In early 2000, a law firm who had filed a court case claiming that thimerosal was not a necessary vaccine ingredient in civil court was able to bypass the National Vaccine Injury Compensation Program (NVICP). During the discovery process the firm received internal documents from Eli Lilly who first patented Thimerosal in 1929. The information below is what the law firm presented to the judge in the case. This document describes the long and sordid history of thimerosal and confirms that this potent neurotoxin can cause neurodevelopmental injury and should have never been used in vaccines. As a result of this case, a rider was added to the Homeland Security Bill the night before it was voted on and approved by Congress that included a provision that any company who makes an ingredient used in a vaccine is covered under the NVICP.

1. <u>The History and Politics Involving Thimerosal Containing Vaccines and Neurological Development Disorders Including Autism</u>

A. 1920's – 1930's: Eli Lilly's Invention, Testing and Successful Promotion of Thimerosal for Use in Vaccines by 1931

From the 1920's through the 1950's, and even much later, Eli Lilly, first as vice-president and then as president of the company, was directly involved with virtually all significant decisions related to product development at Eli Lilly and Company. In the late 1920's for example, during the time when Lilly's efforts led to the development of merthiolate (Lilly's trade name for thimerosal), Eli Lilly regularly called and chaired research committee meetings. "Each scientist had his say directly to vice-president Lilly, who often made the necessary decisions."[54]

[54] "Even more important, in the late 1920's Lilly took the responsibility to call and chair regular research committee meetings. In contrast to [Director of Research Dr. G.H.A. Clowes'] informal and eclectic

Eli Lilly decided to establish fellowships at various universities that were designed "to increase the friendliness of the faculties of the various universities for our house. Various members of our staff are now very welcome in most of the medical centers."[55] However, Lilly only wanted to provide fellowships to scientists who would be sensitive to its needs:

> He (Lilly) urged careful screening of university scientists to be sure that the company was "dealing with a man or men of exceptional ability and trustworthiness."[56]

Eli Lilly's fellowships paid early dividends with Dr. Morris Kharasch, first at the University of Maryland and later at the University of Chicago. Kharasch was apparently a scientist that Lilly felt could be "trusted." He invented thimerosal, which he referred to as an "alkyl mercuric sulfur compound" that had potential due to its antibacterial properties. On June 27, 1927, Kharasch, working in collaboration with Lilly, filed a patent application for the alkyl mercuric sulfur compound, i.e. thimerosal.[57] The product was about 50% ethylmercury. Shortly thereafter, Lilly began to make efforts to develop and market the new product.[58]

In 1928, Dr. G.H.A. Clowes, Director of Research of the Eli Lilly Co., assigned Lilly scientists H.M. Powell and W.A. Jamieson the task of completing animal toxicity studies in anticipation of plans to sell thimerosal (under the trade name merthiolate) for

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methods, Lilly sent a formal agenda in advance of the meeting and encouraged those attending to discuss issues and proposals openly with the result, Zerfas later remembered an 'often times verbal knock-down shake out on some subject.' Each scientist had his say directly to vice-president Lilly who often made the necessary decision." Madison, Eli Lilly: A Life 1885-1977; at page 65 (Exhibit 24) *(Exhibit ELI-1223).*

[55] Madison, at page 64 (Exhibit 24) *(Exhibit ELI-1223).*

[56] Madison, at page 94 (Exhibit 24) *(Exhibit ELI-1223).*

[57] (Exhibit 25) *(Exhibit ELI-503).* When possible, exhibits citations include references to both the attached appendix and the exhibit's designation on plaintiff's exhibit list.

[58] (Exhibit 26) *(Exhibit ELI-392FF).*

human use as an antiseptic and/or antibacterial agent.[59] Powell and Jamieson performed a series of short-term experiments on animals to ascertain what toxicity patterns might be observed. On July 24, 1930, Powell and Jamieson submitted their results for publication to The American Journal of Hygiene, and their article was published in January 1931. Id. In one section of the published paper, Powell and Jamieson noted:

> *Toxicity in man.* Merthiolate has been injected intravenously into 22 persons in doses up to 50 cubic centimeters of 1% solution. . . **The toleration of such intravenous doses indicates a very low order of toxicity of merthiolate for man.** This information has been supplied through the kindness of **Dr. K.C. Smithburn** of Indianapolis who has had occasion to use merthiolate in a clinical way. **Dr. Smithburn** stated in these cases 'beneficial effect of the drug was not definitely proven. It did not appear, however, to have any deleterious action when used in rather large doses intravenously when all the drug entered the vein.

