

## **Part 6:**

### **U.S. gov't allows Big Pharma giant to define Lyme diagnosis**

Journalist Suzan Erem reported on facts about a 1994 meeting between pharmaceutical giant SmithKline Beecham, the U.S. Food and Drug Administration (FDA) and the U.S. federal Centers for Disease Control (CDC). (voicesweb.org, dated May 2, 2010)

Erem cited a report by the 2001 Lyme Disease Association detailing “extensive conflict of interest potential in the development of a Lyme vaccine.” According to the 186-page report, Erem wrote, “a lively debate occurred in 1994 at an important meeting of experts in Dearborn, Mich. A close vote resulted in the narrow definition of Lyme that exists today as standard, a definition that Lyme activists say impacts the profit-making power of Lyme vaccine developers.

Erem quoted from the report: “[Pharmaceutical company] SmithKline Beecham, the FDA and CDC met to decide upon a viable case definition for Lyme disease, one that would enable their data to have meaning and permit their clinical trials to move forward, ultimately passing review at the FDA. A stringent serological definition of Lyme disease, one that seemed to settle, once and for all, who had Lyme and who did not, was essential for products to be approved.”

Erem stated, “If everyone could agree on what Lyme disease was, then everyone could agree when a successful vaccine was eventually developed for it. But if Lyme continued to morph into more and more complicated copy-cat symptoms, no one could ever make a vaccine that would convince the FDA to approve it.

“Worse, if long-term antibiotics with expired patents could cure the worst cases, millions of dollars in vaccine research and development would have been wasted and future profit potential would disappear.”

According to Wikipedia, Dr. Allen Steere, credited with discovering, “led the research effort on Lymerix, the preventive Lyme vaccine by SmithKline Beecham, now GlaxoSmithKline (GSK), which first appeared on the market in January 1999.”

Wikipedia noted, “Some uncertainty remained about the vaccine's ultimate safety before it was released to the public, especially for people with certain conditions.” However, the drug was not taken off the market because of danger. According to the CDC: “[T]he vaccine was withdrawn from the market in 2002, reportedly because of poor sales.” (cdc.gov/mmwr)

Wikipedia states that GlaxoSmithKline (GSK) “took the drug off the market in 2002 for commercial reasons, citing poor sales ... the high price of the vaccine, the need to exclude children under 15, and the need for frequent boosters.”

“Vaccine expert Stanley Plotkin predicted that the withdrawal meant there will never be another Lyme disease vaccine available.” (en.wikipedia.org)

*Next: Profit interests narrow Lyme definition, blood tests*