UNITED STATES
COURT OF FEDERAL CLAIMS

THERESA CEDILLO AND MICHAEL CEDILLO, AS PARENTS AND NATURAL GUARDIANS OF MICHELLE CEDILLO,	)	
Petitioners,	)	
v.	)	Docket No.: 98-916V
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Pages: 1 through 298

Place: Washington, D.C.

Date: June 11, 2007

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IN THE UNITED STATES COURT OF FEDERAL CLAIMS

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Ceremonial Courtroom
National Courts Building
717 Madison Place NW
Washington, D.C.

Monday,
June 11, 2007

The parties met, pursuant to notice of the Court, at 9:00 a.m.

BEFORE: HONORABLE GEORGE L. HASTINGS, JR.
HONORABLE PATRICIA CAMPBELL-SMITH
HONORABLE DENISE VOWELL
Special Masters

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Theresa Cedillo	222	--	--	--	--

P R O C E E D I N G S

(9:00 a.m.)

SPECIAL MASTER HASTINGS: Let's go on the record. Good morning to all of you. My name is George Hastings, and I'm a Special Master of the United States Court of Federal Claims. To my left is Denise Vowell, Special Master of the Court of Federal Claims, and to my right is Patricia Campbell-Smith, a third Special Master. Together we'd like to welcome you all to a special evidentiary hearing of the United States Court of Federal Claims.

Today we are here for two purposes. One purpose is to hear the claim under the Vaccine Act of Michelle Cedillo. Michelle is a 12-year-old who lives in Arizona and who has been diagnosed with autism and a number of other medical conditions. The first purpose of this hearing is determine whether Michelle's own autism and her other conditions were vaccine caused.

However, there is another equally important purpose for this hearing. That is, Michelle is one of nearly 5,000 children diagnosed with autism or similar disorders who have filed compensation claims under the Vaccine Act. These 5,000 claims have been grouped together in a joint proceeding known as the Omnibus

Autism Proceeding.

The committee of attorneys who represent the Petitioners in the Omnibus Autism Proceeding has designated Michelle's case as the first test case in that proceeding. Therefore, in this hearing today and over the next three weeks we will hear not only about Michelle's own condition, but also extensive expert testimony concerning the Petitioner's first general causation theory; that is, the general theory that MMR vaccines and thimerosal-containing vaccines can combine to cause autism.

These two purposes explain why up here on the bench you see three Special Masters, not just one. Under the Vaccine Act, individual claims are to be decided by a single Special Master, and I am the Special Master who has been assigned the particular case of Michelle Cedillo so that I alone will decide Michelle's own particular case.

The other two Special Masters sitting up here with me on the other hand are here in order to hear the general causation testimony to be presented during this hearing. Those two Special Masters will then apply that general causation testimony to other individual Vaccine Act cases that are assigned to them.

I want to begin this hearing then by acknowledging the most important people who are in the courtroom today, the Cedillo family. With us here today, although they will be in and out of the courtroom on account of Michelle, are Michelle Cedillo herself, her mother, Theresa Cedillo, and Michelle's father, Michael Cedillo. I understand and I met this morning several other family members who are with us today. We thank the Cedillos for being here with us.

Also on behalf of myself and my colleagues, I wish to extend our sympathy to Michelle and her family for all they have been through. Clearly, the story of Michelle's life is a tragic one. She and her family have been through some very difficult times and they are deserving of sympathy, but also deserving in my mind of admiration for the way they have coped with Michelle's illness.

We thank the Cedillo family for very generously agreeing to have Michelle's case designated as the first test case in the Omnibus Autism Proceeding. Theresa Cedillo will herself be testifying in this hearing, probably later today. Again, we thank all of the Cedillos for their participation in this hearing.

We also wish to thank the counsel for both

sides who will be presenting their evidence during this hearing. We know that they have worked enormously hard to prepare for this hearing, and we appreciate that hard work. We also thank the expert witnesses who have agreed to testify before us.

We thank the Judges of the U.S. Court of Appeals for the Federal Circuit who have generously allowed us to take over their largest courtroom for the next three weeks. We thank the United States Marshals and all of the other wonderful employees of both of the Courts housed in this building, especially Brian Bishop and Don Palmer, who have assisted us very ably in preparing for and conducting this hearing.

Next, I want to mention some other people who are also very important to this proceeding. That is the families of all the other 5,000 Vaccine Act claimants who have been diagnosed with autism or similar conditions.