Id. at page 306 (emphasis added). As discussed below, Powell and Jamieson's conclusions about low intravenous toxicity were referenced repeatedly by Eli Lilly until the 1980's. Upon closer inspection, however, it is apparent that the Lilly scientists working directly with Smithburn[60] deliberately withheld key facts and, in so doing, manipulated and distorted their conclusions, leading to corruption of later published scientific literature concerning thimerosal.

In their report, Powell and Jamieson failed to include the salient fact that their interpretation of Smithburn's "clinical" use of thimerosal was fatally and deliberately flawed because Smithburn's "patients" were suffering from severe meningitis. Lilly had asked Smithburn to conduct research from late 1929 until mid to late 1930 at its clinical

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[59] (Exhibit 26) *(Exhibit ELI-392FF).*

[60] Neither Kharasch nor Smithburn were Lilly employees. Lilly's spokeswoman, Joan S. Todd, stated in an interview with the Indiana Star that "the drug firm knows of "two doctors mentioning using [thimerosal] on an experimental basis in a study in 1929. They were not our doctors." See (Exhibit 27) *(Exhibit ELI-632).*

research laboratory at the Indianapolis City Hospital. Working closely with Lilly personnel like Powell, Smithburn was involved with testing an experimental treatment after an outbreak of meningitis in November, 1929. By the time the epidemic ended in April 1930, 144 meningitis patients (including the 22 referenced in the Powell & Jamieson study) had been hospitalized and treated at the Lilly labs.[61]

Smithburn injected the meningitis patients with Lilly's new thimerosal product in a series of experiments designed to determine if it might serve as a possible treatment for the disease.[62] The experiments also served a second purpose, i.e. providing a basis for claiming that thimerosal was non-toxic when injected and therefore safe as a vaccine preservative.

Lilly attempted to disguise its involvement with these experiments. The company wanted readers of the Powell and Jamieson study to assume that those injected were normal or healthy, allowing Lilly to make claims that the product was non-toxic when injected. Lilly also knew that dosing patients with high levels of mercury was unethical by its very nature. Lilly chose Dr. Smithburn to perform the actual injections, rather than a doctor employed by Lilly, allowing Lilly to distance itself from human experimentation.

In September 1930, Smithburn published an article in the journal of the American Medical Association entitled "Meningococcic Meningitis, A Clinical Study of 144 Epidemic Cases," in which he described the experimental injection of thimerosal into meningitis victims.[63] The 144 cases were simply described as cases "from the Lilly

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[61] (Exhibit 28) *(Exhibit ELI-500).*
[62] (Exhibit 28) *(Exhibit ELI-500).*
[63] (Exhibit 28) *(Exhibit ELI-500).*

laboratories for clinical research, Indianapolis City Hospital." Smithburn provided details concerning the epidemic:

> The present epidemic of meningitis in Indianapolis began in November 1929. This report includes cases admitted to the Indianapolis City Hospital between November 11, 1929 and April 1, 1930. One patient was received in November, 52 in December, 22 in January, 44 in February and 25 in March.

While Smithburn did not reveal his specific business relationship with Lilly, it is apparent that the same H.M. Powell assisted Smithburn by making bacteriologic and serologic studies, with the additional assistance of Lilly employee F.G. Jones. Both Jones and Powell were identified as "from the biologic department of the Lilly research laboratories." It is clear that Powell must have known that the Smithburn subjects were suffering from meningitis and its severe neurological consequences at the time they were experimentally injected with thimerosal. However, this fact is never mentioned in the published Jamieson/Powell study. This critical omission allowed Lilly to advertise that "toleration of such intravenous doses indicates a very low order of toxicity of merthiolate for man."

