To: Lauren Fuller
Chief Investigative Counsel
United States Senate Health, Education, Labor and Pensions

From: Elizabeth Birt, J.D., L.L.M.
James Moody, J.D.

Date: July 15, 2005

Re: Timeline

Per your request of May 18, 2005 we have set forth below the following information to aid the Committee in its investigation of the actions of federal regulatory agencies and certain pharmaceutical companies in relation to the removal of thimerosal containing vaccines from the market. We have divided this analysis into three specific time periods: 1) pre 1999; 2) July 1999;) post July 1999. We have included a statement of charges as well.

Pre 1999:
In December of 2002 Elizabeth Birt made contact with Dr. Wolfgang Maurer who was the head of the Official Medicines Control Institute for vaccines and blood products for Austria because she had heard of his success with the removal of thimerosal from a Baxter vaccine product for tick borne encephalitis. Dr. Maurer initially became concerned with the use of thimerosal in 1988 when he first took the job as head of the Official Medicines Control Institut, submitting papers to both the New England Journal of Medicine and The Lancet entitled "Unconsidered Risk Due to Thiomersal in Anti-Lymphocytic Globulin Preparation" (1). These papers were not accepted for publication.

In January of 1992 Dr.Manfred Hause of the Paul-Ehrich-Institute raised concerns in an official manner to the Commission of the European Communities, Commmittee for Proprietary Medicinal Products (CPMP). In his letter to the CPMP, he made the following important points, "it is well known that even low amounts of organic mercury compounds may cause rare untowards reactions in man, mainly allergic reactions. Other undesired properties have also have been seen in experimental studies or were described in the scientific literature: mutagenicity, teratogenicity, embryo- and neurotoxicity....Based upon the principle that-whenever an additive which can be a matter of concern is not necessary to ensure some essential property of a medicinal product its use should be avoided- in June of 1991 the Paul-Ehrlich-Institut has encouraged manufacturers to discontinue the addition of organic mercury compounds into immunoglobulins. This initiative has been generally appreciated and in the meantime nearly all manufacturers have informed our institute on the measures taken to implement the recommended change. It can predicted that this will be achieved by the end of 1992." (2)

On September 13, 1994, a hearing chaired by Dr. Manfred Haase was held at the Paul Ehlich Institute regarding the use of thimerosal as a preservative in vaccines. All vaccine manufacturers selling vaccines in Germany were invited. There was no representative of a US federal health agency at this meeting. This said, representatives of the following vaccine manufacturers selling in North America were present: 1) Dr. Thomas Eckhardt, Wyeth; 2) Ron Salerno, Merck Sharpe Dohme; 3) Ricky D. Smith (CLI Swiftwater, PA) and 4) Raafat Fahim (Connaught Toronto/CLL now Aventis Canada). (3) What is particularly interesting from the minutes of this meeting is the opinion of vaccine manufacturer Lederle Arneimittel , stating that "data from the USA confirm that the risk associated with the use of vaccines containing thiomerosal is small." There was no discussion in the minutes of the 1994 meeting of the possible toxic accumulations of thimerosal from the increasing number of vaccines being administered. Yet we do know that Merck's chief vaccine scientist, Maurice Hilleman did examine this issue in depth in a memo to R. Gordon Douglas the Chief Executive Officer of Merck in early 1991. (4) Further, this issue was discussed at the World Health Organization (unknown year but April 15-16) at a meeting which was attended by Dr. William Egan of the US Food and Drug Administration ("FDA"). (5). In addition, according to an email provided to me by Dr. Maurer he did discuss the issue of thimerosal containing vaccines with Dr. Elaine Esber of the FDA in December of 1993 at a meeting in Vienna, Austria. (6 and personal communication between Elizabeth Birt and Dr. Maurer).

Prior to July of 1999 we know that the FDA had a position on the removal of thimerosal from vaccines. This was referred to in an email dated June 29, 1999 from Dr. Peter Patriarca of the Center for Biologics Evaluation and Research ("CBER") in which he states "The fact of the matter is that an "interim plan" (for potential removal of thimerosal) has ALREADY been in place for MANY YEARS…we just need to "speed up" the EXISTING plan.. not create a "new" "interim plan". We are proactive…not reactive. Thanks, Peter P." (7)

In addition to the email of June 29, 1999, Dr. Patriarca also sent an email to FDA personnel on July 2, 1999 in which he states: "FDA began the process of encouraging thimerosal-free preparations before the passage of FDAMA (Food and Drug Administration Modernization Act of 1998) through the IND and pre-PLA processes. I am not sure if we can compile specific examples rapidly…Karen Goldenthal may know);"(8)

On October 9, 2002 Dr. William Egan, Deputy Director of Office of Vaccines Research and Review and Dr. Norman Baylor, Associate Director for Regulatory Policy, CBER. were interviewed by Elizabeth Birt who was then a staff employee of the Government Reform Committee. Both Dr. Egan and Dr. Baylor at this interview denied knowing the existence of any formal plan to eliminate thimerosal from vaccines. Dr. Baylor did say that the "interim plan" referred to by Dr. Patriarca was not a written plan. He stated that globally there was a plan to remove thimerosal from vaccines but it was focused on new vaccines not old ones. On June 19, 2002 at a Congressional hearing conducted by Congressman Dan Burton Dr. William Egan when confronted with Dr. Patriarca's email

of June 29, 1999 specifically DENIED knowing of the existence of any interim plan at FDA to remove thimerosal from vaccines

This pattern of allowing already licensed vaccines to be marketed containing thimerosal on one side and then requiring new vaccines in the pre-PLA (Product License Application) process to be formulated without thimerosal put the FDA in an situation in which they are literally arguing out both sides of their mouth. If thimerosal is a "problem" with new vaccines then why not vaccines which are already been licensed? We believe that the FDA's institutional negligence can be traced back to at least 1992 and perhaps further. The critical sequence of events is as follows: in order to obtain approval of a vaccine or biologic a manufacturer must obtain an IND (Investigational New Drug) approval from FDA. After clinical trials are completed then the manufacturer can file for a PLA. It was evident that thimerosal should be removed from vaccines and biologics as early as 1991. Existing INDs and PLAs were let slide. In fact, on May 6, 1999 Leslie Ball received information from FDA demonstrating that of 437 active INDs, 75 contained thimerosal, 51 did not contain thimerosal and 311 were "questionable (lack of information/could not determine whether Thimerosal was used." (9)

It is highly likely that the FDA "let slide" vaccines and biologics with thimerosal because the manufacturers already had too much money invested in the products and it would cost money to remove the thimerosal, reformulate the product and perhaps have to go through the process of efficacy studies. There is an ongoing responsibility of all vaccine manufacturers to prospectively monitor the safety of all licensed products. It is clear that not only that this was not done but that the regulating agency, the FDA had two standards of licensure depending on the status of the vaccine or biologic in the drug approval pipeline.

Attached you will find a list of the dates associated with the approval of the Hepatitis B, DTaP and Hib vaccines. As you can readily see there is a significant time period between the time a Biological License Application or Product License Application is received and when it is approved. We were not able to obtain the dates of the Investigational New Drug Application. I am sure that they are available on file at the FDA. (10)

At the same time that FDA was licensing vaccines with thimerosal for human use, the animal division of FDA was moving swiftly to remove it from vet products. The person responsible for this was Dr. Linda Tolofson. Dr. Tolofson was never questioned by the Committee on Government Reform as to what prompted the FDA to make decision regarding vet products.

In the fall of 2002 Elizabeth Birt asked three FDA employees, Dr. Norman Baylor, Dr. William Egan and Dr. Leslie Ball whether they had knowledge of the European Medicinal Evaluation Agency's position on thimerosal prior to April of 1999. All claimed to have no personal knowledge of any problem with thimerosal in Europe prior to this date. This is difficult to believe given the amount of communication between individuals within the global vaccine community, the NIH and within the FDA itself.

In addition, other employees of FDA started to examine the European's position on thimerosal as early as June of 1998. An email was sent by Roger Williams of FDA to Peter Cooney and Joseph De George on June 21, 1998 specifically referred to the EMEA/CPMP about "not using Thimerosal in vulnerable groups such as infants, toddlers and pregnant women." (11).

Attached you will find all of the EMEA documents relating to thimerosal given to Elizabeth Birt by Dr. Wolfgang Maurer. Some of these documents are dated as early as 1997. (11) In addition, attached you will find a memo dated June 29, 1999 to Elaine Esber from Fernand Sauer of EMEA. This memo makes the following recommendation: "For vaccination in infants and toddlers, the use of vaccine without thiomersal and other mercurial containing products should be encouraged." In addition, it makes the following important observation: "The main concern with thiomersal are the induction of allergic reactions and due to the presence of ethylmercury, the potential risks of neurotoxicity. In non-pregnant adults, a Permissible Total Weekly Intake (PTWI) of 200 ug of methylmercury has been recommended by the WHO. At present, there is no international recommendation for a maximal intake in infants. Based upon the WHO recommended PTWI and a documented higher sensitivity of fetuses and infants due to the vulnerability of the developing brain, the intake of methylmercury in infants may exceed that which could be considered as safe." (12)