Some of those families I think are in the courtroom with us here today, and we extend to such families a very special welcome. Some others of those families are listening in now by our special teleconferencing system or they intend to listen to the audio portion of this hearing by downloading it from the internet.

To all such family members, as to the Cedillo family, we three Special Masters pledge to you that we will listen very carefully to the evidence put before us at this hearing and give that evidence our very complete and careful study. We realize what a very important task has been assigned to us in deciding these cases, and we will give our greatest effort in carrying out that heavy responsibility.

Finally, for those of you who will be here or listening to this hearing for more than just today, I'd like to give you a brief road map of the proceedings. We will begin at 9 a.m. Eastern time each day. We will take a lunch break of about one hour probably sometime about 1 p.m. We will adjourn each day probably sometime around 6 p.m., but sometimes earlier or later depending on the witness schedule.

Please, all of you with cell phones, please do turn them off.

With that, we are ready to begin the proceedings I believe. We are going to start with opening statements by counsel for the Petitioners. Which of you will be starting, Mr. Powers?

MR. POWERS: Special Master, I will be starting, and Ms. Chin-Caplan will be giving an

opening specific to the test case.

SPECIAL MASTER HASTINGS: Okay. Mr. Powers will make an opening statement on behalf of the Petitioners Steering Company. Mr. Powers, please go ahead.

MR. POWERS: Thank you, Special Masters, and good morning, counsel, folks in the room and folks listening over the web and folks who will be listening later.

My name is Tom Powers. I'm one of the attorneys on the Petitioners Steering Company. It's a group of lawyers who represent the 4,800 plus claimants in the Omnibus Autism Proceeding. It's a privilege to represent these families, and it's a privilege to work on behalf of the attorneys that are representing those families individually.

I'm here today to describe from the Petitioners' point of view three main things. The first is from the Petitioners' perspective why we're here and how we got here. The second is to describe what's happened over the past five years in the omnibus proceeding, and the third is to talk about the expectations from today and moving forward.

First off, the reason that we're here today, as Special Master Hastings has already described, is

that we're going to hear one test case. It's the first of a series of test cases.

This is a test case by the Cedillo family that's going to address general issues of causation on the theory of causation that thimerosal-containing vaccines caused immune system problems and suppression that makes certain children vulnerable or susceptible to viral infections that can cause neurological injuries, including many of the symptoms of autism, and that the MMR in particular is a viral agent that has caused autism in a number of these children, including in Michelle Cedillo.

If you notice from that description, it's not a test case today about the medical or scientific theory that thimerosal in and of itself has neurotoxic or other properties that in and of itself can cause these injuries. There will be later test cases addressing that theory, so this test case is addressing one particular theory of causation.

Why are we here? Well, we're here for several reasons. One of the main reasons we're here is that Congress said claims like this need to come here. They need to come into the Vaccine Program. They need to come into the Vaccine Program because Congress faced a crisis in the 1980s. Vaccines were

causing a significant number of very serious injuries in the pediatric population. A lot of injured kids were having extremely bad reaction to certain vaccines.

To get compensation, those families had to go through the civil litigation process. That's a highly adversarial, extremely time consuming, remarkably expensive process. Congress decided as a matter of policy, and we are not here to debate the policy, but Congress decided and has resolved that as a matter of policy there were three goals in setting up the Vaccine Program.

The first was to protect manufacturers from civil liability. The second was to encourage vaccines to be used and administered and developed, and the third was to provide a fair, just, speedy and generous compensation program for those children, hopefully a small number, ideally rare, but expected adverse reactions to vaccines.

That's the program's goal and so children who are injured by a vaccine need to come to this program, and that's where they are today, the Cedillo family and the other families in the omnibus.

Now, the omnibus proceeding itself is created because of the sheer number of claims. As the

Special Master described, nearly 5,000 claimants who allege that thimerosal, the MMR or a combination of them caused these serious injuries.

These are families, and it's important to understand this. These are families who followed the rules. These are the families that brought their children in for pediatric vaccines. These are the families that immunized their children.

The public policy decision on mass immunization is a tradeoff. It is expected that there will be -- again, hopefully rare and infrequent, but expected that there will be -- severe adverse reactions when millions and millions of children every year are being given millions and millions of pediatric vaccines.

The idea, and it's a social compact. The social compact is that families individually assume an extremely tiny risk of harm for the greater good, and it's an important social compact. It's a social compact that's based on trust. It's based on the families, and these families have trust.