In his article, Smithburn wrote that "the treatment has remained essentially the same throughout the epidemic." He described the use of thimerosal as an experimental effort to treat the disease: "Intravenous administration of an antiseptic solution was tried and found wanting despite the in vitro activity of the agent." Smithburn also reported that efforts were made to combat infection resulting from positive nasopharyngal cultures by the application of ephedrine sulphate in each nostril followed by merthiolate (1 part per 4000 strength) twice daily. Smithburn noted that the treatment was "symptomatic,"

Id., leading to immediate concerns within Eli Lilly as to the potential toxicity of thimerosal/merthiolate and the injuries it could cause.

An interoffice memorandum dated April 24, 1930 was received by Harley W. Rhodehamal, the Director of Research Development, warning of concerns within the company that the product could cause injury and should not be sold in a stronger version, i.e. 1 part per 1000, or 1 part per 2000.[64] The memo, from Lilly Director, Charles J. Lynn, related concerns about "our experience with the merthiolate solution. . ." Lynn felt that a stronger version of merthiolate posed an even riskier proposition:

> Can we expect to have the stronger ointment and jelly used without the complaint which attended the use of the solution in the same strengths? . . . Our experience with the solution ought to serve as a warning and certainly in the face of that warning we ought not to advocate the use of the stronger products without some pretty definite evidence that we will not repeat our solution experience.

Lynn's specific concerns were related to the toxic symptoms observed by Smithburn, but he must also have known that Jamieson and Powell planned to publish a misleading article designed to misrepresent the safety of the product when injected. Despite Lynn's warnings, Lilly eventually went on to sell the solution in the 1:2000 and 1:1000 strengths.[65] There is no indication that Lynn's concerns were ever addressed with additional testing.

On August 18, 1931, Kharasch filed a new patent application in an effort to stabilize merthiolate due to its tendency to acquire "certain burning qualities."[66] Those efforts were apparently unsuccessful, for Kharasch and Lilly later applied for a third

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[64] (Exhibit 29) *(Exhibit ELI-204).*
[65] (Exhibit 30) *(Exhibit ELI-201).*
[66] (Exhibit 31) *(Exhibit ELI-504).*

patent for "organo-mercuri-sulfur compound."[67] That patent application again noted the problems reported earlier by Lynn and Smithburn:

> Certain antiseptic and bactericidal . . . compounds, which . . . tend to form disassociation products and thereby both tend to decompose and to lose their effectiveness as antiseptic germicides and tend to develop **certain medicinally undesirable properties.**"[68]

By the 1930's, merthiolate had quickly become one of Lilly's most important products.[69] However, Lilly researchers remained under constant pressure to develop new products, and to expand markets for established products such as merthiolate.[70] While publicly adopting the "non-toxic when injected" mantra from the Jamieson and Powell 1931 publication, within the company it was recognized that thimerosal/merthiolate remained a toxic substance that could have harmful effects. However, promoting the product as "non-toxic when injected" was critical for promoting merthiolate use in vaccines as a preservative.

In 1935, another article from Lilly scientific extolled the virtues of thimerosal/merthiolate as a vaccine preservative.[71] The article cited Jamieson and Powell's earlier conclusions regarding non-toxicity of thimerosal/merthiolate when injected, and commented that Lilly had been using the product as a preservative in diphtheria toxoid vaccinations since 1931:

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[67] (Exhibit 32) *(Exhibit ELI-505).*
[68] (Exhibit 32) *(Exhibit ELI-505)* (emphasis added).
[69] Madison, *Eli Lilly: A Life, 1885-1977*, at page 65 (Exhibit 24) *(Exhibit ELI-1223).*
[70] Vice President Joe Lilly criticized Clowes and his team of research scientists in 1940: "For five years our research men have developed virtually nothing in the way of an important addition to our catalogue." Id., at page 95. (Exhibit 24).
[71] (Exhibit 33)*(Exhibit ELI-392S).*

> [Thimerosal] had been used on [Jamieson and Powell's] recommendation, in this laboratory since 1931, in a dilution of 1-10,000 in diphtheria toxoid preparations. These preparations were found to be sterile when tested in bulk. The question therefore arose as to whether this preservative could be used with equal success in other types of biological products.[72]

While Lilly continued to promote thimerosal as a "safe" preservative despite receipt of a July 22, 1935 letter from the Director of Biological Laboratories of the Putnam-Moore Company:

