

Orange juice cans have more accurate labels.

Fresno Bee DPT report 1984

Twelve protective units of pertussis. That's what the label says the vial contains.

It's not necessarily true.

Protective units are the measure of pertussis toxin in the vaccine. The toxin provides the immunization against whooping cough, but also is believed to cause brain damage and death.

The toxin is unpredictable. Laboratory records from manufacturers and the Food and Drug Administration show that batches of vaccine can vary from 7.25 protective units, to 37.33. The dosage calls for 12 units. The label says there are 12.

Dr. Carolyn Hardegree, FDA bacterial products director, was asked why the labels and contents don't match.

Her only response, through the FDA's public affairs office, was to point to the federal regulation that allows the variation.

Dr. Kevin C. Geraghty, a pediatric immunologist, wrote to Surgeon General C. Everett Koop this fall, informing him of the inaccurate labeling. He told Koop about the correlation he has found between certain lots of pertussis vaccine and reports of brain damage and death.

The reactions exceed "the official estimate by quite a margin," Geraghty said. "Those lots have all shared the same characteristic. They have all exceeded by double the labeled potency units —24 or more."

Geraghty and 20 other physicians want stricter labeling rules in California. They have asked Dr. Loring Dales of Berkeley, chief of the immunization division of the State Health Services Department, to require that labels accurately list "the amounts of certain toxins in each and every lot of DPT currently being used in patients in our offices and in our own children."

Dales said he has sent Geraghty's request to the Centers for Disease Control, which sent it to the Food and Drug Administration.

We're waiting on word from the FDA," Dales said. "I had no idea such a variable could exist."

If necessary, Geraghty said, the group will file suit.

"It's ludicrous," Geraghty said. "Why should I be able to read the label on an orange juice can and find out what's in it, and yet not have information on the exact amount of the two chief toxins I'm injecting into babies?"

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