Recalls of unsafe vaccine are rare

Fresno Bee DPT report 1984

In the 40 years that pertussis vaccine has been given to American children, only four lots have been withdrawn from the market as unsafe. Sometimes such lots are called hot lots.

As defined by the national Centers for Disease Control, a hot lot is one that generates reports of more than two deaths or two convulsions or a total of 10 adverse reports.

On March 30, a memorandum to Dr. Alan R. Hinman, CDC's immunization director, identified 13 batches of Wyeth Laboratories vaccine and six from Lederle Laboratories as potential hot lots.

The reports of deaths, brain damage, convulsions, abscesses and allergic reactions totaled 413-- including 16 deaths— for Wyeth's 13 lots, and 114 reports —with three deaths — for Lederle's six lots.

How many doses did those lots provide? And where had the vaccine been shipped? Without answers, the CDC couldn't determine the significance of the numbers or connect complaints in other parts of the country. And Wyeth and Lederle gave no answers.

Betty Hiner, of the Food and Drug Administration's Office of Biologics Research and Review, telephoned the companies March 30 about some of the problem lots.

Dr. Harrison C. Stetler and John R. Mullen, CDC officials who had sent the original memo to Hinmän, later reported to him "that Lederle does not respond to the inquires about distribution. . . and Wyeth declined to release this information on outdated lots."

As a result, they said, they couldn't determine whether the lots "represent reporting bias or actual higher reaction rates and whether Wyeth lots have higher rates of reactions than DPT vaccine of other manufacturers."

The lots remained on the market.

(Spokesmen for Wyeth, Lederle and Connaught laboratories, citing litigation, would not comment about hot lots.)

The FDA is considering changes in the regulations so data on vaccine lots and distribution can be obtained from the manufacturers.

Dr. Gerald Faich, the director of epidemiology and biostatistics, said: "We have not systematically asked for that information in the past. We have every intention of getting it in the future."

Faich also disagreed with the CDC's definition of a hot lot, which "is not a universally accepted definition by any means." Faich said the CDC numbers are merely a "statistical clustering of adverse reactions."

"My impression is that there has not been a true hot lot that required withdrawal from the market excepting Sciavo's," Faich said.

Under pressure from the FDA and the CDC, Sclavo Inc. recalled two batches for too many abscesses.

Only two other lots have been

Withdrawn:

• Wyeth's designated lot 64201 was voluntarily withdrawn by the manufacturer after a cluster of 11 deaths in Tennessee in 1979. (See story on facing page.)

• National Drug Co. lot, 40 years ago, referred to in an article in the 1946 Journal of American Medical Association. For every lot taken off the market, dozens of potential hot lots have not been recalled. One was lot No. 1182, made by the state of Michigan in 1975. (Massachusetts also manufactures DPT vaccine.)

Michigan had made too much DPT in its Lansing laboratory and wanted to sell it to other states. That required FDA testing and approval, as with any other manufacturer.

However, the FDA denied approval and returned the vaccine, saying It was 300 percent too potent.

State health officials disagreed and decided to test the vaccine on children in Ingham County (Lansing). Despite more adverse reactions than usual, health officials released 400,000 doses of the DPT vaccine for use throughout the state a month later.

The Detroit News reported that three children were left with permanent brain damage. Lawsuits In those cases and four others were filed against the state of Michigan.

[Vaccination] [Fresno Bee report]