FDA employees were concerned enough about the European's fears relating to thimerosal in October of 1998 to assign Dr. Stephen Hundley the task of performing a thimerosal toxicity review.(13) Dr. Ken Hastings forwarded the initial draft of this study on October 14, 1998 to Carolyn Hardegree of FDA with the following important observation "his conclusion, basically is that there is little in the literature to support the idea that thimerosal is a significant health hazard at the doses used in vaccine products, but there might be some "holes" in the data base that could be addressed by appropriate animal studies (e.g. repro tox, metabolism). I have had some communication with Frank Sistare, Director of Applied Pharm Research in OTR, concerning the possibility doing some tox studies with thimerosal, but one issue that Frank would like some clarification on is the importance of the issue. My response was that this was probably going to be fairly important, based on the need to use thimerosal in multi-use vials, and the fact that the Europeans appear to want to essentially ban it from use in vaccines and that (I thought) there was some language in FDAMA about removing mercury-containing preservatives from drugs and biologics. I think Frank wants to get a sense of the scope of this issue before getting too involved in looking at research possibilities. Can you give us some idea as to how serious this issue is?" (14)

There was at least one FDA employee, Dr. Leslie Ball who disagreed with Dr. Hundley's assessment of the safety of thimerosal. On October 15, 1998 Dr. Ball wrote Dr. Marion Gruber the following "I disagree with the conclusion that there is no basis for the removal of thimerosal in vaccines. On a strictly scientific basis, yes, there are no data that have looked at the specific issue of thimerosal in vaccines. However, there are factors/data that would argue for the removal of thimerosal, including data on methyl mercury

exposure in infants and the knowledge that thimerosal is not an essential component to vaccines." In addition in the first sentence of Dr. Gruber's email to Dr. Ball reference is made to a re-pro tox meeting on Tuesday (October 13, 1998) (where) we have briefly discussed the Thimerosal in vaccine issue. (15) Attached for your review is a summary of the minutes from that meeting and a list of attendees. (16)

On November 23, 1998, Dr. Leslie Ball of the FDA asked internal reviewers to perform a Medwatch query on thimerosal. Medwatch is the FDA's database for reporting adverse drug events. (17) On January 7, 1999 Dr. Ball was informed by Fredrick Varricchio of FDA that there were 7000 reports containing the word thimerosal on FDA's Medwatch. (18). He stated "I have some results for you. Problem is that there are 7000 reports that mention thimerosal. What to do now. Obviously looking at all 7,000 is a brute force approach." On February 16, 1999 an email was sent to the "Mercury Reviewers" from Steven Aurecchia regarding "Screening Spreadsheet for Mercury Studies". This document specifically states "Please make a reference for each of the references you have received, even if it is not a study per se. Just specify the nature of the reference in column two, e.g. case report, general or review article, etc." (19) The results of the data contained in the spreadsheet were never provided to the Committee on Government Reform even though FDA was subpoenaed for all information relating to thimerosal.

In addition to concerns at FDA by August 1998 the NIH had already started planning a study entitled "Assessment of Mercury Levels in Infants Receiving Vaccines Containing Thimerosal". The purpose clause of the consent form of this study states "The University of Rochester, with the National Institutes of Health, is conducting this study to detremine the level of mercury in the blood, hair, and stool of infants who have received standard childhood vaccines." (20)

At the same time "alarms" were being sounded at the NIH and FDA regarding the position of the European community on thimerosal Merck had started researching this compound as early as 1996. This was a full five years after Dr. Maurice Hilleman presented his analysis of the danger of the use of thimerosal to G. Gordon Douglas, then President of Merck. In May of 2001 Elizabeth Birt was contacted by C. Bruce Pittman who was retained earlier by Merck to investigate the chemical properties of thimerosal. In 1997 Mr. Pittman informed his superiors at Merck that thimerosal as an "intact" molecule did not have any anti-microbial properties; in other words it was the ethyl-mercury that killed the microbes, not thimerosal. Mr. Pittman was conducting this research as an employee of Merck and as part of his dissertation at LeHigh University. He was told by his superiors at Merck he could not publish his work. He was able to obtain his Masters degree at LeHigh and his paper was read by his professor in a closed room with the caveat that no copies of the paper were to be made. This research was disseminated to scientists at Merck as high as the Vice President level in 1997. Mr. Pittman presented interim results in late 1998 and his final results in March of 1999. The final report is attached as well as all emails between Elizabeth Birt and Mr. Pittman. In addition, Mr. Pittman told Ms. Birt that in his final presentation in March of 1999 that he informed Merck employees which included officers of the company that between 6 to 8 micrograms of ethylmercury were being delivered to an infant's central nervous system

with each vaccine containing thimerosal. At the end of this meeting Mr. Pittman walked out with the female executive director and mentioned that Merck could be poisoning infants with these vaccines. The individual said nothing. Mr. Pittman left Merck shortly after this because he could no longer be associated with a company that behaved in this manner. (21)

In addition to the concerns over the use of thimerosal as a preservative in the European community by 1998 there was a mountain of peer reviewed research calling into question the safety of thimerosal as a preservative in vaccines and biologics. A study in 1986 sent to Elizabeth Birt by an FDA employee directly calls for the removal of thimerosal from vaccines and biologics. This study, 1986 Adverse Drug Reaction Article written by K.A. Winship, Senior Medical Officer, Medicines Division, Department of Health and Social Security for the United Kingdom states on page 171: "Multidose vaccines and allergy-testing extracts contain a mercurial preservative, usually 0.01% thiomersal, and may present problems occasionally in practice. It is therefore, now accepted that multidose injection preparations are undesirable and that preservatives should not be present in unit dose preparations."

On June 18, 2000 the Committee on Government Reform convened its first hearing addressing the issue of thimerosal in vaccines and biologics. Dr. William Egan of the FDA testified under oath on behalf of the FDA. Chairman Burton asked Dr. Egan the following question: " When did the FDA and CDC first start being concerned about mercury in vaccines.?". Dr. Egan responded, "I guess that the major concern started somewhere around May of 1999?" In addition, Dr. Egan was asked by Congresswoman Chenowith-Hage at the same hearing: "With regards to the introduction of the Hib vaccine and Hepatitis B vaccine, could you advise the committee on what studies were done with regards to these new vaccines that would prove thimerosal safe?" Dr. Egan's response was "There is a long history of the use, the safe use of thimerosal, you know, in vaccines since they were-since it was first introduced. And at that time (1990) there was no data to suggest that the added mercury from the introduction of those vaccines would be harmful." These statements by Dr. Egan either reflect the gross incompetence of Dr. Egan or are patently false. By 1990 there was a mountain of evidence that thimerosal was unsafe and ineffective. In point of fact, in 1987 the Commission of the European Communities initiated a research project of 10 known or suspected spindle poisons including thimerosal. In 1993, as described in Mutation Research, 287 (1993) 17-22 thimerosal was identified as a strong inhibitor of microtubular assembly, a process which is essential for proper neuronal development. In addition, beginning in 1992 FDA employed a researcher by the name of Joan May to evaluate each lot of thimerosal containing vaccines for thimerosal content. If thimerosal had such a long history of safe use, something which is refuted in the medical literature was that an assumption on the part of Dr. Egan or an attempt to conceal the facts from Congress?

1999

By April of 1999 with the position of the EMEA to "encourage" the use of thimerosal free vaccines it was clear that the FDA could no longer rely on their "interim plan" to

gradually require vaccine manufacturers to provide thimerosal free product when formulating new products. On 4/13/99 Drs. Leslie Ball, Douglas Pratt and Robert Ball presented their independent analysis of thimerosal.(22) This analysis was prompted by the Food and Drug Modernization Act of 1997 which required FDA to compile a list of drugs and food that contain "intentionally" introduced mercury compounds, the effect of mercury in nasal sprays and the study of mercury sales 21 U.S.C. Section 413. What is important is that this legislation specifically required Health and Human Services through the FDA to conduct or contract with the Institute of Medicine to conduct a study of the effects on humans of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. If, after the conduct of these studies, in the opinion of the Secretary of Health and Human Services, the use of elemental, organic or inorganic mercury offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from the exposure to, or ingestion or inhalation of mercury. What is a very important point in this slide presentation is that the children were already expected to receive 80-100 ug of methyl mercury their first year of life from food and thus the intake of INORGANIC MERCURY FROM OTHER SOURCES SHOULD BE LESS THAN 120-130 ug DURING THE FIRST YEAR OF LIFE. At the time this analysis was done the FDA knew that American children were routinely exposed to 188 ug of inorganic mercury during the first year of life from the CDC recommended vaccination schedule. The FDA also knew that they had significant gaps in their knowledge relating to the reproductive toxicity, developmental toxicity, biotransformation of thimerosal following intramuscular or subcutaneous administration, and sensitization studies.

On April 14, 1999 the FDA was actively communicating its formal position to vaccine manufacturers on thimerosal. A particularly telling email from Richard Kenney of FDA summed up the frustration of certain individuals at FDA dealing with the manufacturers on the thimerosal issue: **"It seems the only way a letter to industry will have any impact is to impose a requirement (if that can be done under FDAMA!). I vote to encourage manufacturers to work toward removing thimerosal from all products, and require them to formally justify its necessity in any product under IND. With respect to CDER's and other's interest in the issue, we are the only ones where most of our products are targeted toward infants"**.(emphasis added) (23)

On April 20, 1999 Dr. Roland Levandowski sent Dr. Leslie Ball an email regarding thimerosal which made the following important points: 1) in the past the vaccine manufacturers had investigated the use of preservatives other than thimerosal because there was a concern that thimerosal would no longer be available; 2) no action was taken to remove thimerosal from vaccines at that time because the situation was resolved; 3) there was a "lot of discussion of eliminating the preservative from single dose containers which is probably acceptable and may be a good idea to reduce mercury exposure in the environment generally"; 4) the Europeans are using single dose containers without thimerosal and his understanding was that there is no effect on solubility, antigencity, immunogenicity and stability; and the difficulties to be expected if thimerosal is removed

from multidose containers would be bacterial contamination and adverse events related to bacterial growth/endotoxin. Dr. Lavandowski believed that single dose containers without a preservative would be acceptable but each manufacturer would need to develop the data.

