A PARTIAL TRANSCRIPT OF THE MAY 12, 1986 MEETING OF THE IMMUNIZATION PRACTICES ADVISORY COMMITTEE (ACIP) OF THE CENTERS FOR DISEASE CONTROL, ATLANTA, GEORGIA

Samuel Katz, M.D.: Today we have as our guests parents who have been in correspondence with the Centers for Disease Control with Dr. Jeff Koplan, who is the executive secretary of the Advisory Committee. And we have a special agenda which I think most of you have received, and because of the press for time we would like to proceed as promptly as possible so that everyone feels comfortable that he or she can make a presentation. We are to begin with the parent presentation. Is that to be made by Mrs. Williams? Is that correct, who will lead off?

Kathi Williams: I am Kathi Williams and I am the Director of Dissatisfied Parents Together. We are here to speak to you on behalf of parents who want to protect their children from vaccine reactions as well as childhood diseases. As you are the public health officials responsible for helping us do that, we thank you for agreeing to listen to us even though the time periods we have been assigned are much too short to voice all of our concerns. The speakers will introduce themselves. Mrs. Chapman and Mrs. Fisher will be spokespersons during the discussion period. Now, Barbara Loe Fisher, Vice President of Dissatisfied Parents Together and co-author of DPT: A Shot in the Dark, will make a brief statement. Barbara -

Barbara Loe Fisher: On March 29, the Minister of Health of France suspended all DPT vaccinations in that country following the deaths of five babies within 24 hours of a DPT shot. All of the deaths were classified as sudden infant death syndrome, even though one of the babies was 19 months old and far beyond the recognized 12 month age limit for SIDS. One of the pertussis vaccine deaths you will hear about today is that of a 20 month old.

We learned four days ago that France has lifted its suspension and resumed DPT vaccinations after withdrawing two lots of vaccine from the market. The lots were withdrawn even though French health officials decided the 5 deaths were a "coincidence," just as as suspected "hot lot" of DPT vaccine was withdrawn in this country in 1979 after the CDC decided 11 infant deaths following DPT shots in Tennessee were a "coincidence." The resumption of DPT vaccination in France still leaves the unanswered question: did the pertussis vaccine kill those babies?

We know our babies did not die from sudden infant death syndrome. Our babies died sick and in pain with red, hot swollen legs, high pitched screaming, convulsions, in shock and failing to thrive. Did the pertussis vaccine cause our babies deaths? We have good reason to believe it did.

David McCutcheon: Mr. Chairman, my name is David McCutcheon and I

am a resident of Rye, New York. I have come here on behalf of my family to report the tragic death of our 20 month old son, Nicholas, who died on October 22, 1985, 8 hours following his DPT shot.

Nicholas was a healthy, lovely child, known as "Smiley" to his grandfather. He had a normal birth with no complications, no allergies, and was never sick a day in his life. He received his first 3 DPT shots with no adverse reactions. On October 21st, his booster shot was given at 10 a.m. at a time when he was in excellent health. He had lunch and when he got up from his nap at 3 p.m. he was feverish and had an unusual high pitched cry. My wife called the doctor and the nurse said to give him a baby aspirin. My wife inquired about the crying and was told that it hurt where he got the shot, and to put a warm face cloth on his thigh. The rest of the afternoon my wife held Nicholas to console him, and he dozed off at 5:30. She put him in his bed and checked him at 6:10 to find him dead. While he was revived by the police and kept alive on a respirator, he died 24 hours later.

As shocking as these events were, we were distressed at how difficult it was to really learn what happened to Nicholas. After testing the baby for 5 hours, the neurologist, the head pediatrician at the county hospital, as well as the local pediatrician all seemed stumped as to the cause of death, never mentioning the DPT shot. When we inquired about the possibility of the DPT shot causing his death, we were told that this was very unlikely. We pressed as to what they thought, and the response from one doctor was possibly SIDS. A few subsequent meetings with the doctor were at my insistence, and it was I who took the initiative to insist that the pediatrician report the death to the CDC on the "Illness Following Vaccination Report" which was, incidentally, a report that the doctor had never seen.

Despite our loss I am not against vaccines, but being ignorent of the possible side effects of DPT, we must now carry on with the thought that Nicholas might well have been saved had we known more about the possible side effects of the DPT shot. I am distressed about the attitude of the government, certain government agencies, the drug manufacturers, and much of the medical profession in refusing to admit that there is a possible problem with the pertussis vaccine. Thank you for allowing me to speak to you today.

Dianna Anderson: Mr. Chairman and Members of the Committee, my name is Dianna Anderson and I live in Cambridge, Illinois. I have come for my family to report the death of our daughter, Erika.

Our physician had commented more than once on the strength and alertness of our happy, healthy baby. When Erika received her first DPT at three months, I was told that there was an extremely rare chance of a severe reaction. Death was never mentioned.

Within four hours, Erika's leg swelled from knee to hip, became

hard and hot. She began to scream strangely and this continued for several hours. She developed a slight fever and a rash under her chin which later spread to her upper chest. Our physician confirmed a reaction, and said she wouldn't give the pertussis part next time.

In the days that followed, Erika had spells where she would stiffen her body and make a high pitched squeal. Sometimes she would stare for a long time. Her color was often poor. Her appetite decreased, and forceful vomiting became a problem. Booties would no longer keep her little feet warm. Several phone calls and a visit to the pediatrician netted an "assurance" that Erika could no longer be reacting to a DPT, as "DPT is out of the system in 72 hours." Erika failed to show any improvement in the next two weeks. On the last day of her life, she was distant. At bedtime, she showed little interest in her bottle, forcefully vomited, and had one of her rigidity spells.

Thirty-three days after DPT, Erika awoke after sleeping for 12 hours straight, refused her bottle, ignored attempts to play with her, and fell back to sleep. Within an hour, Erika was dead. My husband screamed and my son watched as I tried to breathe life into my precious baby, who just could not be dead.

We have been told that Erika died of SIDS. How can that be when she was sick for 33 days, and the SIDS label requires that a baby appears healthy prior to death? Even the Deputy Coroner questions the SIDS designation. We believe the DPT killed our daughter. The nightly screams of our two little boys, our tears, our nightmares, are echoed in famlies throughout this land. You can help stop those echoes. Then, and only then, may our little Erika rest in peace.

Michael Rodee: Mr. Chairman and Members of the Committee, my name is Michael Rodee. My wife, our three year old son, Mark, and I live in Emporia, Kansas. I am here to report the death of my six month old son, Andy, on August 27, 1985 following his third DPT shot.

Andy was seen by his pediatrician for his six month well baby check the week before his DPT shot and we were told he was a very healthy, normal baby. He was not prone to illness or allergies. Immediately following his third DPT shot on August 23rd, Andy began crying and continued crying throughout the day and into the night. This was unusual because Andy was not a fussy baby.

By late afternoon the next day, Andy seemed to be feeling better. But suddenly that evening, Andy began projectile vomiting after taking a bottle. We did not recognize this as a DPT reaction. Then he went limp, as if he was totally exhausted. Again, we did not know that this was a reaction. We put him in his crib to sleep. Soon after, I went to check on him and found Andy twitching his arms and legs.

We immediately took him to the hospital emergency room. He was treated and held overnight for observation. Early the next morning, Andy again experienced seizures which continued until mid-morning. At that point, the attending physician decided that Andy should be transfered by helicopter to a medical center in Wichita. When my wife and I got to Wichita, Andy was unresponsive to us.

Early the next morning, Andy suffered respiratory arrest and was placed on life support. Different attempts were made to relieve the pressure on his brain and finally a series of tests determined there was no life in his brain. Approximately 96 hours after my son received his DPT shot, I had to make the decision to have him removed from the life support system after doctors advised me he was legally dead.

The Lyon County Health Department called CDC on Monday, August 26th, to report Andy's reaction. However, as far as we know, after Andy died, the health department did not report Andy's death as a vaccine-related death to CDC. They did not feel there was enough evidence to show the vaccine caused his death. We were not satisfied with this and asked the pediatric neurologist to advise CDC, the county health department and the vaccine manufacturer of the circumstances surrounding Andy's death. The pediatric neurologist stated in a letter, and I quote, that our son had "an extraordinarily explosive disease that began immediately following an injection of DPT vaccine. He had a rapidly evolving encephalopathy associated with severe brain swelling and eventual herniation and death."

As far as we know, Andy's death was not reported on a CDC reporting form. I have no way of knowing whether or not my doctor's report was accepted or whether Andy is officially recorded as a DPT vaccine death in CDC statistics. Thank you.

Robb Chapman: My chairman and Members of the Committee, my name is Robb Chapman. I am the father of John, whose death from DPT occurred in 1984.

Assistant Secretary of Health Edward Brandt stated in 1984 that annually, 18,000 DPT shots result in convulsion or an episode of shock/collapse, and another 17,000 are followed by high pitched screaming, for a total of 35,000 severe acute neurologic reactions each year. All of these have the potential to lead to death. Yet when our previously thriving infants get DPT, and within hours or days suffer exactly these reactions and die, we are told DPT played no role in their deaths. Parents need not be scientists to know that this makes no sense.

Our story - of deaths from pertussis immunization - has a 50 year history in the medical literature. The same crude and toxic vaccine blamed for those deaths 50 years ago was still in use in 1978-79 when CDC investigated the deaths of 11 infants in Tennessee within 8 days of DPT; 5 within 24 hours. Although

experts involved in that investigation found almost no chance that DPT played no role in those deaths, the CDC eventually told the American public that the deaths were "coincidences." Quietly, the lot of vaccine given to most of the victims was recalled, and the CDC advised the manufacturer to add a crib death warning to their product insert. The question as to the role DPT played in those deaths was left unanswered.