> Pardon the delay in acknowledging the receipt of your letter dated July 15 relative to merthiolate.
>
> **In other words, merthiolate is unsatisfactory as a preservative for serum intended for use on dogs.**
>
> I might say that we have tested merthiolate on humans and find that it gives a more marked local reaction than does phenol or tricresol.[73]

The letter expressed concerns about the toxicity of thimerosal when used as a preservative for injection purposes and noted that Lilly's test results did "not check with ours."[74]

B. 1940's – 1950's: Mercury in vaccines connected to mercury poisoning (acrodynia)

Lilly sold large amounts of merthiolate to the United States government for use in the war effort (1941-1945). "Merthiolate was an army standard issue and 22 tank cars of the popular antiseptic were dispatched from (the) McCarty Street (plant) during the war."[75] Due to military regulations, and as a result of the toxicity of the ethylmercury preservative, Lilly was required by the Department of Defense to label the product

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[72] (Exhibit 33) *(Exhibit ELI-392S)* at page 261 (emphasis added).
[73] (Exhibit 34) *(Exhibit ELI-1064)*
[74] Id. [This document is currently protected by confidentiality order and is not attached.]
[75] Madison, at page 106 (Exhibit 24) *(Exhibit ELI-1223)*.

"POISON." The "POISON" language was only added to the products in certain instances, as when required by the government, and Lilly continued to fail to warn about hazards of the product for its non-military sales and for sales related to vaccines.[76]

By 1943, Lilly was also marketing a merthiolate ophthalmic ointment, as it expanded its efforts to sell the product. Lilly received an article expressing concern that the product not be used unless "it has been previously demonstrated that the patient is not sensitive to the ointment." The article also recommended "that the package should be labeled to warn the customer that such [sensitivity] tests should be made previous to the use of merthiolate ophthalmic ointment in or around the eye."[77] Receipt of this information confirmed Lilly's knowledge that thimerosal could be more hazardous to some members of the population that might be more susceptible to its effects.

In 1943, twelve years after Lilly's introduction of thimerosal into infant vaccines, the first reported cases of children with neurodevelopmental symptoms were identified in an article by Leo Kanner entitled "Autistic Disturbances of Affective Contact."[78] Kanner indicated that since 1938, a number of children with these unusual features had first been noticed. The oldest child in his cohort was 11 years old, i.e. born in 1932. While Kanner did not have any reason to understand the potential etiological connection and presumably was unaware of the 1931 introduction of mercury into pediatric vaccines, his description of many of the symptoms of what he called "autism" are the same or similar to the neurological and neurodevelopmental problems suffered by many children today, including Jordan Easter. These symptoms included language and other developmental

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[76] (Exhibit 35)*(Exhibit ELI-228).*
[77] (Exhibit 36) *(Exhibit ELI-392D).*
[78] (Exhibit 37) *(Exhibit THIM-PL-MED-1997).*

delays, intellectual defect, etc. Additionally, a number of the children were noted to be normal at birth and for time periods up to several years of age.[79] Id.

Throughout the remainder of the 1940's, Lilly received additional information confirming that certain persons will have greater susceptibility to injury. In 1947, Lilly scientists received an article entitled "The Sensitizing Factor in Merthiolate:"[80]

> No eruptions or reactions have been observed or reported to merthiolate internally, but it may be dangerous to inject a serum containing merthiolate into a patient sensitive to merthiolate.[81]

Shortly thereafter, Lilly received another article[82] noting that merthiolate was a commonly used preservative and stating that:

> It would seem important to determine whether harm would result following [merthiolate's] subcutaneous or intravenous injection in skin sensitive individuals.

In the 1950's, Lilly continued its efforts to promote thimerosal for use in additional vaccines, including Dr. Jonas Salk's polio vaccine. In an article entitled "The Preservation of Poliomyelitis Vaccine With Stabilized Merthiolate," six Lilly scientists (including H.M. Powell) extolled the virtues of merthiolate and announced that they had "solved the problem of the apparent incompatibility of merthiolate and poliomyelitis vaccine."[83]

In June of 1953, in the journal PEDIATRICS, Dr. Joseph Warkany, a researcher who had completed extensive work related to mercury in teething powders and its ability to cause neurological injury in a susceptible subpopulation of children, published

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[79] Id.
[80] (Exhibit 38) *(Exhibit ELI-392M)*:
[81] Id., at page 213.
[82] (Exhibit 39) *(Exhibit ELI-392i)*.
[83] (Exhibit 40) *(Exhibit ELI-661 at page 9)*.

