



Dwight Ross Jr./The Atlanta Constitution

## DTP Vaccine Protest Gets Airing at CDC

**Atlanta**—Calling for a better DTP vaccine and a better vaccine reaction reporting system, members of a parents' organization demonstrated in front of the CDC here before speaking at an immunization committee meeting.

The demonstration was the latest in a series of actions organized by Dissatisfied Parents Together to draw attention to concerns about the safety and efficacy of DTP vaccine.

In a rare collaboration between a lay group and a medical association, DPT had been working with the American Academy of Pediatrics on vaccine injury compensation legislation. But their three-year working relationship recently suffered a setback when the two groups decided they could no longer back the same proposed standards for liability defense.

Meanwhile, the DTP vaccine supply remains tenuous as Lederle Laboratories, the major U.S. supplier, has announced that its liability coverage for the vaccine will not be renewed. Company representatives say they'll continue to produce the vaccine but, to self-insure, will up the price from \$4.29 per dose to \$11.40—adding to the pressure for legislation.

In their presentation to the CDC Ad-

visory Committee on Immunization Practices (ACIP), DPT members focused on contentions that:

- few reactions are reported to the CDC.
- vaccine deaths are often misclassified as sudden infant death syndrome.
- physicians are not adequately educated about vaccine reactions and contraindications.
- Japan's vaccine is purer and less reactive and should be offered to American parents.

Officials from the CDC and organized medicine refuted some, but not all, of these assertions.

Barbara Loe Fisher, DPT's vice-president, told the committee that she began an investigation of whooping cough cases when the AAP issued a November 1985 news release describing "near epidemics" of whooping cough in eight states. The press release cited instances of hospitalization, brain damage, and death traceable to parents' delaying immunizations because of recent publicity about the vaccine's safety.

Fisher contacted health departments in the eight states. Among other things, she found that:

- the number of reported pertussis cases declined between 1984 and 1985 in three states.

*Protesters march outside the CDC before taking their complaints about DTP vaccine to an immunization advisory committee meeting.*

- total pertussis deaths in the eight states declined from five in 1984 to one in 1985.

- the number of cases of permanent brain damage caused by pertussis is unknown in most of the states.

- public health clinics in at least two of the states used more DTP vaccine in 1985 than in 1984.

Whooping cough occurs in a significant number of fully or partially vaccinated individuals, Fisher maintained. She quoted a CDC representative as saying the U.S. has a 95% vaccination rate and that whooping cough is under-reported as much as 10- to 20-fold—10,000 to 60,000 actual cases per year compared with 1,000 to 3,000 reported cases.

"It appears that the alleged recent 'increases [in pertussis incidence]' are primarily due to an increase in reporting of the cases that have always been out there," she told the committee.

The number of reports did increase by about 40% in 1985, a CDC official acknowledged to MWN. "But at least a couple of states had outbreaks," says Dr. Alan Hinman, director of immunology. "How much of the increase is due to increased reporting, we don't know."

Several committee members said the reporting system is inadequate. Committee chairman Samuel L. Katz, who's also chairman of pediatrics at Duke University, called for a change in regulations that require private physicians to report to the FDA and public clinics to the CDC.

Large states may receive data from local health departments, throwing in another variable, noted Dr. Walter Orenstein, who is chief of surveillance investigation and research at the CDC's division of immunology and was at the meeting.

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"But the [reporting] system has been changed in the past year in an effort to improve it," said Dr. Orenstein. "We have new forms, new ways of editing forms, staff reviewers at the state level, and physician reviewers for serious illness."

Drs. Orenstein and Hinman see a need for further improvement, but neither believes mandatory reporting would work. "It can't be enforced," says Dr. Hinman. "And physicians may not report for fear of litigation," adds Dr. Orenstein.

No matter how good the reporting is, Dr. Orenstein continues, analyzing the data base is difficult because of problems with establishing causation. Vanderbilt University, in collaboration with Tennessee's health department, has begun addressing the problem in a four-county study linking children's Medicaid records with immunization status.