Dr. Leslie Ball's response was interesting in that she was concerned that Walter Ornstein the then head of the CDC was expressing an interest in adding influenza vaccine with thimerosal to the routinely recommended childhood vaccinations. It is evident that she was concerned about the level of thimerosal in the influenza vaccines that infants would be exposed to enough so to ask Dr. Lavandowski if he knew who the European manufacturers of thimerosal free influenza vaccines were. (24)

The take away message from these emails is that individuals at FDA knew of the potential problems with thimerosal in vaccines, they knew the European position, they knew how to resolve it by going to single unit vaccines; they knew that the manufacturers had investigated other alternatives when they didn't believe that thimerosal would be available but that nothing was done because thimerosal became available again; and that at least Dr. Ball was concerned that CDC through ACIP would recommend influenza vaccine to all infants with thimerosal.

On May 3, 1999 Ken Hastings replied to Dr. Ball regarding Dr. Hundley's analysis of thimerosal. This email stated the following: "Concerning the document prepared by Steve Hundley, we did the best we could given the information that was available. To our knowledge, there are no studies available to FDA from any sponsor concerning the potential toxicity of thimerosal to infants, and it is possible that a straight conversion of dose based upon relative body weight could be misleading. However, leaving aside the question of the potential for enhanced susceptibility of infants to the presumed neurotoxic effects of potential thimerosal degradants (e.g. ethylmercury), we attempted to analyze the data based on a worse case scenario. Assuming that thimerosal completely degrades to ethylmercury and an infant receives 10 injections of 1mL/each of a vaccine product containing what we assume is the maximum amount of thimerosal, total theoretical delivered dose would be about 570 micrograms of ethylmercury, or 190 microgram/kg in a 3 kg infant. We were unable to find published data that could be taken to indicate that this would represent a significant risk. However, clearly organic mercury is the most neurotoxic form, and some forms of mercury are very potent. Clearly **more information would be helpful in analyzing the potential risk of ethylmercury**. (emphasis added) (25)

On May 5, 1999 Tom Clarkson, a methyl mercury expert from University of Rochester sent the following email to Dr. Ball: "Ethyl mercury has caused more outbreaks of poisoning similar to those caused by methyl mercury. It is more rapidly converted to inorganic mercury in the body than is methyl mercury. Thus is may be somewhat less toxic but is neurological effects are the same. As a first pass one might use the risk parameters for methyl mercury." (26)

On June 10, 1999 Leslie Ball sent an email to Karen Midthun of FDA requesting a copy of the pre-PLA minutes for a vaccine called COMVAX and letters to the sponsor (Merck) addressing thimerosal removal. Dr. Midthun responded the next day as follows: "I have placed a copy of the pre-PLA meeting minutes for COMVAX in your mailbox. The members of the PLA committee with product expertise (Steve Feinstone, chair, Carl Frasch and others) would be most knowledgeable about the physicochemical characterization of the thimerosal-containing vs. thimerosal-free formulations. Post-approval, Merck initiated a phase 4 study (IND 3576, study #12) with COMVAX (thimerosal-free) to gather additional safety data, as well as study (#011) in which they are evaluating three lots of thimerosal-free Comvax given either concurrently or non-concurrently with DTaP and IPV. Thus, clinical data is forthcoming with the thimerosal-free product. (27)

On June 10, 1999 Leslie Ball sent an email to Peter Patriarca of FDA. This email directly addresses the efficacy of thimerosal as an antimicrobial in vaccines. "Re: thimerosal removal and induction of conformational changes in antigenic determinants, this issue is central to whether the FDA will require additional studies for formulations in which thimerosal is removed. There is a CBER precedent on this issue (for better or worse) with COMVAX in which the pivotal efficacy studies were done with a product containing thimerosal, but the PLA was filed and approved with a product in which the thimerosal was removed. At the pre-PLA meeting (I am still trying to retrieve the records of this), Merck was apparently told that no further clinical studies were necessary on the product without thimerosal, and that manufacturing bridging was all that was necessary. Karen Midthun's recollection was that this was a decision by the product reviewers. Any further light you can shed on this decision, and its applicability to other products, would be helpful. Re: your comment on the risk of contamination if thimerosal is removed, Neal Halsey is putting together a manuscript from the workshop held at Hopkins 9 months ago on injection guidelines that concludes that unidose vials are the best option to avoid contamination and prevent medication errors. (As you recall, thimerosal did not prevent the occurrence of abscesses following DTP vaccine from multidose vials.) At the time Halsey wasn't even considering the advantage of unidose vials if thimerosal is removed. Bill Egan has checked with Mark Raza on whether FDA is compelled to follow USP standards for preservatives and it appears we are not. In any event, I think the way to go is to move to single dose vials. CDC (Bob Synder) told me last fall that this would not be a problem for clinics depending on federal purchases if unidose vials were phased in gradually."(28)

What is interesting about these two emails is the perception at FDA that removing thimerosal when going to unit dose vials did not require the manufacturer to do any additional safety testing and that thimerosal as an antimicrobial was ineffective. This contradicts Dr. Bill Egan's testimony before the Committee on Government Reform on July 18, 2000 on this issue. " Mr. Burton: And mercury is a poison? Mr. Egan: Yes, it is. It is neurotoxic. Mr. Burton: And the FDA and CDC are committed to phasing it out. Why not take it out today; 8,000 children are going to be immunized today. We understand that there is a supply for every child in America of nonmercury-orientated drugs. Why is it that we are not phasing it out today? Mr. Egan: There are a couple of

things. If I can first address its use as a preservative, it is an effective preservative, and it is demonstrated to be an effective preservative. All of the preservatives that are used in vaccines are required to meet the USP definition of a preservative, meaning that the test article, the vaccine with the preservative in it, is taken. There are five challenge organisms that are added, there are three bacteria and two fungi, and these are added at 0.1 milliliter of each of the bacteria and fungi in a concentration between 100,000 and a million organisms, and within 14 days the preservative is required to reduce the bacterial count by 99.9 percent." It is clear that Dr. Egan either completed forgot about this conversation with Mr.Raza and was also unaware of the problems of abscesses following the administration of DTP vaccines containing thimerosal or he committed perjury.

On June 21, 1999 Dr. Neal Halsey sent the following email to Dr. Leslie Ball regarding a powerpoint presentation she had emailed him previously: "Your slides are excellent and appear to be complete with the exception of a few important issues. What criteria were used by the various groups to establish standards? What is the lowest possible dose associated with toxicity of any type? Are infants at increased suspectibility to toxicity as compared to older children and adults? **These points are critical as the answers will dictate the urgency that action will need to be taken. Every day of delayed response after tomorrow will be a major source of criticism for the FDA, the ACIP and the APP.** (emphasis added) (29)

On June 28, 1999 a conference call was convened by the American Academy of Pediatrics' Committee on Infectious Diseases (COID) joined by the Committee on Enviornmental Sciences and Fetal and Neonatal Issues along with approximately 20 others including PHS agency representatives (FDA, CDC, NIH, NVP), academicians, toxicologists, mercury experts, etc.. Dr. Elaine Esber's email to Dr. Susan Ellenberg summarizes the telephone conference. (30) The draft recommendation prepared by AAP/COID is attached as Exhibit (31)

Dr. Esber states: "The issue was the draft recommendation prepared by COID/AAP to "use Thimerosal-free vaccines whenever possible and eliminate recommendations for routine Hepatitis B vaccination at birth" citing accumulating information on the risk of mercury containing compounds. The "urgency" of the issue was precipitated by the recent accumulation of information by CBER scientists stimulated by FDAMA which showed that, if all vaccines used contained Thimerosal, the current immunization schedule contains an amount of Thimerosal that exceeds that amount currently recommended by various groups, including the WHO, EPA, ATSDR, FDA and others. The phone call (which lasted over two hours) included a verbal review of the data on mercury containing compounds, and a discussion of the known/unknown risks. There was controversy among the mercury/toxicology experts on the extent of, and interpretation of, the data. It was pointed out by some experts that the data was extrapolated, using "pre-natal" and not "post-natal" exposure, and a different form of mercury than Thimerosal. The concern is that the data may not be appropriate for extrapolation. Nevertheless, some of AAP members and consultants believe that an urgent change in policy is necessary." Dr. Esber's concerns are listed as "Implications for US immunization policy are many. The PHS is concerned that there has been

inadequate: review and deliberation of the data; consideration of the alternatives and implications; and definition of the actions that would be responsible. If an orderly transition is not continued, this action could result in unwarranted loss of confidence in immunization programs in the US and internationally, shortages of childhood vaccines (those not containing Thimerosal might ensure, and other potential far reaching ramifications are envisioned."

Dr. Susan Ellenberg's response to Elaine Esber was interesting; she stated "While I don't disagree with what you say, I think it is a mistake to focus on the potential adverse consequences of a "non-orderly" transition to non-thimerosal containing vaccines and to sound dismissive of the scientific evidence available, without attention to the consequences of taking it slow if thimerosal does cause neurotoxicity in the amounts currently being given. What we need to do is to consider the potential adverse consequences of both types of error-moving too rapidly away from thimerosal if there really is no problem with it, and moving in a more measured way if there really is a problem with it. At this point I don't we think we know which error would produce the worse outcomes. One might make a reasonable case that if half of infants get thimerosal at "unacceptable" levels, and if 10% of these suffer some level of neurological deficit as a result, that would be more morbidity than would occur if half of a year's cohort of infants had delayed immunization with DTaP and Hep B for 6-9 months."

