WYETH
CLINICAL RESEARCH & DEVELOPMENT DIVISION TRIP REPORT

PRODUCT	PROJECT NO.
D-P-T Vaccine	(1)
TRIP DATE: September 6, 1978	PAGE 1 OF 2 PAGES

TRIP SUBJECT

Larry J. Baraff, M. D.
Assistant Professor of Pediatrics
Emergency Medical Center
U.C.L.A. Hospital and Clinic
Los Angeles, California 90024

PLAINTIFF'S EXHIBIT

REPORT SUMMARY

I met with Dr. Larry Baraff at the Emergency Medical Center in the U.C.L.A. Hospital complex on Wednesday, September 6, 1978. Dr. Baraff is currently involved in a large-scale study of the reactogenicity of currently marketed D-P-T vaccine. He has to date administered about 1500 doses, 1200 of which are currently licensed Wyeth D-P-T vaccine. These have been administered in either out-patient clinics, Kaiser-Permanente clinics or private pediatrician's offices within the Los Angeles county-area. He is evaluating the reactions based on home visits by his nursing staff or questionnaires received from parents of immunized infants. They are looking at such variables as change-in-cry pattern, change in feeding pattern, fever, irritability, generalized reactions, i.e., seizures, and local reactions such as swelling, tenderness and redness.

I Far from the expected incidence of one in 15,000 immunizations, there have been five out of 1500 or an incidence of one in 300 of generalized seizures. These have occurred in infants, all under six months of age which is below the usual lower limit defined for febrile seizure disorders. There have been two episodes of total "collapse" characterized by unresponsiveness, hypotension, bradycardia and a shock-like picture occurring within a couple of hours after the vaccine has been administered.

In general, Dr. Baraff feels that the reaction rate both local, generalized and systemic for currently marketed D-P-T vaccines containing whole pertussis (virus) is unacceptable. He claims that his feelings are reinforced by phone calls and letters which he receives constantly from practitioners, clinic directors, and pediatricians in the California area who are equally convinced that the whole virus vaccine is highly reactogenic. Dr. Baraff claims that this is in opposition to prior experience in the pediatric community with the solubilized antigen. He, therefore, is greatly in favor of investigating Wyeth's new formulation containing the solubilized antigen absorbed with aluminum phosphate. He would be able to perform a 100 patient study very quickly comparing two groups of 50 children each receiving three doses of either the new vaccine or the currently marketed product. Agglutination and inhibition titer testing would be done by Dr. Richard Stiehm, Professor of Pediatrics and Chief of Immunology at U.C.L.A. The bloods would be drawn prior to receiving the first dose and 30 days after receiving the third dose of vaccine. Doses would be given at the recommended 2, 4, and 6 month well baby visits. All patients would be well babies attending the maternal and child health clinics at U.C.L.A. and would be under the care of Dr. Baraff or one of several nurse practitioners during the time of the study. Dr. Baraff is prepared to initiate the study as soon as possible and does not foresee any difficulties in obtaining institutional review of this protocol.

Dr. Baraff will be attending a meeting at the Bureau of Biologics with Dr. Hapnclark on Monday, September 11th to present his data and discuss the proposed protocol utilizing Wyeth's new vaccine. He will contact me on arriving back in Los Angeles

Submitted

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