Several independent researchers, most notably Drs. Baraff and Nickerson, have since found the same disturbing clustering of deaths around the time of a DPT shot. CDC's own incomplete records also attest to such deaths.

It has been seven years since the epidemic of infant deaths in Tennessee. We are still using the same crude and toxic vaccine. In these seven years our public health officials have failed to call for a mandate that all doctors report severe reactions. And they have failed to actively investigate the deaths brought to their attention. In 1985, we reported 12 such deaths to this committee. To date, no attempts have been made to investigate our reports.

This leads to our complaint: As the vaccine policy making body of our country's public health service, it is your responsibility to find out how many children are dying from DPT. You cannot in good conscience continue to advise, even legally mandate, that three and one half million children receive a vaccine each year when you don't know its risks.

CDC has an erratic history on this issue: there have been years when your Important Information Statement for parents warned of death as a possible DPT outcome, and years when, apparently, death could not occur.

In his April 1986 letter to us, CDC's Director of Immunization, Dr. Hinman, acknowledges "reports in the literature of death associated with apparent shock following pertussis immunization." He also states, quote, "we do not ascribe causality for reported deaths." This leads to the conclusion that death can occur on the pages of medical journals, but not in actual babies. Your reporting system, by design, is unable to distinguish vaccine induced deaths from coincidences, so coincidence is assumed for all deaths.

So we are still left with our question: How many American children are dying each year? Is it none? Is it eight, as Dr. Hinman has suggested? Or is it the four to five hundred that the Nickerson study would suggest?

Why aren't these deaths apparent and easily counted? Most are misdiagnosed as SIDS by coroners who do not have guidance on this matter from the CDC. SIDS is the unexpected death of an apparently healthy infant, or to quote the National SIDS Foundation, "the only disease whose first symptom is death." SIDS

is not the death of children suffering, shock, high pitched screaming and/or encephalopathy following pertussis immunization.

It is not surprising that these misdiagnosed deaths involve clinical histories and autopsy findings atypical of SIDS. Such deaths would have been exluded from the NIH-SIDS study, making that study irrelevant to the larger question of whether DPT causes death. DPT may not cause true SIDS events, but DPT deaths are being tossed into what is increasingly caused "that wastebasket SIDS category."

We propose a new category in your reporting system: suspected pertussis vaccine deaths - "suspected," as we appreciate the difficulty in assigning causality on a case by case basis. We propose the following definition: A child receives a DPT shot, exhibits one or more CDC acknowledged acute severe reactions within seven days, and begins a mental and/or physical deterioration culminating in death.

Second, we propose that a non-government panel of experts determine which of these cases fit these criteria. Reports from health care professionals, coroners and especially parents would be considered. As parents are the primary witnesses of severe reactions, their direct input is fundamental to any fair system.

Third, reporting of all severe events following immunization in both the public and private sectors must become mandatory. Voluntary reporting, with all the incentives not to report, simply does not work. The obstacles to an aggressive reporting system have been cited often, but the laws required to implement such a system will be passed if you promote mandatory reporting of vaccine reactions with the same vigor with which you promote laws mandating immunization.

Fourth, efforts to educate medical professionals and parents about severe reactions and the need to report them must begin in earnest. In the past, failure to educate these groups has been justified by the need to maintain confidence in our immunization programs. It is a sad day when parents' and physicians' ignorance is needed to preserve faith in the vaccines mandated for our children.

Finally, thoroughly educated coroners are a vital link in the proposed system. Given the guidelines and the mandate to report, they could provide key evidence for or against the vaccine's role in deaths where DPT is suspected.

With the proposed system, these long neglected DPT deaths can be counted. This data is fundamental to discussion of benefit versus risk, contraindications, and recommended age to begin immunizing. It is essential to your Important Information Statement if we are to have truly informed parental consent. And it just might provide the missing incentive to accelerate funding and research for the new vaccine.

This issue is much larger than DPT: faith in this country's entire immunization program will continue to erode until the actual risks of all vaccines are known. We expect no less from our public health officials.

Judy Glomb: Mr. Chairman, Members of the Committee...

Katz: Excuse me, one second. Are you Mrs. Glomb?

Glomb: Yes, I am.

Katz: Would you prefer to make your presentation now or would you like for us to take a minute to discuss what has gone on so far and then connect that.

Glomb: We'll do it now.

Katz: Which is more logical?

Glomb: Now.

Katz: Why don't we do that and then we will go ahead.

Judy Glomb: Mr. Chairman, Members of the Committee, My name is Judith Glomb and I live with my husband and three surviving children in a suburb of Philadelphia. I am the President of the Pennsylvania Chapter of Dissatisfied Parents Together.

My statement will reinforce Mr. Chapman's call for a new mandatory adverse reaction reporting system that will give us an accurate picture of how many children are dying and suffering brain damage following DPT reactions. Most American parents and physicians are dangerously ignorant about vaccine reactions and contraindications, and many physicians do not report reactions to the CDC's vaccine reaction reporting system, MSIFI. To illustrate this fact, I composed 13 questions and called 64 pediatricians in private practice. 54 of them would not even discuss the topic. The 10 who responded insisted that I not use their names.

To keep this presentation brief, I will give the results of 4 of the 13 questions I asked.

* 6 out of 10 pediatricians said they were not aware of the UCLA/FDA study. Only 2 out of the 10 knew that 1 in 875 DPT shots in that study resulted in a convulsion or collapse shock episode.

* 8 out of 10 pediatricians said they do not verbally explain the signs of convulsions or shock collapse or other recognized severe reactions to parents.

* Only 2 out of 10 pediatricians said they provide parents with written informaton explaining the signs of severe reactions.

* 5 out of 5 pediatricians who had children in their practice who reacted severely to a DPT shot did not file a MSIFI report.

These answers suggest that the right information about vaccine risks and reactions is not getting to Ameria's doctors, who in turn are not getting the right information to America's parents.

The Important Information Statement and MSIFI are keystones of the CDC's communication with parents and physicians about vaccine reactions. To the extent that these are flawed, the communication breaks down with often tragic results. Examples of the breakdowns that occur:

1. The CDC's Important Information Form does not use plain language to describe severe reaction symptoms. If a parent does not know that a convulsion can be as slight as repeated twitching of the eyes or mouth or unusual staring episodes, or that neurological signs can include excessive sleepiness or crossing of the eyes, or that shock-like symptoms can include cold, clammy skin, how are they going to know they must immediately seek medical help for their child? How will they know their child should never receive more pertussis vaccine? This is the third time we have requested that the CDC use plain language in the IIS to clearly define vaccine reactions for parents.

2. When a child does die or suffer seizures or shock shortly after a DPT shot, public health clinic doctors and nurses who gave the shot frequently deny that the vaccine played a role in the child's death or seizure. You have done such a good job convincing medical personnel that deaths and neurological damage following DPT shots are only a "coincidence" and are not related to the shot, that there is denial of cause and effect when a reaction occurs. Therefore, many public health clinic doctors and nurses refuse to file a MSIFI reaction report.

3. Children who react severely or die following DPT shots are frequently seen at hospital emergency rooms, not at the public health clinic where the shot was given. Therefore, public health clinics often either do not know the reaction occurred or refuse to report it because they did not treat it.

4. Coroners do not ask parents about vaccine reaction symptoms prior to a child's death following a DPT shot. So these reaction symptoms are rarely included in the autopsy report, much less ever reported to the CDC.

5. If a MSIFI report is filed with the CDC, parents rarely see copies of it to check for errors or omissions.

6. We object most strongly to the recent exclusion of childrens' names from MSIFI reaction reports sent to the CDC. This leaves parents with no way of knowing whether the report of their child's reaction of death was received by the CDC, entered into CDC statistics, or investigated further.

These deficiencies in your IIS and MSIFI system keep you unaware of the actual risks of DPT. These deficiencies deny physicians and parents the pertinent information that could prevent much of this vaccine damage and death. You have assured us that you have set up the best possible system to educate parents and physicians and gather reports of vaccine reactions. Why then has the system not worked for even one family of all those we know, including those parents who have personally reported their children's deaths to this Commitee?

Katz: (partial comments - inaudible) It does say on the intitial schedule that there is time set aside for discussion and you can make additional comments at that time.

Alan Hinman, M.D.: I think that many of the problems associated with trying to monitor adverse events following immunization have already been brought out. But it might be useful to spend a minute or two to summarize how our system for monitoring adverse reactions in the public sector works. It is key to explaining the Important Information Statement which is given to parents accompanying the child to the clinic in the public health sector. This statement describes the disease, the vaccine, the possible adverse events from the vaccine, a precautionary statement as to persons who should not receive the vaccine without checking with a doctor first and, finally, a statement that if the person who receives the vaccine becomes ill and has to visit a physician, hospital, or clinic in the one month following vaccination that you report it. There is supposed to be a telephone number inserted into the form at that point.

Reports received at the local health department are supposed to be screened to determine whether they involve medical contact which is the screening mechanism for the system. And whether the event was just a local reaction - local reactions are not supposed to be reported. If it did involve medical care other than for local reactions, the form is supposed to be filled out, which ultimately wends its way to Atlanta. This is the form which is currently in use.

As pointed out, there is no name on the form. In fact, since the beginning of the inception of this system in 1978-79, we have not collected patient identifying information because we have felt it was not appropriate and that it would be difficult for us to try to insure confidentiality. The name and address is retained at the local level.

The form includes the time and symptoms of the event and this is sent into Atlanta. If death occurs or if the individual was hospitalized, we request a copy of the death certificate, a copy of the hospital discharge summary and a copy of the autopsy report if one has been performed. Beginning in January of 1985, we have made more, I guess, aggressive attempts to obtain this information about hospitalizations and deaths associated with immunization and it is our intent to have all of the death records reviewed by a panel of outside experts. We have not yet commenced this. There are problems in trying to establish the best mechanism for summarizing information and for obtaining opinion as to the cause of death and whether vaccine might or might not have been a responsible factor. This system, I should say, includes all vaccines administered in the public sector, not just DTP vaccine.