One of the experts retained by FDA to perform toxicological modeling was Barry Rumack. One of Dr. Rumack's set of charts that was prepared on June 28, 1999 (32) and presented at the Lister Hill meeting convened in the fall of 1999 which specifically focused on thimerosal clearly shows that low birth weight infants and normal children exceed safe limits for mercury exposure. In addition, Lyn Redwood, President of SAFEMINDS was given a chart by an employee of ATSDR which clearly shows that infants given routine immunizations containing ethylmercury would clearly be over the ATSDR estimated "safe" steady state methyl-Hg blood level required for pregnant mothers. (33)

On June 28, 1999 an Interagency Conference Call was held to bring together the various federal agencies responsible for policy making on the thimerosal issue (CDC, FDA, NIH (Dick Riseling) (34). Exhibit 35 are handwritten notes of a member of the IAG; what is clear from this conference call is that the AAP, specifically Neal Halsey, was going to issue a press release before that end of that week targeting thimerosal and that Elaine Esber of FDA was "pleading for a more deliberative review of the data" which was refused. In addition there are notations that Dr. William Raub, Undersecretary of Health and Human Services "has been meeting with Thurm re methyl mercury". Kevin Thurm was the Assistant Secretary of Health and Human Services at the time. They are mentioned on the second page of Exhibit 35 again. "One pager for Koplan (then Director of CDC) to share with Thurm". In addition a "recap" of this conference call prepared by Dr. Elaine Esber is attached as Exhibit 36.

A document was developed in conjunction with this call. Part IV(A)(1) of this document references prior meeting of the FDA's Medical Policy Coordinating Committee Meeting

and the fact that both Dr. Leslie Ball and Dr. Neal Halsey of the American Academy of Pediatrics were invited to these meetings held as early as June of 1998. It should be noted that Dr. Halsey was invited to the June 1998 but not in his "capacity" as a representative of AAP. (37)

On June 29, 1999 CDC released a document titled "Recap of Thimerosal Issues" (38) The last paragraph of this document is interesting: "The Department must be prepared to communicate to the public immediately when the discussion becomes more widespread, as seems likely. A number of COID members and government liaisons have asked that there be a meeting convened in DC tomorrow to include industry representatives to prepare a joint statement (a Department statement that AAP and others join us in releasing). The AAP leadership has agreed with this approach."

On June 29, 1999 a conference call was held with the vaccine manufacturers. See Exhibits 39 and 40; notes from this conference call taken at 4:20 P.M. reflected the following comments made by Wayne Morges of AMVAX: Is AMVAX looking at removing thimerosal? Response: "will make multidose vial can not exclude preservative; would like to sell single dose vial but would be too expensive; DTaP for AMVAX in Europe is already single dose; Liability issues could be great!" In addition, all available notes of both of these conference calls is attached as Exhibit 41.

On June 30, 1999 Dr. Leslie Ball made a presentation to individuals at the American Academy of Pediatrics on the issue of thimerosal in infant vaccines. Her powerpoint presentation is attached as Exhibit 42. Slide 1 of this presentation clearly states: "for infants up to 6 months, Hg exposure from vaccines given according to US vaccination schedule may exceed some methylmercury exposure recommendations; other exposures to Hg not included, assumes maximum exposure from vaccines, …by age 2, Hg exposure appears to be within recommendations. Slide 4 illustrates that the FDA was clearly aware that children who were less than six months of age would be exposed to ethylmercury from vaccines at a least exceeding WHO, EPA and one ATSDR standard WITHOUT calculating exposure to mercury from the environment (mother's breast milk) estimated by the Europeans to be 80 to 100 ug the first year of life. Slide 6 demonstrates that the FDA was clearly aware that American children would be subjected through the then current vaccine schedule to bolus amounts of ethylmercury which exceeded the daily limits for:1) EPA 0.1 ug/kg/day or 0.7 ug/kg/wk (dose protective of developing fetal nervous system); 2) ATSDR 0.3 ug/kg/day or 2.1 ug/kg/wk (adult); and 3) FDA 0.4 ug/kg/day or 2.8 ug/kg/wk (adults); Slide 15 concludes the presentation by stating "Infant exposure to Hg from vaccines may be avoidable by using thimerosal free products".

On June 30, 1999 Dr. David Blois of Merck called Dr. Kathryn Zoon of FDA and Mr. Mark Elengold; the teleconference with Merck did not happen until July 1, 1999 at 8:00 A.M.; notes from this call reflect the following statements by the manufacturers; 1) transition to a thimerosal free vaccine would take greater than 6 but less than 24 months; 2) the general consensus was that AAP would not act independently, clear that Neal Halsey agrees, and that he (Neal Halsey) still may want AAP to take the lead; 3) Martin

Meyers from CDC was on the teleconference as well and the note reflect his concern that the "core communication message must be continue to vaccinate children. (43)

On June 30, 1999 an email was sent by Melissa Skolfield to various individuals at CDC and PHS as a "summary" of the situation with thimerosal. What is interesting about this email is the following statement: "It also appears (and I could be wrong) that they're trying to leapfrog the ACIP process for changing vaccine schedules." In addition the following statement leads the reader to believe that it is the CDC who is trying to take any power from AAP to set policy on this issue: "Reasonable people in the room included (Jack?) and Norman Baylor (?) from FDA. Marty and Jose were there from CDC. The consensus seemed to be that there are no "good" vaccines or "bad" vaccines which is hard but not impossible. I'd like the CDC to take the lead on this, and I'd like the tone/process to resemble as much as possible the move from one polio vaccine to another. I hope that makes sense as a guiding principle (I assume you have existing Q and As on how the ACIP process works, etc. that can be re-used for example). (44)

On July 1, 1999 Dr. Elaine Esber and Dr. Norman Baylor of FDA called Dr. David Williams, President and COO of Pasteur-Merieux-Connaught ("PMC"). Notes taken during this conference call reflect the concern of PMC of FDA's response to the AAP position and that FDA is encouraged to "**be careful in damning any use of the product thimerosal**". (emphasis added) (45)

On July 2, 1999 Dr. Ruth Etzel of the USDA sent the following email to AAP (46): "The Committee on Enviornmental Health and Committee on Infectious Diseases may want to look at the way Johnson and Johnson handled the poisoned Tylenol affair in 1982. It followed three basic rules: 1) act quickly to recall the affected product; 2) be open with consumers about what went wrong; and 3) show contrition… The AAP should be dedicated to promptly providing truthful information about this situation to pediatricians. We must follow three basic rules: (1) Act quickly to inform pediatricians that the products have more mercury than realized; (2) Be open with consumers about why we didn't catch this earlier; and (3) Show contrition. As you know the Public Health Service informed us yesterday that they were planning to conduct business as usual, and would probably indicate no preference for either product. While the Public Health Service may think that their product is immunizations, I think that their "product" is their recommendations. If the public loses faith in the PHS recommendations, then the immunization battle will falter. To keep faith, we must be open and honest now and move forward quickly to replace these products. Short term shortages may occur. AAP should reassure pediatricians that we are committed to making sure that all children will be vaccinated, although some may be delayed due to shortages. This is what the American parents want to hear from their pediatricians. Anything less may cause them to lose faith in our recommendations."

On July 3, 1999 Dr. Ben Schwartz, of CDC's National Immunization sent out the following email to key individuals at CDC entitled "A Potential Solution" (47). What is interesting is that Dr. Schwartz admits as the parent of a three month old baby that he "would have been reluctant to accept a thimerosal containing product for my baby" but

"very comfortable knowing my child would receive a thimerosal containing products as long as the defined safe cutoff for mercury is not exceeded". Dr.Schwartz's recommendation of combining thimerosal containing and thimerosal free vaccines so that no child received more than between 75 ug and 100ug of thimerosal during the first year of life was not accepted. He made several excellent points in his email regarding his idea including "this change would reassure the public that the PHS and vaccine manufacturers are continuing to do whatever possible to assure optimal safety and maintain public confidence in the vaccination program."

On July 3, 1999 a document entitled, "Communications Considerations Regarding Thimerosal" was developed by CDC. (48) This document details the four "options" available at the time, at least to CDC, relating to the continued use of thimerosal in vaccines. They were 1) Maintain the status quo (i.e."thimerosal-containing vaccines are not a problem, and can safely be administered to children regardless of age or circumstance"; some of the reasons that this approach was considered to be problematic are as follows: a) "it seemingly puts our childhood immunization schedule in conflict with EPA guidelines; which is a status that will require us to have a sound or better scientific foundation than EPA with regard to Hg exposure"; b) "its scientific foundation is essentially "We have no evidence or data that indicates that there is a problem." A statement that will likely then spur lots of people to produce evidence illustrating that this is a real problem (even only through the use of theories) as well as generate a number of adverse event reports alleging a wide range of adverse effects. **Relatedly, we have little data or science to support our position-leaving us particularly vulnerable to the advocates of reduced or zero mercury exposure, who do have some published data to reference.**"; 2) Recommend thimerosal-free vaccines over thimerosal-containing vaccines (i.e. essentially discontinue the use of thimerosal-containing vaccines); some of the reasons that this approach was considered to be problematic are as follows: a) "this position puts the CDC in conflict with the FDA. Further, the FDA has been monitoring and working to reduce thimerosal exposure, and thus has more data than CDC"; b) "The vaccine manufacturers, while supporting the concept of thimerosal-free vaccines, would likely point out that it is the "CDC's childhood immunization schedule- not the individual vaccines- that are the source of the potential problem. **In defending their products, they could suggest that ACIP and CDC were negligent in their processes by not considering additive exposure or levels when they made additions to the childhood immunization schedule**"; c) "The position could be interpreted as an implicit concession that there is a health-risk associated with thimerosal- a perception that would like fuel anti-mandatory vaccination sentiment and generate a large number of adverse event reports and injury compensation claims related to thimerosal-containing vaccines- especially Hep B"; 3) Situational use for thimerosal-containing vaccines (i.e. these vaccines are okay in these circumstances but not so good in these circumstances. For example "you can use them without concern for children 6 months or older" or "avoid thimerosal containing Hep B vaccines for infants under 6 months"; the reasons that this approach was considered problematic are as follows: a) "The creation of two categories of vaccines- good vaccines (i.e. thimerosal free) and bad vaccines (thimerosal containing)."; "Once physicians, parents, the public and others have decided two categories exist, then we essentially end up with the implications noted under Alternative