Several studies of SIDS have shown that many infants have died within a week of DTP vaccination, Fisher told MWN. As many as 10% of SIDS deaths may be associated with the vaccine, she contends.

In 1985 the CDC began collecting autopsy information on all deaths following DTP vaccination, said Dr. Orenstein. The data are being reviewed to identify a clinical syndrome.

"There's probably a lot of mislabeling on sudden infant death syndrome, not just with DTP," says Dr. Orenstein. "We feel the parents have brought up an important issue. But there's no hard evidence for a definition of DTP death at this point."

Central to the need for a better reporting system, DPT representatives said at the meeting, is the need to better educate doctors. They contend most parents and physicians are "dangerously ignorant" in this regard.

In a test of the group's assumptions, one parent devised a questionnaire and called 64 pediatricians. Only 10 would respond, but she found that:

- eight of the 10 don't verbally explain to parents the signs of convulsions, shock

collapse, or other recognized severe reactions.

- only two of the pediatricians provide parents with written information explaining the signs of severe reactions.

- none of the five who had patients who reacted severely to a DTP shot filed a report.

More physician education about contraindications and reactions is needed, Dr. Orenstein agrees. "But physicians may be looking for excuses to not vacci-

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### ***DPT says doctors and parents are 'dangerously ignorant' about reactions.***

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nate for fear of litigation, so we have to be careful."

Looking at potential contraindications, one parent tested the theory of a "genetic link" to some DTP reactions. She found that 28 of 45 families with one known reaction had more than one child who reacted.

DPT members also asked the committee why Americans don't have access to the Japanese acellular vaccine, which reportedly has proved less reactive and just as effective as whole-cell vaccine during five years of use.

"The Japanese data are not very good," said ACIP member Dr. Edward A. Mortimer Jr., vice chairman of epidemiology and biostatistics at Case Western Reserve University. "Eight to nine different manufacturers are involved with three different vaccines. The vaccine is given to 2-year-olds only, and it may not be safer for them than the whole-cell vaccine.

"[The Japanese] are seeing delayed reactions. It's my gut feeling that their vaccine is effective, but the FDA's strictness is a stumbling block that I favor."

Lederle representatives say they've had an acellular vaccine under development since 1981 and hope to begin clinical trials soon. One of the Japanese vaccines is being tested in a U.S. and

Swedish clinical trial of 1,300 to 1,800 6-month-olds, said Fisher. But it won't be completed until 1987.

The root of the problem is money, says Dr. Philip A. Brunell, the AAP's liaison representative to the committee. The CDC is underfunded for immunization and has a tiny staff, he told the parent group, and the Office of Management and Budget has cut several million dollars from pertussis vaccine research.

In the meantime, DPT will continue working on compensation legislation, though not with the AAP.

The groups' split apparently began with an AAP news release and poster sent to pediatricians' offices. The poster, aimed at parents, said that if the U.S. didn't use pertussis vaccine, "today almost 500,000 children could fall victim to pertussis. Over 14,000 cases would end in death."

DPT officials called the AAP information inaccurate and misleading. Quoting a CDC estimate, Fisher said 400 pertussis-related deaths a year could be expected in the absence of the vaccine.

The AAP subsequently withdrew the poster—acknowledging that the information was based on old data—and replaced it with a new one that calls on parents to seek a doctor's advice about the risks and benefits of DTP vaccination. Fisher says the parents' group confronted the AAP with the error but that the original poster wasn't recalled until after DPT issued a news release about it.

The groups now disagree on the defense standards to be adopted in pending legislation. The AAP favors using federal vaccine safety standards as defense—enabling drug companies to support the legislation. But DPT maintains that federal standards are inadequate.

An AAP spokesman told MWN that the association has gotten indications that Rep. Henry Waxman (D-Calif.) may soon take steps to introduce a compensation bill—possibly as early as the end of this week. ■