We have had reported to us in the first six years of the MSIFI system for 1979 through 1984, 99 deaths occurring within 28 days following DTP vaccination. Of these, nearly three-quarters were classified as SIDS deaths and the others were classified as other conditions. The other conditions included several which appeared to be likely independent of immunization, that is a bacterial infection or something like this. But in some fraction of these, I believe it is nine or ten, it was impossible to ascribe from the information provided a certain cause of death. In the period 1985 and thus far in 1986, we have had reported to us a total of 82 deaths occurring within 30 days of receipt of DTP vaccine. Of these, 60 - excuse me, the number is 67 deaths - of which 53 were categorized as SIDS and 14 as non-SIDS for 1985. For 1986, there were 11 categorized as SIDS and 4 as non-SIDS. So I'm sorry the correct total would be... (inaudible).

It is very difficult as you are aware to try to determine the relationship and possible causal role of an event such as vaccination with a subsequent event such as death. There is not, so far as we can tell, a characteristic medical syndrome. We have heard some of the problems with the system which is not perfectly implemented. I think it has improved steadily since its inception. It pertains only to vaccinations administered in the public sector. This is where the Important Information Statements are used. Reports received from the private sector are forwarded to the Food and Drug Administration, but our analyses deals just with public sector events.

Katz: Thank you, Dr. Hinman. Dr. Egber, would you like to say something about the reports that are sent to the Food and Drug Administration?

Dr. Egber: No. No.

Katz: Dr. Hinman, do I gather from what you said that reports from the public health sector stay at the CDC but those reported by private physicians do not?

Hinman: That is correct.

Katz: They are forwarded to the Food and Drug Administration.

Hinman: That is correct. To the office at the National Center for Drugs and Biologics, which is in charge of the post-marketing surveillance of all drugs and biologics.

Unidentified Committee Member: (his question and comments are inaudible)

Fisher: Is this the discussion time?

Katz: Yes, you may add something if you like.

Fisher: Dr. Hinman, in April - last April - Mrs. Chapman and I came to this Committee and the question we repeatedly asked was "What criteria does the CDC use to define a pertussis vaccine death?" I still don't understand what criteria you use to distinguish pertussis vaccine deaths from SIDS deaths.

Hinman: We accept the definition - to date we have accepted the classification and diagnosis that is on the report.

Fisher: Without any independent CDC investigation into whether or not that diagnosis is correct?

Hinman: We request hospital records, death certificate and autopsy reports but we accept the death classification given to us. As I mentioned, before January 1985.. (the rest of his comments are inaudible)

Fisher: Coroners then have received no guidance from the CDC as to how they might try to distinguish a pertussis vaccine death.

Hinman: That is correct.

Fisher: Does CDC have plans to so educate coroners?

Hinman: Not at the present time.

Fisher: Why? Why don't you have any plans?

Hinman: At the moment, I don't know how I would differentiate an event which you might consider the cause of a pertussis vaccine death and one which you might not consider the cause of a pertussis vaccine death.

Fisher: In other words, the CDC does not know how to distinguish a pertussis vaccine death from a SIDS death.

Hinman: At the present time, we are collecting and categorizing these deaths as they are provided to us. We are not ourselves imposing a definition.

Fisher: Dr. Hinman, when a baby dies after exhibiting classic pertussis vaccine reaction symptoms - high pitched screaming, convulsions, shock/collapse - do you feel that that should very definitely be classified as SIDS?

Hinman: I don't know.

Leslie Chapman: What is being done to find out?

Fisher: You don't know? When the definition of SIDS does not include those physical and mental symptoms? Why would you even have a question that it would be diagnosed as SIDS?

Hinman: SIDS is both a clinical and pathological profile. In studies of SIDS a substantial proportion of children who die suddenly are found to have had some symptoms before they die - a respiratory infection or other symptoms. I think it is difficult to draw a precise line as to what might be considered symptoms and what might not.

Fisher: Do SIDS deaths normally involve convulsions and collapse/shock episodes and high pitched screaming?

Hinman: Not particularly.

Fisher: Not particularly. I would think then that it wouldn't be very hard to try and distinguish a pertussis vaccine death from a SIDS death when you are exhibiting clearly pertussis vaccine reaction symptoms that have been in the literature for 50 years. I don't understand what the problem is.

Katz: I do think that you are emphasizing a point that I can agree with from some of the things that have been said, but I think the problem in definition doesn't lie here as to what is sudden infant death syndrome. I think you are quite correct in that a youngster who has been ill for days or weeks, as have some of the cases you described, does not legitimately come under the category of SIDS. But the problem isn't with the Centers for Disease Control or the Division of Immunization, nor regrettably is it their function to educate pathologists or coroners or other people who do autopsies.

I regret that I can't tell you myself off the top of my head what is the best way to achieve that, but I think it is far beyond the defined role or the ability of the Centers for Disease Control to redefine for your local coroner or pathologist, or whoever does autopsies, what a sudden infant death is. The cases that you have cited, I would certainly agree with you, could not in my opinion qualify as SIDS.

Fisher: But Doctor, it is your responsibility to survey vaccine reactions. And if the vaccine reaction reporting system is trying to find out how many deaths occur that are related to the

vaccine, somebody has got to make a determination. I mean, if not you, who? You are the policy making body for the government.

Katz: I think what I am trying to say to you is that I think there are many other things that may be mislabeled SIDS from child abuse to asphyxia to poisoning to metabolic disorders. And I don't think that a single agency, the Centers for Disease Control, in looking at what may be no segment or a tiny segment or even more than a tiny segment can be charged with the responsibility to reeducate the coroners of the United States. If you want to go to the College of American Pathologists or whatever group - we all share this - I don't mean the onus is yours. But I don't think that we can look to Dr. Hinman for responsibility for the expertise or the function and practice of coroners, nor can you expect him with the budget that is assigned to this organization to go out and double check on every autopsy that is done in the United States as to whether the diagnosis is correct.

Anthony Morris, Ph.D.: Not every autopsy. Just some autopsies. Those that might be associated with DPT. No one is going to ask that you go out and do every autopsy.

Katz: But I think as these ladies and gentlemen have pointed out, it isn't even reported in many instances that it may have been associated with DTP. How they screen that is an extremely difficult problem. I am only trying to say that I think you have pointed out a problem that exists in the grassroots. It doesn't exist in Atlanta.

Fisher: The coroners' findings are accepted here for your statistics for pertussis vaccine deaths.

Hinman: One of the things we hope to do is assemble a panel of ...( the rest of his comments are inaudible).

Chapman: If there is evidence, as I think there is, that DPT deaths may well be being misclassified as SIDS, then I feel it is very much the responsibility of this Committee to pursue the misdiagnosis of deaths from vaccines. I don't care if they say they are from a car wreck, if there is evidence and I think we have provided on numerous occasions stories that indicate that these deaths are being tossed inappropriately into the SIDS category, I think it is your responsibility.

Fisher: The other thing is that it is very alarming that decisions are being made at the public health clinic level by medical personnel not to report reactions that occur after the shot. Because they are making an independent decision right there that it is not connected to the shot. It would seem to me that all reactions ought to be reported.

Katz: We have two people here who represent various public health ... (inaudible)

Unidentified Committee Member: (her comments are inaudible)

Fisher: If a baby has high pitched screaming for hours or days after the shot and is never seen by someone, that reaction is not reported? In other words, the criteria is that you have to be hospitalized or treated by someone.

Hinman: The criterion that has been sent to the states by our method of operation for the MSIFI system is that the reaction must have required medical attention or a visit to a hospital, clinic or physician.

Karen Cline: Does that include an unexpected death? My daughter died in my home, she did not see a physician.

Hinman: Yes it would include those deaths.

Chapman: I would like to hear a comment on Dr. Nickerson's study on SIDS deaths in California ... (inaudible) ... an excess of those occurred, an excess of 6.2 percent of all deaths occurred within 3 days of a DPT. Now if you take his excess of 6.2 percent (inaudible) and apply it nationwide to the 8,000 to 12,000 babies whose deaths are attributed to SIDS each year, you come out with 400 to 600 or so deaths that, according to Nickerson's study, you might call - quote unquote - vaccine related. I think this is so much evidence about your responsibility here regarding this issue.

Katz: (inaudible) The only answer I can provide you is a direct one: the national experience in other countries who are trying to disassociate SIDS with an immunization procedure. Again there is a very definite relationship which confuses the causality between DPT and SIDS.

Chapman: (inaudible) I would prefer, if possible, if you could talk about the Nickerson study and ...(inaudible).

Katz: Dr. Mortimer says he can.

Edward Mortimer, M.D.: I just recently had an opportunity to review it. And it is very difficult to determine exactly what Dr. Nickerson ... (inaudible)... and it was never published. However, the major question is how do you, say, relate this all to the Nickerson study and to the NICHD study. And probably, without going into all of the epidemiological data, why the Nickerson study may not be accurate. For one, about 30 percent of the cases were unreported. In other words, they don't have information on 30 percent.

Chapman: The immunization question was not answered on...

Mortimer: That's right, they don't have the answer to the immunization question.

Chapman: But for about 80 percent they do.

Mortimer: And, well, it's about 70 percent there was an answer. And that kind of a missing group of patients also is often the group that has no temporal relationship to the question whatsoever. And I think that, that is what is called reporting bias. And it may well be in there, I don't know. I'd like to see how Dr. Nickerson did this thing. I think it was largely done by public health nurses or something. The second thing is, in this regard, I don't think we can consider the Baraff study any longer to be one that shows a relationship because Dr. Baraff in the Los Angeles Times in an interview point blank stated publicly that he made an error. There is nothing there. There is no relationship between DTP and SIDS and that he agrees with the large NIH study. What this - I think we have to wait ultimately for a detailed report by Nickerson.

