

The attenuated rubella virus vaccine: how public health agencies and the manufacturer thwarted post-release surveillance

Medical Veritas Editorial Staff

P.O. Box 790

Pearblossom, CA 93553

Email: pearblossominc@aol.com

Abstract

Professor of Microbiology at University of Maryland, B. G. Young, Ph.D., became interested in conducting a follow-up study of adverse vaccine effects occurring in 10,000 individuals that initially received live attenuated rubella virus vaccine (HPV-77) in 1969.

Dr. Maurice R. Hilleman, Division of Virus and Cell Biology Research of Merck Institute of Therapeutic Research, published *Live Attenuated Rubella Virus Vaccine* in the 1969 Proceedings of the International Conference on Rubella Immunization held in Bethesda, Maryland at the National Institute of Health. In the summary section of that publication, he wrote, "Data file cards have been prepared on each of these children's name, address, and vaccination data so that they can be followed for their life-span for untoward effects should this be judged desirable. Adequate numbers of contact control subjects to exclude contagiousness have also been included in these studies."

The subject data that Merck was directed to maintain as part of licensure agreements, was requested for post-surveillance study, but never released. FDA's Bureau of Biologics stated, "There is no requirement [in licensure of *Merck, Sharpe and Dohme* for production and marketing of live rubella virus vaccine] for follow up of these named individuals."

© 2004 Pearblossom Private School, Inc.—Publishing Division. All rights reserved.

Keywords: rubella vaccine, adverse vaccine effects, post-surveillance study