#2."; 4) "(Slightly) Modified use in line with the current immunization schedule (i.e." Physicians and parents should use prudent product or brand choice to reduce ethylmercury exposure to levels below those provided by the EPA's mercury exposure guidelines.; the reasons that this was the preferred approach are as follows: a) "It puts the focus on the childhood immunization schedule, which is the crux of the issue."; b) "It can be framed as a logical, responsible, and science-based next step toward the eventual removal of thimerosal from all vaccines"; c) **"It resolves the apparent conflict between our childhood immunization schedule and the EPA's Hg exposure guidelines."; d) "It enables us to reference the EPA's guidelines, and by implication, the scientific basis that underlies those guidelines; e) "Relatedly it enables us to reference and utilize the FDA's science and activities surrounding thimerosal, including the 1976 review, the vaccine clinical trial data, FDAMA, etc."; f) Thanks to c, d and e, this recommendation becomes science-based (vs. based on hypotheses, speculation, and extrapolation).**"; g) "It will likely earn the endorsement and cooperation of vaccine manufacturers."; h) "This course of action may not completely appease those who advocate actions that will more immediately reduce Hg exposure from vaccines to zero, but the concept of "prudent product or brand choice" does provide physicians and parents the ability to accomplish that goal if they so desire. Further as the course of events in the last week suggest; some of toxicologists and other advocates will see this as an opportunity to espouse their position to the media"; i) "This alternative will likely fuel those opposed to mandatory Hepatitis B vaccination of infants and children for school entry, but all the alternatives are likely to do that."; and j) "Ideally, this course of action should have the endorsement of the ACIP so that we are consistent with our processes for changing or modifying the country's immunization recommendations. This endorsement could come from ACIP at their next scheduled meeting." (emphasis added)

Attached to this document is Table One which set forth an example of possible exposures to thimerosal from the products then available. The chart also stated "Using the 5th percentile for weight, the cumulative methyl mercury exposure by 6 months of age, based upon reference guidelines (EPA), should not exceed 80ug."

On July 3, 1999 the following email from **Merck was received by Jose Cordero of CDC: "This is the language agreed on by 5 vaccine companies yesterday. It will not be official until reviewed at PhRMA on Tuesday morning, but meanwhile you may use it as you see fit as a statement from Merck. It is also being sent to others, e.g. Sam, this weekend. The statement completely avoids making recommendations to practitioners about selection of vaccines in the interim period until all vaccines are T-free. Thus it avoids the "good vaccine/bad vaccine" dichotomy. But the statement also is not "business as usual" because it is clear about intent to remove T rapidly and whenever possible. Perhaps this is the best balance we can find to assure that we not undermine confidence in immunizations and vaccines, but still take control of the story in a way to prevent exploitation by anti-vaccine groups. I hope this balanced tone gives concerned practitioners in discussion with parents the information to make vaccine selections in accordance with their perceptions of the issue."**(49) (emphasis added)

On July 3, 1999 another conference call was held by members of the IAG. At that point Dr. Jeffrey Copeland the then CDC Director was in contact with Dr. Sam Katz. In addition it was clear that the issue was serious enough that a meeting with Kevin Thurm then Assistant Secretary of Health and Human Services was going to take place the next week before the release of the AAP statement. Also the CDC was then aware that the story had been "leaked" to the internet and were concerned about the state of the public's knowledge on this issue before they had a joint statement agreed upon. (50)

On July 4, 1999 Dr. Leslie Ball sent an email to Norman Baylor with her comments on the proposed PHS/AAP joint statement. She states in this email "I agree with the approach of focusing on the child and not the vaccine." Dr. Baylor responded to her email as follows: " CDC will not really have a list. **What they are trying to do is come up with a schedule whereby the parent can minimize the amount of thimerosal that their child receives. I think Elaine came up with the term calorie counter, e.g. fat is bad for you but there is a minimum daily requirement. So if your child can receive all his/her immunizations without exceeding the guidelines for maximum intake of mercury, then in theory, s/he will be okay.**" (emphasis added) (51)

On July 5, 1999 Martin G. Meyers, M.D. NVPO, Regina Rabinovitch, M.D. NIH, Peter Patriarca, M.D.FDA, Jose Cordero, M.D. for Walt Orenstein NIP/CDC and Scott Dowell, M.D.NCID/CDC "liason members" to AAP issued a letter that stated the following: "As your liason members we do not vote on proposed Academy policy but we would like to comment on the "final draft" circulated on Saturday. **We continue to be gravely troubled by the recommendation to encourage "use (of) vaccines that do not contain thimerosal". We believe that this will result in a delay for many children to get some of their immunization, the development of vaccine shortages, and will place the pediatrician in the "middle": she will have to choose between giving the less preferred vaccine or no vaccine. Over the weekend, we and our colleagues have developed the concept of "prudent selection" which the PHS plans to be its recommendation to accompany the release of our joint statement. This will outline a series of options within the context of the existing guidelines that permits the pediatrician to use up their existing supplies of vaccines. We urge you to consider revising your recommendations or at least taking the time to consider the option we intend to put forth. We would be pleased to allow you to examine our working paper as soon as it is available (hopefully be Tuesday a.m.). It would be far better were the Academy and the PHS aligned together in our recommendations.**" (emphasis added) (52)

This letter was sent out to individuals within the PHS by Dr. Meyers with the following message "The COID's "final draft" needs a response as they are voting on it by 9 am Tuesday. We need to give them an out from the confrontational position and hopefully to get their recommendations and ours to line up sooner rather than later. I suggest a short note that we would send to Hope Hurley this afternoon from the liason members-that would get it circulated to both AAP committees and likely also to the Exec. Board..." (53)

On July 6, 1999 Dr. Leslie Ball of FDA sent an email to individuals at her agency regarding CDC's "Q and A's" relating to thimerosal. She makes the following important points " Regarding the FDA calculations for Hg exposure from thimerosal, presented to the IAG on 6/28/99 and AAP on 6/30/99: Above all, it is important to emphasize the original intent of the FDA calculations. The purpose of these calculations was to determine whether infant exposure to ethyl mercury exceeds established guidelines for exposure to methyl mercury. They were not intended to serve as maximum exposure limit; the manner in which CDC is now using them:

These were meant to be preliminary calculations based on the most conservative assumptions (meaning maximum exposure to thimerosal in the first 6 months of life). We appreciated that there would be alternate (and perhaps better) approaches."... **"if the CDC is planning to use these calculations as dosing guidelines, there are two important considerations: 1) These calculations do not account for other sources of Hg in the environment. Even infants can have additional exposures, e.g. breast milk. 2) Has the application of these calculations as exposure guidelines received the sign off by toxicologists? In prior discussions, the toxicologists seem reluctant to state that any Hg level was "safe". This approach leaves open the criticism that the PHS is arbitrarily designating a certain level as acceptable when there continues to be so much uncertainty about the science in this area."** (emphasis added) (54)

On July 6, 1999 the following email was sent by Lawrence Bachorik of FDA to Norman Baylor and Dr. Leslie Ball "HHS is looking for a good, clear, understandable statement on risk, today. They are proposing something like this and would like a couple of knowledgeable FDA people to review it. "Even if a child happened to receive all vaccines containing thimerosal during the first six months of life, the amount of ethyl mercury would total (how much). This is more than EPAs? guideline for methyl mercury exposure? from all sources?? However, there is a significant safety margin built into the EPA's guideline (can we quantify this margin?), and there is no evidence of any harm caused by this level of exposure to ethyl mercury in vaccines". Is there any way to put this level of exposure into perspective? Please respond soonest: HHS says they want something yet today." (55)

On July 6, 1999 a document we believe is from AAP entitled "Thimerosal in Vaccines-an Interim Report" was generated. This report makes it clear that "Pediatricians are encouraged to use vaccines that do not contain thimerosal whenever possible, especially for premature and very small term infants...The use of products containing thimerosal is often preferable to withholding vaccination. **Adjustments in timing within the ranges proposed in the immunization schedule provide additional opportunities to minimize the exposure of small infants to thimerosal...The major toxicity of organic mercury compounds is expressed in the central nervous system, though the kidneys and immune system may also be affected. Organic mercury readily crosses the placenta and blood-brain barrier...Guidelines were not designed for intermittent or bolus exposures. Based on the assumption that these exposures will continue for long periods of time, maximum recommended allowable daily exposures range from 0.1 micrograms of mercury per kg per day for the EPA to 0.4 micrograms per kg**

per day for the FDA." (emphasis added) It should be noted that the entire document was not provided. (56)

The joint statement that was issued by the AAP and the PHS included the following points: 1) acknowledged that some children may have been exposed to levels of mercury that exceed one Federal guideline on methylmercury during the first six months of life; 2) asserted that there is no evidence of any harm caused by thimerosal in vaccines; 3) called on vaccine manufacturers to reduce as expeditiously as possible, the mercury content of their vaccines; 4) encouraged doctors and parents to immunize all children, even if thimerosal free vaccines are not available; and 5) encouraged doctors and parents to postpone the Hepatitis B vaccine (which contained thimerosal at that time, and was given immediately after birth) unless the mother tested positive for Hepatitis B (53) This document was not the position favored by AAP or FDA it was clearly co-authored by individuals at CDC, HHS and the vaccine manufacturers. It was not based upon the then available science; it was not formulated to protect infants from a potential risk of neurological and immune system damage from thimerosal containing vaccines; it's sole purpose was to preserve the "integrity" of the immunization program and to limit liability on the part of the vaccine manufacturers. (57)