Chapman: Dr. Hinman referred to plans to do a follow-up on the deaths that are reported to see whether or not they are related (inaudible).

Unidentified Mother: I have a little daughter, she is almost 11 months old. I'm from Marion, Georgia. She had her DPT shot at 7 weeks old, a week early because my doctor was going on vacation. She was healthy and he said, don't worry, she can have her shot.

He had me sign a paper for her to have her shot. I knew nothing about the shot except that children should be immunized to keep them from becoming ill. And I said, "Why am I signing a paper for my child to have this shot?" And he said, "Oh don't worry," and he took hold of my arm, "She'll be fine." And then he told me to talk to the nurse so that the nurse came into give the shot and I asked the nurse why I had to sign a paper for my daughter to have this shot that is supposed to be such a good shot and keep her from being ill. And this nurse said to me, "Oh don't worry, there is this controversy over the shot." I saw no paper, and I understand I should have received a paper on what could occur if she had her shot - like this projectile vomiting and fever and so forth. They just told me that if anything happens to give her Tylenol.

Well, my baby screamed right away after the shot. She fell asleep that night. Then in the middle of the night she screamed and screamed. She thrashed her little arms and legs. Then she would go "Ohhhhhhhhh," she was in such pain. And she went on for three and a half weeks this way. She had fevers everyday like I said. I would have to put her in the sink and give her baths. And I called the doctor and asked the doctor, "What should I do? My baby is ill." He never called me back for three months after the shot. His associates told me on the phone to give her Tylenol, raise the bassinet, keep her head elevated.

About the fifth day after the shot, I was going to clean the

bathroom and my baby started gagging. I heard a funny noise and went and here she is going, "Aghkk Aghkkk." And I tapped her on her back, and she just started throwing up and throwing up and did that for two and a half weeks. It was mucus.

She wasn't sick before the shot. She had maybe slight allergies. I called the doctor three times before the shot before Friday when she got the shot and said "My baby can't breathe when I nurse her, I don't know what is wrong." And they said, "Oh, don't worry. Just elevate her head and give her Tylenol. Same thing. She'll be fine." And when I told the doctor this on Friday, he said, "She is just fine."

You know, he didn't tell me anything about the shot. He didn't take into consideration that this child may have had a problem and shouldn't have received the shot because maybe she had such bad allergies that she shouldn't have it. O.K., I knew nothing about allergies, I knew nothing about anything. I had a baby for the first time in my life, and I am a new mother and I am trying to nurse her and take care of her. And she is almost dying in my arms. She had the fevers, everything.

Anyway, I called the La Leche League because the poor baby was so sick and I asked them, "What should I do? My baby can't nurse. She won't take anything. It has been three days now." And thank God for this girl at La Leche, finally after I called her the second time two weeks later, she introduced me to Leslie. And told me her baby died from the shot, and said it sounds like symptoms from the DPT shot, which the doctor ignored completely. His associates ignored it. They didn't even call the baby to come in so they could look at the baby. And I've since gone to another pediatrician who was going to give her her four month DPT shot. And luckily I found out from Dr. Geraghty that she shouldn't have another shot because she could die or become mentally retarded.

By the way, my baby did look mentally retarded at times. She sat like this (at this point the mother opened her eyes wide and stuck her tongue out of her mouth) and just looked straight. And I put a flashlight in her eyes and her eyes would not dilate or anything. She would just sit there. When my mother saw it, she couldn't believe it. She finally believed me. She said, "My God, there is something wrong here."

And there is something wrong. I feel that doctors should warn parents because we are human. You guys are parents, you doctors are parents. Everybody should know what is going on with this shot. You should be more honest. It is unfair that you are keeping things from people. Granted we need a shot to keep babies from getting this disease but how come babies are still getting the disease with the whooping cough shot. Why are they getting the disease still? I don't understand that. And why when they get the shot is it making them sicker and dead and mentally retarded? I don't understand that. And if there is a better shot in another country, why can't we use it? What is wrong with us? Why can't we

change? And furthermore, if one of you people who maybe are against us being here talking about these problems, if you had a child who reacted.... (tape ran out)

You should keep a better system. Doctors should make the babies come in and look at the baby and say, "Oh my God, it needs medical help" and if it dies, keep track of it and find out. If there is something wrong with the shot, my God, change it. Why not? What is so hard about it? If there is a better one, why can't we change it? I don't know who to address it to. You are in charge of the CDC I understand so I am asking you, why can't we?

Katz: You have asked about seven questions, so I...

Fisher: Thank you very much.

Mother: Please. I can't help it.

Katz: I know. There is nothing wrong with it.

Mother: Thank you for listening.

Katz: That is why we are here today to try to let you people ask your questions. I will try to field a few of them if I can for you. I don't think you got very good medical attention and I can only apologize for that as a physician. If your child had as many problems as you described, that is not a child you treat on the telephone. I can only apologize for my colleagues that you didn't get more prompt medical attention. You raised a number of other questions and I think they become tangential, but I think they are quite germaine. I think there is a prevalent plea that all we have to do is pick up a vaccine from Japan and everything will be wonderful because it is a perfect vaccine that will have no problems that you associate now with the vaccine. It is not as simple as that, and not quite as true. Ted, would you be willing to comment on that? Dr. Mortimer just made a visit to Japan. There have been several groups which have visited Japan to investigate what has gone on with the vaccine and there are a number of studies going on in this country now. People are not just sitting and neglecting your questions.

I'd like to add just one personal note. I have had nine children and every one of them has had DPT. And if I had any more awareness of what goes on with DPT than you, I should have. If your complaint is that you have been uninformed, I have been very informed of everything I have ever heard of. And yet I felt it was very appropriate as a parent to recommend to my children to be immunized. I don't disassociate myself or lack empathy. And I think most of the people around this table also are parents or grandparents. We are not so different from you. Don't misunderstand us.

Fisher: I know, but you don't have a child who had a reaction. That is the problem right there.

Katz: We have children who run the same risk of reaction, whatever that risk may be.

Fisher: I know, but you don't...

Katz: Ted, do you want to comment on that?

Mortimer: Well, I'll just say very briefly that I very much hope that the Japanese vaccine will provide us with help in this area. It is very difficult to evaluate the Japanese vaccine in a number of ways. I personally believe that the Japanese data are not as conclusive as we would like. No data are ever as conclusive as we would like. That is number one.

Number two, there are 9 or 8 different manufacturers and 3 different vaccines. Number three, the Japanese are not giving their vaccine until two years of age. A two year old child is very different from a two month old child.

Number Four, for very good reasons, thanks in part to the late Senator Kefauver, obtaining a licensure for a new drug or biological in the United States can only be achieved under very strict controls. I support this very much. By legislation, there are certain regulations and there are mandates about how one does it. It is good that we have those regulations because they protect us against other drugs. An example that you all know is Thalidomide. The drug or biological - the vaccine - must be shown to be as safe as possible and as effective as possible.

In the two year old kids, the Japanese vaccine is no more safe than is the whole cell vaccine. Another point is that the Japanese are seeing reactions different from the kinds of reactions we are seeing. Reactions which they can't quantitate in terms of giving us the numbers, but reactions that worry me. I was over there a couple of weeks ago and heard about it. I don't like it. They are describing it as a delayed reaction. They are rather unique and I think they probably are DPT reactions. And there is some other concerns about whether it breaks down, a term I use, over a period of time. Maybe that relates to the delayed reactions.

In short, we don't have good evidence that it is safer in two or three month old babies. We must have that evidence. And we don't have evidence that it is effective in two month old babies. I think that it probably is. But my gut feeling is not enough to get it licensed. Every effort is being made to find the answer or the answers to some of these questions. On theoretical grounds, the Japanese type vaccine should be better, but whether it will prove to be so or not (inaudible).

Katz: Before we go on I would like to ask Dr. Jordan, who sits with the Committee as the representative of the National Institutes of Health and the National Institute of Allergy and Infectious Diseases and has been involved with the vaccine development program of the United States, to comment on some of the areas in which pertussis immunization has been a very high priority item.

William Jordan, M.D.: Investigators in the United States, including some at the laboratories at the Food and Drug Administration, have been working to find ways to produce an effective and safe acellular vaccine somewhat like the prototype vaccine developed by the Japanese. And these are in various stages of production. We have ourselves as an Institute, with the help of one of our commercial firms, imported one of the Japanese vaccines and tested that in children in the United States so that we can see whether it is safe and will produce the kind of antibodies we want. Even the Japanese vaccines are not consistent among themselves because they have varying proportions of the components of the bacteria that we think are responsible for the protection induced by the vaccine.

One of the real key questions is that we really don't know, once we break the whole cell apart, just how many components we need to put in the vaccine for a more purified antibody. There are some who think we need several, and some who think we need only the part that we refer to as the pertussis toxin. As a matter of fact, the United States Public Health Service has invested considerable sums of money in supporting the field trial of two of the Japanese vaccines in Sweden, where there is a fair amount of pertussis going on, because this is the way we can find out whether they work or not. We were unable to be sure, because of the information on the studies done in Japan, just how effective the Japanese vaccines are.

This extensive trial will give us a chance to find out. There are two kinds of vaccines being tested: one that has several components in it, and one that is essentially the purified toxin. We have also collected blood specimens from these children to measure the antibodies they are developing through the vaccine. We hope that we can correlate their antibody response with their failure to get pertussis or to get pertussis so that we can then determine what antibody we need or what part of the pertussis organism to produce the vaccine. And then we will know for sure what has to be in the vaccine, in other words, if it is only one part of one component or several. We can then use this information to look at the various candidate vaccines that are being developed, and several are by producers in this country and France and Great Britain. And I think it will help the assessment for the potential of licensure down the road.

