The Historical Development of the Mercury Based Preservative Thimerosal.

Before the invention of modern antibiotics and antiseptics, physicians experimented with "germicides," including acids and mercury-containing compounds, to try to stave off microbial pathogens. Thimerosal was born of these efforts in the early 20th century. Thimerosal is an organic compound made up of equal parts of thiosalicylic acid and ethylmercury. It is 49.6 percent ethylmercury by weight. Thimerosal was developed by Dr. Morris Kharasch, a chemist and Eli Lilly fellow; first at the University of Maryland (1922-1927) and then at the University of Chicago. He filed for a patent on June 27, 1929, for what he described as an alkyl mercuric sulfur compound (thimerosal), which he felt had potential as an antiseptic and antibacterial product.

In October 1929, Eli Lilly and Company registered thimerosal under the trade name Merthiolate. Merthiolate was used to kill bacteria and prevent contamination in antiseptic ointments, cremes, jellies, and sprays used by consumers and in hospitals. Thimerosal was also used in nasal sprays, eye drops, contact lens solutions, immunoglobulins, and most importantly here - vaccines. Thimerosal was patented the same year that Alexander Fleming discovered penicillin. To the medical profession, who were without antibiotics during the 1930s and 1940s, thimerosal (marketed as Merthiolate) and other antiseptic products were welcome additions to combating life-threatening bacterial infections.

Eli Lilly investigators, H. M. Powell and W. A. Jamieson, reported in 1931 that various animals seemed to tolerate high doses of Thimerosal. Rabbits, for example, tolerated on the order of 25 milligrams per kilogram of body weight—comparatively much higher than those ever used in vaccines. However, many of those animals given higher doses did die of evident mercury poisoning just days later. Also notable in these early animal toxicity studies and many later research efforts: The researchers failed to assess or perform socialization behaviors and cognition tests. In other words, though the animals may have survived Thimerosal exposure, their social behavior might have been altered as a result of mercury-induced brain damage. During this time period, Powell and Jamieson also reported on the first injection of Thimerosal into humans. In 1929, during an epidemic of meningococcal meningitis in Indianapolis, K. C. Smithburn administered Thimerosal to twenty-two ill patients at Indianapolis City Hospital.[i] The Thimerosal had no apparent therapeutic benefit, and all the patients died, seven of them within one day of Thimerosal administration.[ii]

Despite the deaths of all of these patients, Powell and Jamieson described the experiment as a success. The drug was administered intravenously and the authors reported that their patients seemed to tolerate the high dosages of the 1 percent Thimerosal solution. The scientists involved in thimerosal research at the time published a paper that made a brief reference to this study: “Merthiolate was injected intravenously into 22 persons…these large

doses did not produce any anaphylactoid or shock symptoms." But neither of these side effects is associated with toxic mercury exposure, which can take months before presenting symptoms. This study was not designed to examine toxicity; only 7 of 22 subjects were observed for only one day, the specific clinical assessments were not described, and no laboratory studies were reported. (REF. NTP nomination) Apparently, because of the abbreviated survival period, the longest that Powell and Jamieson were able to observe a patient was only sixty-two days after the administration of Thimerosal.[iii] Importantly, the Powell and Jamieson study neglected to mention that the patients given Thimerosal by Smithburn were not healthy individuals. It is possible, therefore, that any short-term neurological or other deleterious effects of the Thimerosal would have been masked by or attributed to the patients' meningitis infections.[iv]

In the paper, the authors acknowledge that Dr. K.C. Smithburn, the clinician who treated the meningitis patients, was not convinced of its efficacy: "beneficial effects of the drug were not definitely proven." Drs. Powell and Jamieson also noted in 1930 that a "wide range of toxicity and injury tests should be done."[1] There is no evidence that Drs. Powell and Jamieson took their own advice and conducted studies to address these concerns. Eli Lilly used the Smithburn, Powell, and Jamieson results for decades as evidence of Thimerosal's safety paving the way for inclusions into various antiseptic products, including nasal sprays, eyewashes, vaginal spermicides, and diaper rash treatments.[v] Starting in the 1930s, pharmaceutical companies began to use Thimerosal in vaccines for the intended purpose of preventing bacterial contamination due to repeated needle punctures into multi-does vials of vaccine.

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[i] Smithburn KC, Kempf GE, Zerfas LG, Gilman LH. Meningococcic meningitis: a clinical study of one hundred and forty-four cases. *J Am Med Assoc*. 1930; 95:776–780

[ii] United States. Mercury in medicine report. *Congressional Record*. Washington: GPO, May 21, 2003: 1011-1030

[iii] Powell HM, Jamieson, WA. Merthiolate as a germicide. *Am J Hyg.* 1931;13:296–310

[iv] Geier DA, Sykes LK, Geier MR. A review of Thimerosal (Merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness. *J Toxicol Environ Health B Crit Rev.* 2007 Dec;10(8):575-96

[v] Geier DA, Sykes LK, Geier MR. A review of Thimerosal (Merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness. *J Toxicol Environ Health B Crit Rev.* 2007 Dec;10(8):575-96

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[1] ELC002353-67; Rosenstein, Carolyn et.al.; "The Bactericidal and Antiseptic Action of Preservatives Frequently Used in Biological Products, and the Effect of these Preservatives on the Potencies of These Products;" *The American Journal of Hygiene*; September 31, 1934.