain damage from pertussis — the P part of the DPT shot — is rare, one 310,000. Critics in the medical community say it is substantially higher, as many as one in 15,000 children.

Everyone agrees that the vaccine is necessary. It has virtually eliminated pertussis — whooping cough — which in 1934 claimed 7,500 lives, most of them children.

But experts on both sides say the vaccine must be unproved.

A three-month investigation by The Bee has found

• The Food and Drug Administration and several manufacturers of the pertussis vaccine knew of its problems at least 20 years ago, but some doctors believe they have net been adequately warned of its hazards.

• The vaccine varies widely from lot to lot, even when produced by the same manufacturer, and the law allows all bottles of the vaccine to be labeled with standardized information. Thus, doctors are given no clue that one bottle might be as much as 450 percent more toxic than another.

• Toxicity tests on the vaccine are inadequate and often bear no relationship to results at the local doctor’s office.

• Certain highly toxic batches of vaccine, known as hot lots have been marketed with federal safety clearance.

• Important information about when the vaccine should not be used, generally accepted around the world, was not given to American doctors. Six years ago, drug manufacturers tried to include more cautious language in the package leaflet, but FDA officials put pressure on them to withdraw the language.

The FDA's answer is that the benefits of the vaccine, even as it exists, far outweigh the risks of whooping cough epidemic.

"Since 1964, government health officials have known about DPT problems," said Dr. Kevin C. Geraghty, a pediatric immunologist in Contra Costa County.

"These are people shuffling paper who don't have to walk into a room and see a baby twisted and gnarled and seizing, see a mother's life destroyed. I think, if these people had to do that, they would have acted differently."

Geraghty heads a group of 10 who formed Bay Area Physicians for the Study of Pertussis Vaccines last year.

"The problems that the drug companies are facing with litigation is due to their own complacency and their failure to listen to complaints from doctors and counsel within their own company going back at least 20 years," Geraghty said.

Robert Kaufman, a Michigan attorney who works exclusively on DPT vaccine damage cases, said, "The children themselves function as laboratory animals as the toxicity of the vaccine is accurately determined for the first time in clinical use.

According to Dr. Vincent A. Fulginiti of the University of Arizona, who is considered an expert in DPT, the process works this way: Doctors inject the pertussis bacterium and allow the child's body to separate out the good from the bad.

"The medical profession has known this is a dirty vaccine as early as 1933 and done nothing about it," said Ed Hodges of Pittsburg, president of the state group of the national Dissatisfied Parents Together.

Hodges became involved two years ago when his daughter, Kara, died four hours after her first DPT shot. She was 2 months old. (A multimillion.dollar suit has been filed.)

Dr. Martin Smith of Gainesville, Ga., vice president of the American Academy of Pediatrics, said: "The information about the reactivity of the vaccine and its various problems has been accumulating over a long period of time. Until there was opportunity and time to fit that information together, it didn't impress anyone.

"We've tried to get the information out to doctors, but we can't force-feed it to them."

Attorney Allen McDowell of Chicago said: "The drug companies had the ability and were able to produce an improved vaccine years ago, one less reactive than the one

they continued to use. It’s pretty difficult for them to deny it when we have their own internal documents."

Martha Homma, speaking for Lederle Laboratories, said she could not discuss the company’s internal documents because of pending lawsuits. "It’s not fair to quote from them. This is a complex issue."

Homma said Lederle has continued its "intensive scientific research" program through the years. "If we could have made a better vaccine, we would have."

A spokesman for Wyeth Laboratories, which dropped out of the market in June, would not comment. "We don’t want to talk about DPT."

"One thing is very clear," Geraghty said. "None of them — the FDA, the CDC nor the drug companies — have ever done anything to scientifically look at a reaction and gather all the data like they would for a toxic shock, AIDS, whatever. They have not done it With DPT."

Frustrated in his direct requests, Geraghty used the Freedom of Information Act to obtain microfilmed reports from the CDC — the national Centers for Disease Control in Atlanta. Several thousand adverse reactions to DPT were reported between 1979 and 1983.

"I’ve spent six months going through those microfilms and they are an embarrassment," he said. "Forms are woefully inadequate. Many are not filled out. They’re often illegible. So how can they tell the public they know the numbers?"

The CDC’s chief of the surveillance investigation research branch, Dr. Kenneth .J. Bart, said there were 4,503 adverse reports from public health clinics during that period. However, he said, underreporting is "significant."

[Vaccination] [Fresno Bee report]