But until we are convinced, as Dr. Mortimer says, that the Japanese vaccine is as effective as our current vaccine, which is pretty good and effective, and is as safe in the two month old, which is where we would use it like the current vaccine, we don't want to rush to judgement and swap an experimental vaccine with the currently licensed vaccine. I think that is about where we are.

Katz: Thank you, Bill. There is one other set of comments that has been raised, and I don't know whether someone from the CDC is prepared to answer, and that is what is the current status of

whooping cough in the United States. The last woman who spoke raised the question that maybe whooping cough disease is occurring.

Fisher: Dr. Katz, wait a minute. We are entirely off the schedule that we agreed to.

Katz: Sorry.

Fisher: We have jumped ahead now to the development of a new vaccine and in relationship to that, we have one question to ask you.

Katz: I am sorry. I thought we were in the discussion period and I was trying to direct the discussion to the questions that you folks raised.

Fisher: Right. But we only have a half hour to go and we have three more topics to discuss. I'd like to ask one question pertaining to what Dr. Mortimer was saying, that pertains to the approval of bringing in a new vaccine into this country.

Japan has been giving their children a purified acellular vaccine since 1981. The Japanese scientists have repeatedly stated in the literature and told us that their five year experience with this vaccine indicates that it is just as effective and a lot safer than the whole cell vaccine that we are using right now. Yet Dr. Hinman and others at the CDC have expressed doubt about the Japanese vaccine's effectiveness, and urged continued use of the whole cell vaccine pending the lengthy trials in Sweden.

Drs. Alan Hinman and Edward Mortimer, both of whom sit on this Committee, have been retained by DPT vaccine manufacturers to give depositions against children who have been brain damaged by the whole cell pertussis vaccine.

On September 6, 1984, Dr. Edward Mortimer stated in a deposition during the DPT damage lawsuit of Cossette Krause, quote "Several years ago because of the increasing amount of litigation over DTP, members of the so-called Redbook Committee of the American Academy of Pediatrics agreed in a sense that we would sort of divide up the cases to try to help the manufacturers in these lawsuits, and therefore I and a number of my colleagues agreed to serve as expert witnesses."

On February 26, 1985, Dr. Hinman served as an expert witness for Connaught Laboratories in the vaccine damage lawsuit brought on behalf of DPT damaged Amy Jo Davis. In a video taped deposition, Dr. Hinman stated, quote, "I am aware of the fact that it is the policy of the Public Health Service that Public Health Service employees will not normally participate in private litigation... I am testifying in private litigation today as a result of a policy decision within the Department of Health and Human Services who issued this policy decision. My understanding is

that it was arrived at by Dr. Edward Brandt, former Assistant Secretary [of Health]," end of quote.

As individuals responsible for making vaccine policies and approving the use of new vaccines, you must remain impartial and objective in order to effectively carry out those responsiblities. How can you remain impartial when you are testifying in court against children damaged by the very whole cell vaccine that you promote? How can you objectively evaluate the Japanese vaccine or any other foreign vaccine, when you are testifying for American vaccine manufacturers whose primary defense in lawsuits is that there is no safer alternative to the current whole cell pertussis vaccine?

Katz: I think you can ask Dr. Mortimer and Dr. Hinman to speak for themselves. But let me remind you of one inaccuracy in your question. That is, this Committee has nothing to do with the licensure of vaccines. This Committee has the responsibility to make recommendations ...

Fisher: I understand that.

Katz:... for their utilization. So that nobody on this Committee sitting around this table has anything to do with the decision by the Food and Drug Administration for licensure. Dr. Egber represents as a liaison member to the Committee to keep us informed of what is going on. She is a representative of the Food and Drug Administration. If you want to comment succinctly, Elaine, about the licensure process as distinct from recommendations.

Elaine Egber, Ph.D.: I assume you are all familiar with the licensing process, it ...

Fisher: I didn't mean to give that impression. You do play a role in the testing of a new vaccine and the recommending for use, not licensing.

Katz: Once the vaccine is licensed, we promulgate statements as to how it can best be used in the public sector.

Fisher: Right.

Katz: Ted, do you or Alan want to respond at all?

Mortimer: I can respond very simply. I think the track record of the U.S. manufacturers in trying to develop an acellular vaccine, and their track record going right now should be well known. They are trying very hard to develop an acellular vaccine, to find ways to use the Japanese acellular vaccine. Until they can prove that it is safe and effective, they can't use it. And I know that one of the U.S. manufacturers has the rights to the acellular vaccine.

Katz: Alan?

Hinman: Just to point out that I was not retained by any laboratory. I testified essentially at the request of the Assistant Secretary of Health. I did not testify against the child. In fact, my testimony was clearly unrelated to the kinds of circumstances ... (inaudible).

Fisher: Is it not difficult for you to be objective when you are recommending vaccine policy, and at the same time you are testifying for vaccine manufacturers on behalf of the whole cell vaccine?

Hinman: I believe, Mrs. Fisher, as I have said many times before, taking into consideration the benefits and the risks of the whole cell vaccine, the benefits outweigh the risks.

Katz: I think I understand the question you are asking in another way. I think we face a problem which exists in many areas. It is very difficult to get people to testify about the Challenger Space Shuttle who haven't been involved in the development of the Shuttle, who are not experts in all of the engineering and physics that goes into it. You exclude if you say that anyone who has had anything to do with research, with development, with licensure, with recommendations, you exlude them from ever becoming involved as expert witnesses. I think you really end up with expert witnesses who are not experts because they haven't been involved.

I appreciate your concern about conflict of interest. I think that is something that judges and lawyers have to take into account. I think also you should appreciate, and I can't speak for everyone, but I can certainly speak for those around this table, that when one does appear whether it is in litigation or deposition or whatever, one does not appear for or against a pharmaceutical firm or for or against an aggrieved individual. One hopes that he or she speaks for the truth and for expert evidence or testimony regarding the situation.

Fisher: But there are relatively few people sitting on this Committee and there are many professionals, neurologists, etc. in this country. It would seem to me that those who...

Katz: They testify.

Fisher: I understand that. But this Committee and the Redbook Committee are kind of special in that they are involved in the making of vaccine policy and many times involved with the clinical trials of new vaccines. It would seem to me that as a matter of public policy that it would be a good idea to keep those two activities separate.

Katz: I wish you would tell that to the courts because my phone doesn't stop ringing. You know, I could spend my life - I could

resign from Duke University and resign from this Committee - and do nothing but spend the next several years involved in litigation regarding vaccines, meningitis, other areas of infectious disease where I am considered expert. That isn't what I want to do with my life and that isn't what I think is appropriate. But when you go to a lawyer or to a judge, they look immediately to the people who have authored articles, who have done research, who have been involved, that they consider most knowledgeable.

I agree with you. I wish there was a much broader panel of people who could take their turn. But I think each of us ends up at one point or another feeling, "How can I say no? This is an area that I have spent my life in, and if I can shed some light, I will do my best." They are not getting rich on it, don't ever worry about that. I don't accept fees. For the few times I have testified in cases or have given depositions, I have made it very clear in advance that I would accept no fee for doing it.

Fisher: You notice I did not say "paid by."

Katz: No. No.

Fisher: I did not mention money.

Mortimer: I think that one of the reasons they want people who are involved and have been involved in making vaccine policy is that those are the questions they are asking for. How did this come about? Why did it come about, doctor? Why is this disease prevantable? They have to have such people.

Fisher: I will just let the question stand as asked.

Katz: Do you have some other comments? I have been making some notes and I would like to have a chance to go over...

Unidentified Committee Member: (inaudible) I have a comment. I think perhaps Mrs. Chapman used it as a rhetorical device when she mentioned the ineffective surveillance tool, and she wondered why they weren't accepting reports. I don't recall a case being presented here, even though I appreciated the presentations because I found them to be very instructive, that did not involve a private physician. And that explains entirely why not one of those cases would have found its way into CDC reports.

Fisher: The Rodee baby was vaccinated at a public health clinic.

Rodee: My son received his shot at the Lyon County Health Department in Emporia, Kansas.

Member: I see. Excuse me.

Rodee: Yes sir. It is in the testimony I gave.

Member: Thank you.

Chapman: And it is not really a rhetorical question.

Committee Member: Well, the point that I wanted to make is that, as Dr. Hinman said, the MSIFI, of course, is a reporting system designed to pick up adverse reaction information from the public sector as opposed to the private sector.

Chapman: Although our first presentation was a proposal to change that and we feel that if this Committee is involved in recommending that the immunizations be mandated throughout the land, we really feel that it has equal responsibility to mandate or encourage the passage of laws to report reactions to find out ... (inaudible) ... to know the risks. It is astounding that the people here assembled do not appear to feel that they need to know how many babies are actually being damaged or killed - the actual body count. (inaudible)... Do you feel you have the responsibility to tell the American public and doctors just how many children are being brain damaged and dying and really find out the numbers?

Katz: I was going to respond to that (inaudible)... I think you have pointed out some things that I would like to see remedied, but I think because we have a pluralistic health care system where some children are taken care of in the public health clinics and some children are taken care of in a private setting, there isn't as good integration as there should be. The fact that one set of reports comes to the CDC and another may be sent to FDA, I think, does lead to some confusion and perhaps some lack of integration. But I don't think that is the major problem. That is a problem, and I would like this Committee to see if it could make some recommendation to remedy that.

But I think another problem that I would like to see you dedicate your energies to because you are achieving, intelligent, and motivated people, is that the Centers for Disease Control and, in particular, the Immunization Branch need help. Their energies are being diffused into multiple directions, as are the people in state health departments. You may want to hear from some of them. But if you could use the same amount of energy to convince Mr. Reagan's Administration that the Centers for Disease Control needs an augmented budget directed specifically at immunization programs and immunization surveillance. I testified before Congressman Waxman two weeks ago, and the budget that is intended for immunization for the coming year doesn't buy one fighter plane for the defense department. But it is being reduced.