It's based on the trust that the vaccines being used are as safe as they can be, and it's based on trust that if an individual family suffers a serious injury there will be a fair compensation

system that they can go to.

These are the families that trusted the system, and these are the families that followed the rules, and these are the families that suffered injury for the greater good.

There's no doubt that mass immunization programs are a great public benefit. They have prevented huge numbers of infectious diseases and prevented tens of thousands of deaths and serious injuries that historically individuals in society have had to bear the burden of, but these are the families participating in that program again, trusting in the program, who are now here seeking compensation because they unfortunately were the ones that got hurt.

It's important to remember that this is a no-fault system, so in this test case and in the other test cases that you'll hear it's not about did anybody do something wrong. It's not about negligence. It's not about liability. It's about proving by a preponderance of the evidence more likely than not that thimerosal, that MMR, a combination of the two, caused or was a substantial contributing cause for the serious injuries that these children have suffered.

It's important also to remember the legal standard and what Congress wanted and what case law

says will apply here; that close calls -- close calls -- on causation ought to go to the Petitioner. Again, that's to provide a just, fair compensation system for the inevitable injuries that are going to result from mass immunization programs.

It's not scientific certainty because, frankly, the science is in dispute. That's what you're going to hear in these three weeks, and that's what you're going to hear in all the test cases. The science is in dispute, and this issue is not scientific certainty. It's more likely than not on a balance of the evidence.

What this is not about is antivaccines. I can tell you that as somebody representing these injured families and talking to a lot of these families, it is shameful frankly some of the institutional disinformation and distortion that you hear.

Whether it comes from industry, from the pharmaceutical industry, from the HMOs, from the medical establishment or from the government itself, from government agency spokespeople, saying that these families are out to sink the Vaccine Program and these families are antivaccine, that these families think we should not have shots to protect people from

infectious diseases, and that is disinformation. That's distortion. That isn't true, and it's shameful.

I want to talk about what's happened in the five years since this proceeding began. General Order No. 1 in July 2002 set up the Omnibus Autism Proceeding. The dynamic has been from day one, and even from before the omnibus was set up, that you have the Respondent, the Department of Justice, really acting as the attorneys for the Respondent, the federal Department of Health and Human Services, but when it comes down to it it's the federal government. The federal government is the Respondent in these cases.

From day one, the Defendant and industry have been on the same side of the table standing shoulder-to-shoulder doing everything they can to make sure that this climb towards proving causation is as long and as steep and as hard as it can possibly be. Numerous obstacles that I'll describe in detail have been placed in the path of the Petitioners seeking that fair, speedy, generous, expeditious compensation that Congress said they're entitled to.

Way back in 2002 before this process was set up -- the vaccine Court was here, but the omnibus

wasn't -- some families had filed lawsuits in the civil justice system asking Courts and particularly asking juries to decide the issue of whether they had been injured by vaccines, suing the pharmaceutical industry and the vaccine manufacturers directly.

Well, as one would expect, and I filed one of these cases in Portland, Oregon. As one would expect, and I totally expected it, pharmaceutical industry lawyers were on the other table telling the Federal Judge to dismiss the case and send these children out of the courthouse. They shouldn't have a claim in front of a jury, and they should instead come to the Vaccine Program.

What I didn't expect then was that the U.S. Government would stand literally physically shoulder-to-shoulder with industry telling a U.S. District Court Judge that these children ought to be tossed out of Federal Court and that they ought to come here, taking the same side as industry from day one, and that continued through the course of the program.

It took a long time to get the omnibus proceeding set up, and credit I think goes to the Special Masters, the Special Masters here and the Chief Special Master, who really were fairly creative and designed a proceeding that can accommodate a huge

caseload of related claims and set up the omnibus proceeding.

DOJ fought at several key steps in the way to implement that proceeding. For example, the Special Masters decided that with 4,800 claims coming into the program with a statute of limitations and radically unfair, Draconian short statute of limitations that cuts off a lot of claims before the families even know they have a claim, with the clock running on those claims that there would be a rush to get cases filed in this program and so they provided a very simple mechanism to let families do that in a quick, easy, inexpensive way.

Rather than having to quickly file full sets of medical records and expert reports and affidavits, to fill out a short form petition to stop the clock on their claim and get a place in line in the program. DOJ fought that.