Post 1999

On July 16, 1999 the National Immunization Program ("NIP") drafted a document entitled "NIP Policy Options for Monitoring Thimerosal Free Vaccine Order Placement) The purpose of this document was to suggest options pertaining to NIP's role in monitoring or controlling State vaccine orders placed through CDC's contracts for thimerosal containing vaccines. Option One was to have NIP issue an advisory to all immunization projects that they are to order only thimerosal-free vaccines beginning with a date to be established. One of the "Cons" of this approach was "Could very well be opposed by those vaccine companies who would rapidly lose market share as a result of NIP's unilateral declaration". Another "Cons" was that it "Could jeopardize CDC's new consolidated vaccine contracting approach which guarantees access to the public health market for all vaccine manufacturers." In connection with the development of this document, a document entitled "Questions and Answers Regarding Thimerosal" was drafted by the NIP. This document estimated that the total first year cost to go to a completely thimerosal free vaccination schedule would have been $88 million dollars (conversion of existing "pipeline" of thimerosal containing vaccines $31 million and annual additional cost of thimerosal free vaccines at $57 million dollars. The CDC was concerned about this additional cost and existing contracts that had minimum purchase requirements from the manufacturers as well as existing contracts that did not have price limits on specific vaccines. (58)

On August 5, 1999 Dr. Leslie Ball sent the following memo to Robert Pless and Roger Bernier of CDC " I faxed you two archival references from the literature. Of note, the Kinsella article from 1941 mentions only one patient treated with merthiolate for bacterial endocarditis who demonstrated mercury poisoning on autopsy (dose not given). The Powell and Jameson article (1931) includes a table (p 307-308) of patients treated

with merthiolate 1% solution. While the article states that "these quantities in the repeated doses did not produce any demonstrable toxic effects", these data came from clinical use in 22 subjects, 7 of whom were followed only one day. No clinical testing (blood or urine) were noted. It is unlikely that safety monitoring performed here would be comparable to current standards". (59)

On August 11-12, 1999 the National Vaccine Program held a conference on thimerosal in vaccines. An email was sent from Geoffrey Evans of HRSA regarding the Lister Hill meeting. This email stated "The purpose of the meeting was to get everyone "on the same page" regarding the issue of mercury in vaccines, **not to set policy, but to exchange information.** (60)

On September 23, 1999 an email was sent from Dr. David Norton regarding a change in the joint statement position to return to the routine immunization position of vaccinating newborns in the nursery with thimerosal containing vaccines. This email contains the following statement **"NIH experts have determined that the cumulative mercury exposure from presently licensed vaccines does NOT exceed the max threshold established by the FDA".** Ed Bailey ,M.D. responded to this move by Massachusetts by stating "I just got the fax and frankly am concerned that this may not be the right move at this time. Granted that there are infants at risk who really benefit from the vaccine when given in the nursery in-hospital. However, for those at low risk there is not an immediate need. If there is no urgent need for this cohort and if a thimerosal free vaccine will soon be available then why are we confusing professionals and the public by reversing our position when in reality we have no new firm evidence that it is safe. The risk of confusing the public and encouraging empowered conservatives on this issue is real and could have far reaching negative effects on the whole vaccine initiative and for what purpose." (61)

On September 24, 1999 Lou Cooper, M.D. of AAP sent the following email to Bruce Gellin, M.D., Sam Katz, M.D. and Walter Orenstein, M.D the then acting head of CDC. "Ed. Can't say I am pleased about the material you sent, but my response has several parts. 1. I support states in adjusting immunization policy where appropriate for local circumstances. CDC and AAP committees generally make room for such adjustments. I am not sure of the data which support a MA variation at this time.; 2) This particular shift seems first of all to be based on revision of all that was discussed by the PHS including the FDA and CDC and multiple AAP experts in July and the consensus of what was presented at the broadly-based conference at NIH on Aug 11. So that is troubling.; 3) I agree with you that the timing of a shift back to universal Hep B vaccine in Massachusetts newborn nurseries BEFORE there is sufficient thimerosal-free vaccine seems to add an unnecessary element of confusion for clinicians and the public and fuel for the antivaccine arguments of folks already so inclined.; 4) At this stage of our knowledge of Hep B vertical transmissions, sophisticated health systems should have well-routinized appropropriate serologic testing for all pregnant women getting prenatal care. There was full agreement about what to do for what should be a small number of untested women who present higher risks; 5) **So for me, bottom line is that it sounds like someone(s) with vested interests that give perspective different from mine and**

our AAP COID is massaging data and reaching a conclusion that I hope doesn't spread to other states (emphasis added); 6) When sufficient thimerosal-free vaccine is available, the issue will be moot. Democracy is tough. Thanks for letting me comment. I have shared this with three folks who may have more to offer and should be alert to what MA is doing." (61) What is interesting about this email is that as earlier as September, only two months after the joint statement was crafted there was movement AWAY from delaying the birthdose of Hepatitis B until sufficient thimerosal free vaccine was available. We are unsure who the individuals with "vested interests" who are "massaging the data" are but we suspect it was individuals at federal health agencies in concert with individuals at the vaccine manufacturers.

On September 29, 1999 an email was sent by Ray Strikas to individuals at CDC to participate in a conference call before the October 20-22 Advisory Committee on Immunization Practices Meeting ("ACIP") was to be held. (62) It should be noted that this pattern of holding "special meetings" before ACIP meetings is well documented in the Committee on Government Reform's analysis of the conflict of issue problem relating the rotavirus vaccine. What is interesting about this email are the comments of individuals at the CDC and FDA on what would be presented at the ACIP meeting:

"General: **I still don't think we are using data on "permissible" methyl mercury exposure levels to properly assess risk. The whole issue of relating what we're giving in vaccines to their impact on blood and tissue levels of Hg rather than relating them to the chronic exposure standards of ATSDR, EPA etc. seems to have not been something we have been able or willing to delve into. Until we do that,** I **don't think that we are analyzing the situation appropriately. Bottom line- I would like to see NCID, NVPO, NIP and NCEH develop a deliberative process and report the outcome in an appropriate medium.** (emphasis added) However, until that is done, it is a fact that CDC, ACIP, and AAP have not changed their recommendations regarding administration of flu vaccine and I think that can be said in several venues (Synder)." Dixie Synder, M.D. is an employee of CDC and currently in charge of the Vaccine Safety Datalink Project.

"If there is a need to look specifically at the issue of thimerosal and pregnant women and infants getting influenza, we should do this in a way that can be referred to. I think Dixie also supported this. If it were me, I would bring together a few knowledgeable people and sorting through the possibilities for using the vaccine versus what we know and don't know about thimerosal. I think ½ day or day to go over the issues, make some calculations, and develop a position paper on this would be the way to go. **You could then refer to the process and defend it to anyone who wants to criticize it. I would suggest someone from ATSDR, myself or Ed, George Lucier from NTP, and Bern Schwetz from FDA to handle the Hg risk side and some vaccine and influenza people to handle the benefit and situation side (Sinks).** (emphasis added)

Suggested partial rewrite and approach by Ed Kilbourne: "Like many childhood vaccines, influenza vaccines contain thimerosal as a preservative. Despite the lack of any specific data documenting harm from the very small quantities of preservative present, it has been

judged prudent to develop thimerosal-free vaccines, and vaccine companies have already started to do so. Although this year's vaccines do contain thimerosal, **the documented, severe health consequences from failure to vaccinate far outweigh any possible risk from thimerosal. Accordingly, the (ACIP) recommendations regarding who should receive influenza vaccine are unmodified. And that is all I would say. I would not go into a quantitative analysis comparing the exposure with the ATSDR MRL or analogous numbers put forth by other agencies. I would not go into safety margins, which are debatable. I would not go into the differences between fetal and adult brains. And I certainly would not center the whole communication around the thimerosal issue. Ultimately, what you hope to address is the overall public health problem. The concern of substance is influenza, not the possible ill effects of thimerosal.** (emphasis added)

The article should reflect those priorities in approach. (Kilbourne). Notice was (originally) intended to let people know there were no changes in recommendations. It was not to revisit the issue of what is "acceptable" based on what evidence (or lack thereof) (Fukada).

"The risks of not vaccinating high-risk children far outweigh the unknown and probably much small risk, if any, of neurodevelopmental effects posed by exposure to thimeroal containing vaccines." **"How can you say this if it is unknown? While the risks of not immunizing children may be clear, the risks of thimerosal are uncertain-your statement is too strong." (Sinks)."There are no data or evidence of any harm caused by the level of exposure that some children may have encountered in following the existing immunization schedule." "Nor is there any evidence that it doesn't pose a risk because nobody has looked-aren't there some studies showing increased exposure to Hg following immunization with Hep B? (Sinks)** (emphasis added).