I think it if we could get some help in that way and use your clout and your leverage and then say, "O.K. we got you some help, now you get that system working better for surveillance of immunization reactions." He doesn't have the troops to send out into the field someone to investigate every report that comes up, as much as he might want to. They are out taking care of AIDS

today because that's got the headlines, not pertussis immunization unfortunately. There are a lot of problems that intersect here, but that certainly to me is one of the ways in which I could see a very positive response from this sort of gathering.

Fisher: Doctor, we would be happy to do that if we really felt, and maybe there is a different feeling here today - I sense a different feeling - if we really felt that you honestly and truly wanted to find out how many children are dying and becoming brain damaged by vaccines. If we had full confidence that that is what you truly were going to do, we would move heaven and earth to get you more funds.

Katz: I hope you don't have any doubt of that. I am not looking to have my eulogy written that I spent x number of years on a Committee hiding childrens' deaths. That is not my role in life. I am a pediatrician. I believe in fostering childrens' health and happiness and potential. So that I really am as motivated as you. My concern is how to take this motivation and the situations as they exist, and come up with some positive ways. And I don't necessarily agree with you that everything that you think is a vaccine related incident, is. But you don't agree with me that those I think are not, aren't. And the only way it is going to happen is to have them better investigated each individually.

I listened to a paper at pediatric research meetings last week in Brooklyn, New York in Kings County in which hospital officials investigated SIDS cases, cases that were brought in by the medical examiner that were labeled SIDS. And of 29 such cases, they felt they could show that 26 didn't meet the definition of SIDS. That there were legitimate other causes. They did not happen to be vaccine related, but that isn't the issue. The issue, I agree with you, the term SIDS is being used inappropriately.

I think there are a number of positive responses that we can make to you but I would like to let you finish your other topics and then come back at the end for summations.

Karen Cline: Dr. Katz and Members of the Committee, my name is Karen Booker Cline. I am the mother of Sabra Lynn Cline, whose death was reported to you in October of last year. I am also the president of the Oklahoma chapter of Dissatisfied Parents Together.

In October, we came before this Committee and we asked you to immediately include a family history of severe reactions to DPT as a contraindication to receipt of pertussis vaccine. Your reply, drafted by Jeffrey Koplan, M.D., stated, quote, "There is little evidence that severe reactions to DTP run in families, and the ACIP believes that, if this were a problem of consequence, it would be quite apparent."

It is unclear to us how this would be quite apparent. As was discussed earlier, the CDC's reporting form - MSIFI - does not contain personal identifiers. Therefore, there would be no way of knowing if more than one report was received from the same family. The reporting form does not ask the question if another member of that family has had a severe reaction. So there is no way that you would have that information.

Dr. Hinman apparently has also questioned it when he stated in a letter to us that "As to the possibility of a 'genetic factor' as one cause of reactions following immunization, CDC does not dismiss this idea. Currently, little literature is available on this issue and what is available, is not conclusive," end of quote.

There have been indications of a possible or even probable genetic link in medical and lay publications that have arisen from time to time for the past forty years. In 1946, Werne and Garrow reported the death of identical twins within 24 hours of their second shot. In a 1979 FDA meeting, Mrs. Geraldine Norris, maternal and child health representative, told of the results of a telephone survey regarding instances of death events within 24 hours of DPT that were, correctly or not, labeled SIDS. She stated, "Two of these instances within 24 hours were twins and in each of the sets of twins, one twin died and the second twin was admitted to the hospital in critical condition."

A July 10, 1985 article in Britain's The Guardian told of the deaths of five month old fraternal twins just two hours after immunization with DPT. Also in 1985, Kevin Geraghty, M.D., presented data on a small study he had done in which two of the cases were brothers with clinical diagnoses of pertussis vaccine encephalopathy. The death of the Derwin twins in Caddo Parrish, Louisiana in December 1985 within 24 hours of DPT adds further to the growing indications that perhaps there is indeed a genetic link in some cases of severe DPT reactions.

In April 1986, I conducted a small informal survey in which I distributed a questionnaire to some families. Forty-five families responded to our request for information; 28 of them had more than one child who had a severe reaction. The data from those families is included in the written information before you. Using the figures from Dr. Hinman's and Dr. Koplan's 1984 Reanalysis, I asked Dr. William Coberly, Ph.D., Chairman of the Mathematics Department, University of Tulsa, and Meg Brady Carr, Ph.D., Mathematics Department, University of Oklahoma, to calculate the statistical probabilities of two severe reactions in a family with three children, given the presumption that these events are merely coincidental.

For the purposes of this analysis, we did not include all severe reactions. We only included convulsions or shock/collapse episodes. The probability was calculated to be approximately 8 in 100,000. We also calculated the probability of two cases of

permanent damage in a family with 3 children, again assuming coincidence. We used the officially recognized figure of 1 in 310,000 for this calculation. That probability was calculated to be approximately 3 in 100 billion, yet several families in our survey had more than one case of permanent damage.

My survey was not a scientific study by any means, but it is further evidence of a possible or probable "family link." I hope that you will note the disturbingly consistent pattern of family histories that we have previously brought to your attention as possible risk factors.

As vaccinations are mandatory in most of our United States, the government and its policymakers must be held responsible to search out and determine what factors put children at a higher-than-usual risk of reaction, damage and death.

This is where we can be of help. Because we know families who have been affected. This is where can help because we don't have to stand for the status quo and wait around for a safer vaccine. We can institute policies that will right now protect high risk children from damage and death from severe reactions, so that we don't have to come before you and report deaths. We don't have to come before you and say we need a better reporting system. Let's get the numbers down. Let's drop the numbers of severe reactions.

We once again call for immedicate inclusion of a family history of severe reactions to DPT as a contraindication to receipt of pertussis vaccine. If severe reactions and damage are as rare as your statistics suggest, the exemption of siblings and children of those who have severely reacted will not affect herd immunity. It is our fervent hope that following this interim step to protect innocent babies from damage and death, that a serious and well designed study will be undertaken with the sense of urgency that this issue deserves.

Unidentified Committee Member: (question inaudible)

Cline: There were not too many families. I don't know how many families there were... (inaudible)... I distributed questionnaires to about 15 contacts, who then distributed questionnaires to their contacts, so I don't know. These were families that we already knew had at least one severe reaction. Not all of them had damage, not all of them had a death. But we knew that all of them had at least one severe reaction in the family. So this is not a random sample...(inaudible).

(There is a gap in the tape, which at this point skips to Dr. Hinman)

Hinman: (inaudible) ... whether or not there is a familial clustering of adverse effects associated with the DTP. Six of those studies have primarily looked at allergy histories. Six of

these studies found no relationship to a family history of allergy and subsequent occurrence of a DTP reaction. And six found that there might or was a correlation between a family history of allergy and a DTP reaction. Probably the biggest of these studies was conducted by a man named Hopper and reported in the 1960's. And this looked at family members by degree of relationship and the likelihood of reactions, and found significant relationships between a family history of seizures and a family history of allergies in children who had reacted. (inaudible) ... the form currently has always asked about a family history of convulsions...(inaudible) ... did not specify what degree of relationship and it now does.

If you look at the item under past history down here, it asks about convulsions particularly in siblings, it does not ask about family history of reactions other than a family history of uncontrolled convulsions.

Fisher: Is there any plan here at the CDC to make a family history of allergies or severe reactions a contraindication?

Katz: Alan?

Hinman: Well, the data on a family history of reactions to DTP vaccine are not conclusive .... (inaudible). As far as a family history of allergies is concerned, a real problem is defining what one means by a family history of allergies. If one considers what are commonly called allergies, we would fairly rapidly reach more than half of all children who have a family history of allergies. Potentially, you could reach ...(inaudible).... allergies would be very very difficult to ... (inaudible)... the issue of a family history of severe allergies in relation to pertussis vaccine is one which we ... (inaudible)...

Katz: (inaudible)... as one who works in pediatrics with children who have a family history of allergy .... (inaudible).. be more specific than that... (inaudible)... seafood, tomatoes, ragweed, and various substances... (inaudible) but I think more specific... (inaudible)... other family members who had a severe reaction to immunization. I think that sounds perfectly legitimate.

Fisher: We are finding a lot of milk allergies in children who have reacted. I know I talked with Dr. Steinman several years ago...

Katz: Sorry, who?

Fisher: Dr. Lawrence Steinman at Stanford. I asked him if his study indicated that children who have a milk allergy are at higher risk for reacting and he said, "Yes." I asked him, "What should a mother do if she has a child who has a milk allergy?" And he said, "Tell her to take my study to her pediatrician." Now as far as I know, there has been no more discussion about it. Ten percent of the children in this country have a milk allergy, and we are finding a tremendous number of children who have milk allergies who are becoming pertussis vaccine damaged.

Chapman: The report we made last year of the 11 deaths, in October, showed that many of those babies had allergy to milk.

Katz: It is a tougher one, I must admit, because I come from a department which has spent forty years studying milk allergy and that is another one that is very very difficult to define. There may be one baby who threw up once when he was fed milk and is changed to a soy formula. Does it mean he had a skin test that proved positive for milk? Does it mean he had a RAST test? Does it mean that he had ectopic dermatitis? It is a harder one to be specific about. I don't belittle it in any way, but among children who have had feeding problems or one difficulty or another, I have to admit for my fellow pediatricians, one of the commonest things that gets said is, "Oh, the baby is allergic to milk, we'll change the formula." And it may be indicative of forty other things that are going on. I don't exclude it from data as to whether it has significance, but that is a very difficult one to be precise about.

