

MANSFIELD
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REVISED

FDA Vaccines and Related Biological Products Advisory Committee
Remarks of Kenneth R. Dardick, 31 January 2001 (REVISED)

My name is Kenneth Dardick, MD. I am a Family Physician in Mansfield, Connecticut where I have practiced since 1976. I am board certified in both Family Practice and Internal Medicine and have taken advanced training in tropical medicine and diseases of travelers. I have earned the Diploma in Tropical Medicine and Hygiene from the London School of Hygiene and Tropical Medicine and the Royal College of Physicians and am an Clinical Assistant Professor of Medicine at the University of Connecticut. My patients come from both Windham and Tolland counties, areas where the incidence rates for Lyme disease are among the highest in the United States (State of Connecticut, Lyme Disease Cases and Rates per 100,000 population 1993-1999).

Especially during the months of early Spring, Summer and Fall we diagnose and treat a constant stream of patients with Lyme disease and with concerns about Lyme disease and other tick-borne illness. Since 1995 we have diagnosed 90-100 cases of Lyme disease each year in our patients. Many have the classic ECM rash of early Lyme disease. Some are more complex with systemic symptoms of fever and muscle aches, some have neurologic findings of Bell's palsy. Others have arthritic symptoms with swollen joints (often knees or elbows). Rarely, patients have required intravenous therapy, hospitalization or prolonged treatment.

Concern about Lyme disease and other tick-borne illness is widespread in our community. Children learn in school how to protect against tick bites. Campers, hikers, and gardeners all pay attention to ticks and unusual rashes.

It is in this setting that the physicians in Mansfield Family Practice have adopted the administration of Lymerix vaccine. To date we have given nearly 2000 doses to our patients. We have reviewed with each patient the appropriate risks and benefits of vaccination.

A few patients have chosen not to have the vaccine. Many have requested it. Side effects have been mild, mostly sore arm, low-grade temperature and rarely last longer than 1-2 days after vaccination. These side effects are comparable with other vaccines we administer for common childhood illnesses and the more exotic vaccines we administer to those traveling abroad. We have not observed any sign of chronic illness or long-term ill effect that can be attributed to the vaccine. During this same time we have seen many patients ill with Lyme disease. It is too early to tell for sure, but our diagnosed cases of Lyme disease in the year 2000 appear to have dropped from the previous 5 years.

On the whole, Lymerix has been well accepted by our patients and our professional staff. We believe there will be ongoing benefit to those who have chosen to be immunized with this vaccine.