"Acrodynia and Mercury."[84] Warkany was intrigued by the fact that vaccinations with mercury preservatives had preceded the onset of mercury toxicity symptoms:

> In several children of our series and in some recently reported, various immunization procedures preceded the onset of acrodynia in addition to mercurial exposure. This could be purely coincidental or the vaccination material may play a role as an accessory factor. It is noteworthy that many vaccines in sera contain small amounts of mercury as preservatives which are injected with the biologic material.[85]

C. 1960's and 1970's: Recognition of hazards from mercury in vaccines and misrepresentations to the FDA; Merck discusses need for a "replacement program."

In 1960, despite significant information concerning the toxicity of thimerosal, including scientific evidence that certain persons were more likely to be injured due to their susceptibility, Eli Lilly decided to begin promoting their over-the-counter version as "non-toxic" in an apparent effort to increase sales.[86] In 1963, Lilly received more information indicating that injection of merthiolate in vaccines could cause injury and that testing was necessary:

> There is another point of practical significance: does the parenteral injection of merthiolate-containing fluids cause disturbances in merthiolate-sensitive patients?
>
> It is known that persons that are contact sensitive to a drug may tolerate the same medications internally, but it seems advisable to use a preservative other than merthiolate for injections in merthiolate-sensitive people.[87]

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[84] (Exhibit 41) *(Exhibit THIM-PL-MED-1754).*
[85] Id. at 381. (Emphasis added)
[86] (Exhibit 42) *(Exhibit ELI-99).*
[87] (Exhibit 43) *(Exhibit ELI-392H).*

Despite increasing knowledge and understanding of the potential for danger, Lilly made a conscious decision in 1964 and January 1967 to continue to label its packages of merthiolate as "non-toxic."[88]

In May of 1967, an article was published in APPLIED MICROBIOLOGY entitled "Enhanced Toxicity for Mice of Pertussis Vaccine When Preserved with Merthiolate."[89] The abstract states:

> Pertussis vaccines preserved with 0.01% merthiolate are more toxic for mice than unpreserved vaccines prepared from the same parent concentrate containing the same number of organisms.[90]

The merthiolate (thimerosal) in question "was obtained from Eli Lilly & Co., Indianapolis, Indiana."[91] Twenty mice were injected with vaccine with no thimerosal and none died. However, 30 mice were injected with the same vaccines, plus the thimerosal, and 5 died.[92] "Mortality was greatest, however, when merthiolate was injected with the vaccine."[93] The article went on to postulate that "it would not be surprising if injection of this vaccine influenced the susceptibility of the mouse towards a mercurial preservative."[94] Lastly, the authors noted that "other laboratories" had observed toxicity of final lots of preserved vaccine when the vaccines themselves were "atoxic or only slightly toxic."[95]

In August of 1967, a Dr. Jansen confirmed that labeling thimerosal "non-toxic" was inappropriate and requested "that they delete the "non-toxic" which appears on the

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[88] (Exhibit 44) *(Exhibit ELI-73)*; (Exhibit 45) *(ELI-69)*.
[89] (Exhibit 46) *(Exhibit THIM-PL-MED-1195)*.
[90] Id. at 590.
[91] Id.
[92] Id. at 592.
[93] Id.
[94] Id. at 593.
[95] Id. at 593.

front panel."[96] On August 29, Lilly changed the label, removing the "non-toxic" language and leaving "non-irritating to body tissues." [97]

By 1971, Lilly had finally tested thimerosal's use as a preservative and concluded that the concentration used in vaccines (1 in 10,000) could be "toxic for tissue cells, lymphocytes, etc."[98] J.W. Smith, Ph.D., the head of the Biological Regulatory Requirements Department, concluded that "merthiolate must be in the concentration of less than 1 in 1,000,000 in order not to be toxic to the tissue cells." Thus, in this September 7, 1971 memo, Lilly recognized that the concentration in vaccines was **100 times** higher than the level it considered to be safe.