Fisher: Couldn't you undertake a serious investigation into the possibility that you need a contraindication. Or if you don't want to make it a contraindication, could you put out information warning physicians that perhaps, among other conditions, a physician should consider a family history of severe allergies, particularly in the child, or a history of reactions in the family to DPT? Something?

Katz: (inaudible)... I don't want to give you one just person's point of view, but my feeling would be that if these are questions that have some degree of suspicion, that they should be properly investigated. And in order to do the proper investigation, we get back to that same question, somebody has to say that this is a significant priority and we will fund such a study or such an investigation.

Cline: Dr. Katz, as I said in my statement, this could be taken as an interim step to protect babies right now while we are getting the data that you need. If any future data should prove it to be an incorrect assumption on our part, it could be removed. But, I also wanted to inject a little personal experience briefly to explain to you what I mean when I talk about milk allergy.

My oldest child had a very severe milk allergy. At eight months, he was given one teaspoon of cereal mixed with regular formula. He immediately threw up, got hives and stopped breathing. That is what I refer to in my family as a milk allergy. He has had four severe reactions to four doses of DPT vaccine. My daughter who was born subsequent to my son had a severe reaction to her first vaccination, following indications that she also had a similar milk problem. So that is what I am talking about when I talk about a milk allergy. That doesn't hold true in every one of these cases, but that is my personal experience.

Unidentified Committee Member: Maybe I should say a word in regard to your concern ... (inaudible)... and I really sympathize with your concerns. Let me go back to put this into perspective. I haven't heard it been said, what I would like to say now, and that is that I was at CDC some twenty years ago when CDC first got any money to support anything to do with vaccines. Before that, there were no people, no vaccine support funds at all... (inaudible)... the public health had been a state matter for each individual state to deal with. And still the states have major (inaudible)... and in terms of reporting of cases of disease, this is a decision made by the states to decide what is to be reported. And in dealing with the CDC, to decide what isn't reported.

In fact, there is not a federal Czar that sits here and says, "You will report." This is something that one, maybe, would like to have a broader set of reports coming in, but how far one goes is really hard to know. So that very recently, and by recently I mean the past decade, the CDC has been given money to support

immunization programs, to support programs in the states for immunization and for surveillance of cases of disease. We are dealing with a number of different vaccines and a number of different problems. But the staff is a small one, a very small one indeed. The monies made available in the past for vaccines and vaccinations is very very small indeed. And every year there is a fight defended by the Director of CDC just to hold that amount of money to get sufficient funds for public health clinics that are in the states. The state health departments often used to have a difficult time themselves in getting the funds they need for immunizations. So there is neither a very large staff nor a very large amount of money available to do the things that need to be done.

I think we would all like to see a lot more being done than is being done. I think we would all like to see more research going into the improvement of vaccines. And, indeed I as well as others around here have gone before Congress to testify about the need for this... (inaudible).

I would say again, to put it into perspective, I would like to see the CDC, which is not a huge staff, not a huge authoritarian power... (inaudible)... we ought to be doing a better job all around...(inaudible) when we get reports, make an investigation...(inaudible)... I am not saying it can't be done but it is difficult and there are limits as to what the CDC can do... (inaudible).

Fisher: (inaudible)... the CDC has set up a very efficient system and obtained funds to send CDC personnel to state health departments, where they are advising them and educating them. The CDC has very effectively played a key role in convincing state legislatures to pass mandatory vaccination laws. The CDC has set up an incredible system for making sure that every child who enters school has to be immunized. It seems to me that if you can mount that kind of an effort and set up that kind of a system that is so efficient in making sure that every child is vaccinated in this country prior to going to school, that you can certainly set up a system that will give us an accurate accounting of how many children are dying and becoming brain damaged by the vaccines that you so effectively promote.

Philip Brunell, M.D.: There are a lot of things that I heartily agree with. We have no problem with you. We would like to support you and we hope that you support us. We think we have a problem with the current vaccine. We would like to see a better vaccine. There are many many deficiencies in what we are seeing. And we have sent a motion to the Board of the Academy asking them to strongly support additional funding for pertussis research.

Now one of the issues that came up in one of the requests that was made, was to ask for funding specifically for pertussis vaccine. They thought that, politically, that would be a better way of getting a response from the Congress. And I and the other

members of that group objected completely because pertussis vaccine, a new pertussis vaccine, is not the only issue. We have a problem, I think we all agree with. The problem is, pure and simple, money.

I'll tell you about another meeting that I attended between those two meetings in which there was a request for surveillance. And Dr. Chin who, as you know, is the previous chairman of this group, said, "It is simply a matter of money. We can give you whatever you want." But you get what you pay for. CDC jawbones with the states every time they can to get the states to do things. The states have their own list of priorities. And Jim said very clearly, "If you want to pay for it, you can have anything you want."

We have a major problem with funding. Now I have heard, and perhaps one of the other people in this group can give you the precise figures, that an item was put in - of several million dollars - which is probably the rounding error in the overrun of a single fighter plane - for new pertussis vaccine research. And that was taken out of the budget by the Office of Management and Budget.

Again, I am getting these things third hand, but I think you had better look into this.

Fisher: We agree with you on that, but...

Brunell: So we share your concerns and are upset about it. And we think that something really needs to be done. I told you at another meeting that if the adults in this country were required to get a shot of DTP as a condition for holding their job, as children are in this country to go to school, we would sure have a better pertussis vaccine.

Now, on the other hand, what has happened is that there is great concern about the pertussis vaccine. We are concerned about it, this group is concerned, and we respond by doing what you have requested: make the contraindications as rigid as we can as we think is prudent; warn physicians; try to disseminate that information. Again in the new Redbook, we made it easier to report. I have asked the manufacturers to put an 800 number in their package insert. These are all issues that we are concerned about.

The fact of the matter is that we have got to do something with the information. You have asked Alan to send people out to investigate the pathology reports in cases of SIDS. That costs money. Someone has to count the data, that have to look at them, they have do draw some conclusions about what they mean. This costs money, bottom line.

But in terms of writing recommendations, I am concerned that we have now bent over backwards to the point where children are

being injured by not getting the vaccine they need. I think it's a combination of the recommendations that have been written, and some of the things that the media have done, and some of the things that our attorneys have done... and let me give you an example. I'll bring you the clipping from my local paper. We had 80 cases of pertussis this past year. At one point, our I.C.U. unit was filled with children with pertussis. We couldn't get any other children in.

We have one mother who has a brain damaged child. That is on the front page of our local paper. If you read the rest of the article, she didn't bring her child for immunization because she was afraid to have the child immunized. So again, I would ask you for prudence in trying to help us in terms of writing recommendations that are going to protect children against immunization as well as against disease.

Now one of the things which I have just learned about which is of even greater concern: in underdeveloped countries or less well developed countries, they use the Redbook as they use ACIP recommendations. They are trying to follow recommendations that are written in this country, and I must say that I think they are written to protect immunizers against lawsuits rather than to protect children. They are using those recommendations and following the letter of the law, and what is happening to children in these underdeveloped countries where there is a tremendous threat of pertussis, are not being appropriately immunized. So I think we have got to balance what we are hearing here.

But as far as I am concerned, the bottom line is getting more bucks into this program and not only for pertussis surveillance, not only for vaccines. Dr. Jordan has just told you that there are a bunch of candidate vaccines and we are not sure that any one of them is going to work. I think we had better get back to the beginning and start finding out what in this organism causes disease and really get a broadscale basic research program as well as just going out and testing vaccines that may or may not work.

Fisher: Dr. Brunell, money is not going to be answer, the only answer. Until attitudes fundamentally change in ACIP and the AAP, you are not going to have high risk children being screened out. You are talking to the wrong group here if you say that the contraindications are too narrow. Because so many of us have children that if we had known they were high risk, we could have saved them. My own son was immunized after having had a reaction to his third shot and I didn't know it was a reaction and neither did the physician or the nurse. He was immunized when he was coming off of an illness. He should never have been immunized at that time. And I held him while he was being immunized, and I didn't know. And a lot of these parents didn't know. And until attitudes are changed... you are so concerned about the prevention of disease that you are not looking at the price that

we are paying in this society.

Brunell: Barbara, I disagree with you. I think we are very concerned. And I have told you that I think that the group now bends over backwards to be more concerned about vaccine reactions than perhaps they ought to be in terms of prevention of pertussis.

Katz: I think we ought to halt the questions on this one. We are running out of time. We have to go on to the next segment.

Jeffrey Koplan, M.D.: (inaudible)... There have been a number of outbreaks reported recently in the press and elsewhere of pertussis disease occurring in vaccinated populations. This has raised the question to her and others as to what does this say about the value and efficacy of the vaccine currently used. Concerns about its safety have been raised repeatedly in this discussion and others and she wants some discussion as to the value of the vaccine.

Fisher: Dr. Koplan, we were also denied the opportunity to make even a short statement on this subject. After someone from ACIP makes a statement, we have a three-minute statement that we would like to make on the subject, if we may be allowed to do that.

Katz: About vaccine efficacy?

Fisher: Yes, about vaccine efficacy.

Katz: I read it. That is the one in the packet.

Fisher: Right.

Katz: O.K. Do you want to do that first?

Fisher: Thank you very much. Mr. Chairman and Members of the Committee, in 1981 my fully vaccinated sister came down with whooping cough in Texas. Her three year old daughter, who had received four DPT shots, also caught whooping cough. Her three week old newborn daughter, who was too young to be vaccinated, almost died from the disease. That was a frightening experience for our family, and I began to question the effectiveness of the pertussis vaccine. And when my oldest son became multiply learning disabled from a reaction to his fourth DPT shot, I began to question the safety of the pertussis vaccine.