Influenza vaccination of pregnant women: "I would feel much better if you could share the actual numbers that were persuasive to you all in crafting the statement (Dowell). **"I think that this needs to be more quantitative and should reflect the uncertainty that exists. At least mention that you are basing these conclusions on what is known about oral ingestion of methyl Hg or see the language we worked upon for the last notification on Hep B vaccine. (Sinks).**

"Perhaps wording to the effect that the mercury exposure form a flu vaccine would be less than (? A week's dietary intake for a woman who eats fish once a week?) or some such statement at the end of the third paragraph would put the issue in perspective." (Dowell, Walt Orenstein and perhaps others). "The chronic, daily mercury ingestion reported (in several studies- primarily Seychelles study) greatly exceeds the amount of mercury that a pregnant woman would receive from a single annual dose of thimerosal-containing influenza vaccine." "This sentence might well be deleted. I don't think it adds anything, and in some ways is misleading. I am not sure that I would want to argue, for example, that one could take the allowed amount of mercury for a year and administer it as a bolus injection with the same outcome as having it spaced out evenly over a year; the issue then becomes how

much of a bolus can one give at one time without harmful effect, and this data does not exist (or at least I'm not aware of them). (Egan, FDA). (emphasis added)

"In order to prepare such a statement that CDC folks can be comfortable with, we should redraft the notice to readers to contain more information about Hg blood levels that a pregnant woman might experience as a result of the flu vaccination and why such levels are judged to be safe. (Bernier for NIP)" (emphasis added).

What this email clearly illustrates is the extent of the CDC "spin" on the entire thimerosal issue. Their primary focus is on protecting the integrity of the immunization program not on safety. Time after time the CDC makes blanket statements regarding the "safety" of thimerosal with no data. It is certain individuals at FDA like Dr. Ball who are consistently attempting to correct the record. It is the FDA that is stating that there is no science to back up CDC's position.

On October 6, 1999 an email was sent by Roger Bernier of CDC to CDC employees regarding preparations for the upcoming ACIP meeting. It is clear from this email that CDC has a great deal of influence on the content and direction of ACIP meetings. (63)

On October 8, 1999 an email was sent by John Livengood in response to an email sent by Eric Mast regarding a "harmonized schedule". What is interesting about this email is point 5: "This will be a discussion at ACIP, and the harmonized schedule is not only up to ACIP to decide. (hence the odd process of harmonization)." (64) If CDC does not consider ACIP as the committee to make decisions on immunization policy then who gets the final "word"?

On October 19, 1999, CDC circulated a "Proposed ACIP Statement on Thimerosal". CDC also prepared a powerpoint presentation which is attached to the statement. What is interesting about these documents is the concern at CDC of the cost to the agency of returning thimerosal containing vaccines "CDC estimates there is at least $5.9 million in thimerosal containing DTaP vaccines purchased through CDC's contracts in state, local and provider's present inventories." "There is no return credit for vaccines not used when supplied through public purchase." "The number of vaccine manufacturers with whom CDC contracts for DTaP would be reduced from 4 to 1." "One company would be excluded entirely from CDC's market." "Another company's market share would drop from 44% to 0%." "The Hepatitis B (P & A) vaccine that is preservative-free is no sufficient to meet the national need though consideration of a combination Hib-Hep B vaccine could reduce this problem" "There may be increased risk with respect to vaccine supply when the U.S. market is totally dependent upon one manufacturer." "Sole source contracts eliminate competitive pricing". In addition to the powerpoint document **a chart was prepared listing the "pros and cons" of stating a preference for thimerosal free vaccines. One of the "pros" is listed as "faster potential reduction in number of infants with exposure" on the next line the "con" listed was "potential liability and loss of confidence if adverse association is later documented."** (65)

The book "Evidence of Harm" contains most of the discussions at CDC relating to Dr. Tom Verstraeten's Vaccine Safety Datalink Study as well as Mr. Blaxill's presentation to your staff. The following documents highlight the degree of manipulation of the process at CDC's National Immunization Program to quash the results elucidated by Dr. Verstraeten in his analysis of the data.

On April 10, 2000 Dr. Tom Verstraeten sent the following email to Roger Bernier of Bob Chen of CDC: "Attached is the response to the first conference call with the PIs of the VSD. It lists the suggested analyses and the results of these. It also served as a basis to a second conference call. Most suggested analyses have been carried out. Missing is some more specific information from the FDA on the true Thimerosal contents of the lots (unfortunately so far the variation appears to be minimal). After the VSD meeting last week there seemed to be agreement that the automated data will not provide more additional information. Although some feel that chart abstractions could provide more precise data on health care utlilisation (the main suspected cofounder), others feel that the most sensible next step is a clinical study including a neuropsychological assessment of kids with different exposure levels (66)

On April 14, 2000 Roger Bernier of CDC sent the following email to Bob Chen, Robert DeStefano and Tom Verstraeten: "This is followup on the action items agreed to yesterday to make sure we are of one mind about the next steps…Tom is to prepare a description of the shortcomings of the study design and analyses completed to date so that we can discuss and put the new observations in context. I am Jose are to prepare a set of options about where we go from here. One avenue would have us focus additional energy in chart review activities while a second avenue would proceed more directly to further work to measure outcomes more accurately in a sample of vaccinees. (67)

On May 11, 2000 an email was sent on behalf of Bob Chen and Roger Bernier about establishing an ACIP Working Group on Thimerosal This a pattern used at CDC to circumvent the open hearing process. Basically, "work groups" are established which are not subject to the federal rules on administrative committees such as public notice and documentation. Policies are developed at these "work groups" so that when the advisory committee meeting takes place it is essentially a "done deal". (68)

On May 19, 2000 Tom Verstraeten was asked to perform another set of analyses on the VSD data by Walter Orenstein. Dr. Orenstein specifically wanted to know the effect of thimerosal containing vaccines if the exposures were cut off at 50ug. At this time that would be the maximum amount of mercury per office visit assuming that the infant was given a thimerosal free Hepatitis vaccine. In addition, he wanted additional analyses completed on using otitis media as a potential confounder and "another diagnosis that is not an acute disease (as gastroenteritis or conjunctivitis) but something where parental pressure may make a difference in whether a diagnosis is made (e.g. something like food allergy so something else "soft"." (69)

On June 26, 2000 the following emails were exchanged between Roger Bernier and Bob Chen of CDC. These were post Simpsonwood. "**Roger, while I feel a modicum of**

effort should go into understanding the differences between the VSD and Harvard datasets, both are administrative data only however with their intrinsic weaknesses and will not give us much more true info despite further torture. We should therefore NOT wait any longer for launching Phase II and definitely NOT make Phase II contingent on their further analyses… The recommendations of the VSD PI's has been two fold a) alert
Policymakers to findings of Phase I and 2 and 2) the need for Phase II as the definitive way to answer the question. Somehow the 2nd recommendation keeps getting put off."
From Roger Bernier to Frank DeStefano, Bob Chen, Tom Verstraeten regarding the Harvard Pilgrim study: "**We also had a request today from William Weil to see the Harvard data. I think it is best at this time only to share the slides used at ACIP and not any other information or analyses which have not been presented publicly.** Also, we need to formulate a set of next steps for analysis and research on thimerosal. We are getting questions from reporters and I need to articulate our current position. Can you draft something that we can use as the basis for conversation among ourselves? I assume it would focus on getting the most out of the datasets we already have and then doing something more depending on where we end up with the current datasets. Does that make sense?" (emphasis added) (70)

What is abundantly clear from this email exchange is that the VSD investigators were telling Dr. Bernier something that he did not want to "hear". Basically the use of the VSD to answer the question of the relationship between thimerosal containing vaccines and neurodevelopmental disorders was at a stopping point.

On June 16, 2000 the following email was sent to Dr. Bernier relating to an upcoming joint statement from Bill Egan of FDA: "Roger, here are a couple of comments and a possible re-write for the promises. I don't think we can be specific that there will be additional thimerosal free vaccines at this time. It would be best if you could get the companies to make a statement…One interesting note on the next page of this exhibit is a statement by Dr. Egan "The SBB DTaP has been available since 1997. It might be better to say that this "has been available for some time". (71) This statement raises the question, why would it be better to hide the effective date of availability of this product in a thimerosal free formulation? Did the FDA want to hide the fact that they were approving thimerosal free products prior to 1999 to save "face"?

On June 13, 2000 an email was sent by Tom Tsaari of AAP to all members of COID, Liasons, and ex-officios. This email discussed the ACIP Workgroup meeting which was held at Simpsonwood that was "attempting to develop strategy and proper posture when the thimerosal study was finally discussed publicly during the next ACIP meeting on June 21st." Tom Tsaari also reported: "Following the CDC presentation to the COID of the "Risk of neurologic and renal impairment associated with thimerosal-containing vaccines" you may recall that a number of potential confounders were raised by our group that might potential diminish the strength of the already weak (low RR less than 2) associations that seemed to link thimerosal containing vaccines and the occurrence of speech and language delays, ADD/ADHD and unspecified neurodevelopmental delays.