In 1972, Lilly received an article that confirmed that thimerosal had caused 6 deaths because too much of the preservative had been used.[99] "The symptoms and clinical course of the 6 patients suggests subacute mercury poisoning." The same year, the British Medical Journal reported cases of skin burns resulting from the chemical interaction of thimerosal and aluminum. The study noted that "mercury is known to act as a catalyst and to cause aluminum to oxidize rapidly, with the production of heat."[100]

Shortly thereafter, the FDA required that Lilly provide all available information concerning the toxicity of thimerosal. Lilly reported to the FDA, in a February 14, 1973 letter, that "as with other chemicals of its generation, information relating to safety and efficacy of thimerosal in animal models is sparse."[101] But Lilly went further, implying

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[96] (Exhibit 47) *(Exhibit ELI-68).*
[97] (Exhibit 48)*(Exhibit ELI-67).*
[98] (Exhibit 49) *(Exhibit ELI-643)* [This document is currently protected by confidentiality order and is not attached.]
[99] (Exhibit 50) *(Exhibit ELI-392K(1)).*
[100] (Exhibit 51) *(Exhibit ELI-392-O).*
[101] (Exhibit 52) *(Exhibit ELI-392).*

that thimerosal was non-toxic and citing Jamieson and Powell as supporting scientific evidence.[102]

In 1975, squirrel monkeys treated with thimerosal-containing nose spray were autopsied. The article concluded that mercury accumulated in the brain "which may represent a potential hazard in the chronic use of thimerosal as a preservative in products intended for human use."[103]

On April 27, 1976, Lilly's Manager of Industrial Sales, W. Orbaugh, responded to a letter from Rexall Drug Company in St. Louis, Missouri. Rexall had been concerned about the potential hazards of merthiolate/thimerosal and had requested, pursuant to the trademark/marketing agreement maintained with Lilly, permission to place a warning on the product that stated: "Frequent or prolonged use or application to large areas may cause mercury poisoning."[104]

Lilly responded aggressively, ordering Rexall not to add the warning and purposefully misstating the potential hazards of a product it knew to be toxic:

> We object to the connection of our trademark with the unjustified alarm and concern on the part of the user which the statement is likely to cause.
>
> We are not aware of any instance of 'mercury poisoning' after decades of marketing this product. This is because the mercury in the product is organically bound ethylmercury and has a completely non-toxic nature, not methylmercury.[105]

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[102] (Exhibit 53) *(Exhibit ELI-392QQ at pages 1009, 1017).*
[103] (Exhibit 54) *(Exhibit THIM-PL-MED-192)(Exhibit ELI-731).*
[104] (Exhibit 55) *(Exhibit ELI-412E).*
[105] (Exhibit 55) *(Exhibit ELI-412E)* (Emphasis added).

In 1977, Mukhtarova published an article entitled, "Late After-Effects of the Nervous System Pathology Provoked by the Action of Low Ethyl-Mercuric-Chloride Concentrations" in a Russian journal.[106] In that study, Mukhtarova examined **adults** who were exposed to microgram or one-tenth of microgram quantities of ethylmercury for some two-three months, amounts much lower than those to which Jordan Easter was exposed for a broader period of time. Several years after the exposures, Mukhtarova documented neurological injury and neuropathology in the majority of individuals examined.[107]

By the late 1970's, if not earlier, the vaccine companies fully recognized the need to replace thimerosal because of its potential hazards. In an October 12, 1979 memo, Merck scientists discussed the "potential problem" of having mercury in its flu and meningococcal vaccines, as well as the Hepatitis B vaccine that was in development:

> Should a program of replacement be initiated now to guard against any spontaneous rally to avoid its (merthiolate's) use in injectables?[108]

The memo goes on to note that "we already have such a program under way by necessity because our gonococcal antigen(s) is inactivated by merthiolate."[109] This document indicates that the industry had actual knowledge, as of the late 1970's, that mercury in vaccines should be replaced. It is important to note that these concerns were expressed prior to additional mercury when the Hib and Hep B vaccines were added to vaccine schedule in the 1980's and 1990's.

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[106] (Exhibit 56) *(Exhibit THIM-PL-MED-1966).*
[107] Id.
[108] (Exhibit 57) *(Exhibit MRK-464)* [This document is currently protected by confidentiality order and is not attached.]
[109] Id.