These questions were clarified during research on the book DPT: A Shot in the Dark, which I co-authored with Harris Coulter, Ph.D. But when the American Academy of Pediatrics issued a press release in November, 1985 stating that in 1985 there were "near epidemics of whooping cough" in Georgia, Hawaii, Indiana, Iowa, Minnesota, Oklahoma, Oregon and Texas that resulted in hospitalization, brain damage and death, and that these "epidemics" were due to parents "delaying immunizations because

of recent publicity about the vaccine's safety," I began a three month investigation into pertussis morbidity and mortality in the U.S.

I obtained information from the eight state health departments about whooping cough cases in their states in 1985. The full reports of what I found is being provided to Dr. Koplan. Because of time constraints today, I will only summarize a few findings:

1. In three of the eight states - Hawaii, Indiana and Oklahoma - the number of reported pertussis cases declined in 1985 compared to 1984.

2. Pertussis deaths declined in the eight states from 5 in 1984 to 1 in 1985.

3. The number of cases of permanent brain damage caused by pertussis is unknown in most of the states.

4. More DPT vaccine was used in public health clinics in at least two of the states in 1985 compared to 1984.

5. More than half of the total pertussis cases with a known vaccination history in six of the eight states occurred in individuals who had received 1 or more DPT shots. In Oklahoma, more than 70 percent of the pertussis cases with a known vaccination history had received 3 or more DPT shots.

6. Only one state health department provided hard evidence that pertussis cases were tied to parents withholding vaccine from children specifically because of fear of pertussis vaccine reactions, and that was a cluster of 9 cases.

Obviously whooping cough is occurring in a significant number of fully or partially vaccinated individuals. The U.S. has a 95% vaccination rate and yet whooping cough is underreported by as much as 10 to 20 times, according to Dr. Hinman. So instead of the 1,000 to 3,000 cases reported each year, there are actually 10,000 to 60,000 cases. It appears that the alleged recent "increases" in whooping cough incidence are primarily due to an increase in reporting of the 10,000 to 60,000 cases that have always been out there.

We know the vaccine is only protective for 2 to 5 years and that once immunity has worn off, there is a susceptible older child and adult population carrying the disease, often in atypical form, and transmitting it to vulnerable newborns. Under these circumstances, it is difficult to reassure parents that if they vaccinate their children, they won't catch whooping cough. Doesn't this fact necessitate a reevaluation of the benefits and risks of the vaccine? And don't we need a more effective pertussis vaccine as well as a less reactive one?

I would also like to add that it is difficult to evaluate

pertussis morbidity and mortality statistics provided by state health departments because each state has set up different criteria for what information is gathered as well as how that information is tabulated and reported. Therefore, it is impossible to determine, for example, (1) how many of the total pertussis cases occurred in children too young to be vaccinated; (2) how many cases were appropriately vaccinated with DPT; (3) how many cases had 1,2,3,4, or 5 DPT shots; (4) how many cases were lab confirmed; and (5) how many cases resulted in hospitalization or permanent damage.

It would be useful if the CDC could develop guidelines for the states and encourage uniform gathering and tabulation of pertussis data so these questions could be answered. Without a clear picture of the nature of pertussis in the highly vaccinated American population, how can we make an accurate benefit risk analysis for the vaccine?

Brunell: I agree with you 100 percent.

(inaudible comments from several members)

Hinman: The fact is that as immunization levels increase, we expect a higher proportion of cases that occur to occur in people who have been vaccinated. And a simple extension of this is that if a 100 percent of children are vaccinated, any cases that occur would occur in a vaccinated child. And there is a predictable relationship: there would be fewer cases that would occur, yet those that did occur would occur in vaccinated children. As a simple rule of thumb, if we have 90 percent immunization levels with a 90 percent effective vaccine, we would predict that about half of the cases that would occur would occur in persons who had received the vaccine.

As far as the current pertussis epidemiology in this country, about a third of the cases occur in individuals who received the complete series of at least three doses of DTP vaccine. About a third occur in children who have received no vaccine, many of these because they are too young to be vaccinated; and the remainder occur in children who have received one or two doses of the vaccine. This is not inconsistent with vaccine efficacy of 80 to 90 percent reported immunization levels in this country.

The household investigations, which are carried out in most states related to pertussis cases, allow us an opportunity to look at seconday spread in households of pertussis when there is a case of pertussis. And these have demonstrated over the past several years an efficacy of between 80 and 90 percent for a series of three or more doses. This is very comparable to the levels that are reported in the studies from Japan in household contacts with the acellular vaccine... (inaudible)... so I think that although it may seem a little disconcerting at first, there is a logical explanation for the occurrence of pertussis disease in vaccinated children.

As far as the current patterns of pertussis, I agree that it is a mistake to ascribe the increases we are seeing now to parents being frightened of the vaccine. In fact, it appears that, although this may be a factor in some areas and in some children, it is not a major explanation for the current pattern of pertussis in the United States. Several things seem to be occurring. One is a greater awareness of pertussis and probably increased reporting. Secondly, a part of the increase that we are seeing is in older individuals: school age children, adolescents and young adults. Groups which have not really previously been thought of as playing an important part in the pertussis constellation. And we are increasingly seeing cases that are being reported in adults which presumably might not have been reported at all, pertussis might not have been suspected.

So I think that the increase we have seen in the last two years in pertussis may well be due in large measure to increased awareness and increased reporting. Certainly we are seeing more cases reported to us in the young adult and adolescent population. Finally, I guess, just a comment about funding and research activities. Within the department, a proposal was prepared last year requesting something on the order of 7.8 million dollars for accelerated pertussis research. It focused on increased funding for field trials of pertussis vaccines both in Sweden and a second trial to be carried out in the United Kingdom, as well as a large scale study similar to the National Childhood Encephalopathy Study in this country, as well as increased research aimed at developing serologic measures and improved diagnostic techniques. This request was submitted by Secretary Heckler to the Office of Management and Budget but did not leave the Office of Management and Budget.

So that was the general order of magnitude of the funding request that was prepared a year ago. Finally, I will just say that there is (inaudible) in the medicaid childhood population in Tennessee, which is looking at the medical contacts both before and after receipt of vaccine on a statewide basis in the medicaid population so they can get a more complete picture of adverse events associated with all vaccines, particularly DTP. And they have recently issued requests for proposals (inaudible) ... to look for ultimately a larger scale encephalopathy type study in this country.

Katz: (inaudible)

Chapman: (inaudible) ..the AAP poster that said 14,000 deaths will be caused per year....(inaudible)... there are people in our network who did not report severe prior reactions to their doctors because they were so frightened by that, in the words of Dr. Jennison, "error" of the Academy. That is not a money problem. I am sure you gentleman spent a lot of money getting that 14,000 figure before American parents, which frightened them in some cases, to the death of their children. I would like to

know when we can expect a corrected poster reducing that figure to 450, or whatever it is now, so that these parents who take their children into their pediatricians can be corrected of this very incorrect information.

Brunell: I am sure if you ask the Academy, they will respond. I can't respond for them.

Chapman: The second one is, which I think you can respond to, a very very serious problem. And that is the statement that you made at the April 1985 meeting of the AAP here in Atlanta. When presented with the question, "If a baby dies shortly after a DPT shot, how is a physician to know if this is a SIDS or a DPT related death?," your answer to the assembled physicians was that you suggested that the physician "ask his lawyer." At which point, the assembled pediatricians erupted into gales of laughter. Parents of dead babies in that room, whose deaths were wrongfully classified as SIDS, almost threw up.

Brunell: Now wait a minute here.

Chapman: No wait. When somebody in your position suggests to physicians that they consult their lawyers about what to tell parents, and parents of dead babies do not get the truth, and physicians think this is a "ho ho," then there is something wrong....

Brunell: Mrs. Chapman, I think what you were hearing in response to the question which you posed to me at that meeting was...

Chapman: I didn't say I posed it.

Brunell:... was frustration...

Chapman: I did not pose it.

Brunell: ... of the physicians in fielding that question. It's simply a reiteration of what you have heard before. It is very difficult to define SIDS. In the new NIH study, which should be out shortly on SIDS and DPT in which they don't find a relationship, they took the autopsy material from all the cases. They gave them to a panel of experts blinded, to remove any bias. That is how difficult it is. And sooner or later if you go back to examinations of the brains of children who have died from DTP, and I am sure you are as familiar with this paper as I am, there is no pathological picture of DTP. Some of the children in that study obviously had conditions such as subdural hemorrhages which had occurred months before...

Chapman: I am not saying that...

Brunell: It's a tough question! And I am asking you -

Katz: I am sorry. I am going to have to insist... I can be impartial by telling you both that I am going to have to call the

discussion off. Dr. Brunell is here as a representative of the Academy of Pediatrics and your quarrel right now is with the Academy... (inaudible).

I'd like to thank you all for coming. I don't say this just to pacify you or placate you. I think we learned by talking to together, by communicating. Anyway, I would like to suggest at least a few things that I will personally take responsibility for insuring investigation:

One is to work with the Academy of Pathologists, or whatever other groups there may be which are appropriate, to look at more appropriate utilization of the terms SIDS as an autopsy diagnosis. Secondly, to look and see if we can promote a better correlation of reports that come from the public and private sector regarding adverse reactions to immunization procedures. And third, to look at a reconsideration of the question of risk factors that may relate to previous family members having had serious reactions to DTP or other vaccines.

In turn I would like to ask you to take seriously, not just a dollar sign, but the mission of educating our state and our national legislators to the fact that there are priority items which relate to things that they often take for granted because they have been around for so long, because the primary diseases themselves may not appear as pressing and as high priority; that particularly state health departments and the Centers for Disease Control be considered in the budgetary process to provide the personnel and the wherewithall to carry out some of the studies that you have legitimately requested, and which no one would resist here, who would participate actively in if we could call on the personnel and the facilities to do it.

Thank you very, very much.

Parents: Thank you.