Tom Verstraeten, the poor EIS officer saddled with this project followed through admirably to look at the impact of 1) birth weight, 2) otitis media incidence, 3) stratification of the results by clinic units to identify practitioner bias, 4) coding irregularities, 5) confirmation of key diagnosis as determined by referral to H & S specifialists (hearing and speech); 6) the bias of combining divergent data from 2 clinic groups where one health organization is much larger and the other better equipped with specialists that made referral easier and expected, 7) biases influenced by medical care utilization and 8) the RR values assigned to a number of alternative diagnoses (flat feet, conjunctivitis, "worried well" and gastroenteritis) in the study population. A thousand charts of affected individuals were subsequently reviewed for the above cofounders (all since the COID last heard from Tom the end of May) and the data was recalculated to look for raw RR rates and trends. **Despite some significant differences in practitioner derived diagnoses compared to specialist confirmed diagnoses, particularly with ADD, the relative risk rates (RR) and the RR trends were either unchanged or actually somewhat higher. The associations simply would not go away using the VSD assumption model that Tom and the CDC has used as the backbone of the analysis…During the smaller ACIP workgroup meeting that Peg and I attended, feelings expressed included 1) this study should never have been done because it was bound to create this controversy due to lack of specificity of the diagnoses in question (Marty Meyers) to: 2) we risk a pertusiss outbreak if we restrict DTaP choices (one DTaP is thimerosal free) and vaccine shortages occur (Richard Clover of AAFP); 3) there is no need for CDC to change their recommendations from October 1999 on how to use thimerosal containing and T free vaccines because we are already phasing out thimerosal from the VFC supply with DTaP as the last hurdle. Since the appearance of effects of neurodevelopment don't appear until the total mercury doses from vaccines exceeds 50ug per visit, giving a single thimerosal containing DTaP dose (25ug) along with T-free Hib, IPV and HBV at 2, 4, 6 months should be perfectly safe. Peg and I reiterated what we believe the AAP approach to all this will be to facilitate a complete transition to thimerosal free vaccines for kids, at least those 6 months of age and younger ASAP, in part to appease the AAP Enviornmental Health committee stance. Because there is a T free DTaP available, AAP may express preference for use of only T-free vaccine specifically in that age group. ACIP is not in favor of expressing a preference for a particular vaccine for fear of alienating the other manufacturers and disrupting a free market environment. They have real fears of a shortage of the lone T-free DTaP vaccine, despite assurances from the manufacturer to the contrary…ACIP would like us to be on the same page at this point. My concern is that ACIP has tended to down play these concerns in their previous policy on immunization and are asking us again to assume their posture. I don't think we can, philosophically, since we have left the impression in our last Thimerosal statement with membership that we would like to move as quickly as possible to a T-free world."**(72)

On June 13, 2000 the following email was sent by Bob Chen regarding the report from Simpsonwood: "Instead of "…the participants specifically recommended that administrative datasets (like the VSD) not be analyzed for such associations…" to "the participants did not think that the analysis of administrative datasets (like the VSD)

would be productive for such associations because of the difficulty in discerning true casual associations…" because the recommendation not to do this kind of analysis was not really an explicit recommendation—but was expressed as a concern. (73)

On June 14, 2000 the following email was sent by Bob Chen to Roger Bernier, Susan Chu, Walt Orenstein, Frank DeStefano and Tom Verstraeten: "FYI. I've located the original email that I sent Michael Gerber at NIH that engaged the VSD in the thimerosal studies. Nothing in Mike's reply nor in the subsequent conf call with the WG raised concerns about used the VSD for studying this issue." (74) This email implies that the CDC was worried about the fact that they even undertook this study since they were criticized at Simpsonwood for conducting it in the first place.

On June 14, 2000 Tom Saari of AAP sent an addendum to his previous email to COID members: "Neal (Halsey) was not there. **Roger Bernier led the charge for the ACIP group. He would like to avoid a repeat of last summer's confrontation with AAP's board on this topic but would also like us to see things his way in taking a go slow, let things work their way out, stay the course approach**;" (emphasis added). It is interesting that the one person who brought the thimerosal issue to AAP's attention the year before was now left out of the entire process; Neal Halsey; it is also interesting that the CDC is perceived as "pressuring" AAP to see things "their way". (75)

On July 11, 2000 Roger Bernier sent an email to Tom Verstraeten "suggesting" that Tom's comments regarding the Simpsonwood presentation not be shared with the outside consultants. (76)

On June 19, 2000 the CDC issued the following Q and A document relating to the VSD study. This document was crafted to play down the results of Dr. Verstraeten's analysis. What is also interesting is that it explicitly counsels parents not to file claims under VICA as follows: "Since "ADD" or "speech and language delays" are not specified as adverse events in the Vaccine Injury Table, these injuries do not qualify for compensation. The Health Services Resource Administration reviews the table and makes changes based on confirmed scientific/medical findings." (77) This is patently false; off table claims can be litigated under the VICA statutes.

The next document is entitled "Next Steps in the evaluation of possible associations between thimerosal exposure and selected neurodevelopmental effects" One of the steps outlined was to "replicate VSD findings in another HMO". Jose Cordero of CDC had doubts on the validity of such a study. His handwritten notes state: "Frank: I am concerned about this proposed plan. In my view it does not address the key issues with the current analysis, (1) direct measure of exposure and (2) specificity of outcome and underlying conditions. Although the Harvard Pilgrim analysis should be done, it would be far from a conclusive study. Seems to me that we should obtain data on the impact of thimerosal vaccination on infants, particularly premature babies to full term. We need to understand the pharmacokinetics of ethyl Hg in infants in order to develop a more accurate model of exposure level to Hg and body burden. A good exposure measure should be couple with a standardized outcome definition." (78)

On June 26, 2000 Frank DeStefano sent out the following email to Bob Davis a VSD investigator: "I agree with the thought of getting these published. I get a little leary of the terms generating and testing, since I myself don't know that mercury is harmful, esp that methyl mercury is harmful. Even though ethyl mercury has an unknown relation to methyl in terms of metabolism and cns/renal toxicity, I tend to reserve the term generating to more of the types of studies where large datasets are examined for heretofore unknown associations. The fact that I am already getting "tongue tied" in semantics is even more reason to steer away from this. Perhaps just two studies back to back would be acceptable. **Let me know what you think about this particular argument, since it has marked political ramifications. With regards to the HP study, we need to be a little careful, since the main question will be whether or not it had adequate power to detect an association that was only found when we lumped GHC and NCK together (and even I think it was driven primarily by NCK data)**".(emphasis added) (79)

On July 2, 2001 a report was sent to Melinda Wharton of CDC by Bob Chen which was prepared by Phil Rhodes the epidemiologist who took over the analysis of the VSD data after Dr. Verstraeten left CDC. Clearly the CDC at this point is analyzing the VSD data in a manner that adjusts the relative risk based on the inclusion or exclusion of specific clinics at NCK. What also interesting about Dr. Rhodes' analysis is his statement : "The very large reduction in the event of thimerosal at three months for all three analyses but especially for speech delay". This is similar to Dr. Verstraeten's initial impression of the data in which he concluded that after three months the thimerosal effect was not there in the datasets. (80)

On July 2, 2001 Roger Bernier sent the following email to individuals at CDC with regard to a FOIA request from SAFEMINDS: "Briefing materials for vaccine manufacturers were never prepared because the briefings referred to in the status report were actually carried out over the phone one or two weeks prior to the Simpsonwood meeting in June of 2000. These phone conversations were not really briefings but short descriptions of the preliminary data we had obtained. As we were trying to keep things confidential until the Simpsonwood meeting, the amount of information transferred was kept to a minimum and was sufficient only to alert the companies that we had obtained a signal of concern and they were invited to send a scientific representative to Simpsonwood to learn more about the data. There were no sign in sheets since these were telephone calls." (81)

In August of 2002 a VSD meeting was held in Denver Colorado. One of the presentations which is attached has to do with VSD Team Website Security. One of the powerpoint slides states the following: "Protecting Scientific Information; From FOIA, the congress, the courts, Is the website any less secure than email or paper copies? It can't be shredded". (82)

Statement of Charges

We believe that the following charges can be brought against specific federal agencies and individuals at these agencies in their capacity as employees under the following statutes:

I. FDA: Criminal negligence in failure to regulate the safety and effectiveness of biological products under Title 42, Ch1, Chapter 6A, Subchapter II., Part F., Subpart 1, Subsection 262, (2), (C): The secretary shall approve a biologics license application—(i) on the basis of demonstration that---(I) the biological product that is the subject of the application is SAFE, PURE, and POTENT;

II. HHS, CDC, and FDA: Criminal negligence in failure to regulate and promote vaccines as provided for under the National Vaccine Injury Compensation Program, Title 42, Chapter 6A, Subchapter XIX, Part 2, Subpart C, Section 300aa-27: Mandate for safer childhood vaccines (a) General rule: In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—(1) **promote the development of childhood vaccines that result in less serious adverse reactions than those licensed as of December 22, 1987, and promote the refinement of such vaccines**, and (2) make or assure improvements in, and otherwise use the authority of the Secretary with respect to, the **licensing, manufacturing, product testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.**

III. FDA: Criminal negligence in not instituting a Class I recall of all vaccines administered to infants containing thimerosal in July of 1999 and again in June of 2000 when the results of VSD study were discussed at Simpsonwood. A Class I recall under 21 CFR Section 7.4(a) may be imposed by FDA after taking into consideration the following factors: 1) whether any disease or injuries have already occurred from the use of the product; 2) whether an existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard; 3) assessment of the hazard to various segments of the population e.g. children…who are expected to be exposed to the particular product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk, 4) assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed; 5) assessment of the likelihood of occurrence of the hazard, and 6) assessment of the consequences (immediate or long range) of the occurrence of the hazard.

IV. HHS, FDA, CDC and ACIP employees and contractors: Criminal conspiracy to defraud the government by deception or artifice and to obstruct the

wholesome administration of the laws and affairs of the United States. Includes any conspiracy for the purpose of impairing, obstructing or defeating the lawful function of any department of government. See, e.g.,Haas v. Henkel, 216 U.S. 462 (1910) (and progeny). Statutory reference, 18 USC Section 371, Part I Crimes, Chapter 19, Conspiracy: If 2 or more persons conspire to either commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or purpose and anyone or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years or both.

V. HHS, FDA, CDC and ACIP employees and contractors: Criminal obstruction of justice: whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of law under which any pending proceeding is being had before any department or agency of the US, or the due and proper exercise of the inquiry is being had by either House or any committee of either House or joint committee of the Congress, shall be fined under this Title or imprisoned not more than five years or both. Statutory reference, Title 18, Part 1, Crimes, Chapter 73, Obstruction of justice, Section 1505.