DOJ resisted that, and even though they lost on that issue for those families who are here and those families listening to this broadcast, you all have received that letter from your federal government saying you haven't done what you need to do in our opinion, and your claim is subject to dismissal, fighting every step of the way again families who

played by the rules.

These families filed their claims like they were told to do. They relied on what the Special Master said would be the process, but they still get a letter saying well, you haven't done what you need, and we're reserving our right to toss your case out. That's just not right.

Something else that we've seen happen in the last five years in this program is a simple inability to get important, critical information and evidence that these Petitioners need to prove individual cases and to prove general causation.

In the civil justice system there's a process called discovery. It's available as a matter of right. If a party to litigation believes that somebody on the other side of the litigation has relevant information, material information, they're entitled to simply ask for it and they get it, and if they don't get it the Judge tells the other side you've got to cough it up.

There's no right of discovery in the program. The parties, and I'm speaking for the Petitioners. The Petitioners don't have the right to simply ask for and receive from the other side, from the federal government, important information about

the science and the medicine in these cases.

That's an unusual situation when you look at the facts in this litigation and the facts related to the Vaccine Program. A lot of the evidence and a lot of the information on the science and the medicine is controlled by the federal government; in fact, even generated by the federal government.

The federal government funds studies. The federal government actually conducts studies among its various client agencies and client entities looking at this issue, developing information, developing facts, developing things that would potentially be evidence, but we can't get them. They have it. They're generating it, and we largely cannot get it.

For virtually every bit of information that we've received, the Petitioners have received from the Respondent, we've had to litigate. Special Master Hastings has been on this case for five years from day one, and we for years have been having to put in front of him motions to compel, motions demanding that the Special Masters force the Department of Justice to turn over important, relevant information.

Information about studies that the government is doing, information about studies that the government has planned, things that one would

normally get again in civil litigation as a matter of right.

If they're going to rely on a study, we want it, and we ask to have the files of the investigators to look at the data, the actual data that the investigators used, to even take the depositions of the investigators to really sort of look and see if those studies are legitimate, if those studies hold water and if they're relevant to get that information.

It's not just for our benefit. It's for the benefit of the Special Masters because absent a jury the Special Masters will be deciding these cases, and our position has always been that to make the best decision you need the best information. Transparent, open, acceptable, available to both sides, not just to one side. We've had to fight those motions for the last five years.

One big area where we sought information is related to the Vaccine Safety Datalink. The Vaccine Safety Datalink is a huge database involving millions of children, and it gives you a unique opportunity to match the vaccine exposures of groups of children against their medical outcomes, an extremely powerful database.

This is probably, as various government

entities have described it, perhaps the richest source of information, the richest source of data that would allow people to do population studies to determine whether there are associations or causal associations between various vaccine exposures and various health outcomes. We've been fighting for three and a half years to get access to the Vaccine Safety Datalink and have been frustrated in all of those efforts.

In 2002, the Vaccine Safety Datalink that the federal government had administered and managed for many years was outsourced, so by the time we were asking to get access to the Vaccine Safety Datalink the federal government was able to say well, we don't possess it anymore. It's not ours anymore.

Where is it? Well, it was outsourced with the promise of $200 million over the course of 10 years to manage it to the national trade association for the health insurance companies, for the HMOs.

Public resource, a rich source of information that addressed critical issues of fact and public policy relating to vaccine safety, and that database is locked up and the government has hidden the key. We have been fighting to get that, and we're going to continue fighting to get that.

During the course of this litigation

Petitioners have also gone to industry as a third party, although industry is completely protected from any liability in this system. As the people who designed, tested, manufactured and distributed these products, we thought as a matter of common sense that it might make sense to get information about the safety of their products from the manufacturers.

Again, the vaccine industry and their lawyers intervened several times. Even though they cannot be liable in this program, they still show up to argue why they shouldn't simply have to give information and provide information that again would be made available as a matter of course in civil litigation.

It's another example of the federal government and industry standing side-by-side, shoulder-to-shoulder, standing between the Petitioners and important relevant information and keeping that information from the Special Masters to boot.

Now, the Department of Justice is I think somewhat proud of having produced some documents, a couple of hundred thousand pages of documents. It's important to understand what those documents are. Those are product license applications. About 98 percent of the documents produced by the federal

government to the Petitioners in this litigation are those PLAs as they're called for short.

Again, you've got the government and industry working together because those PLAs are materials that are submitted by the manufacturers to the FDA to get products approved, to get warning labels approved, to get licenses approved, to sell and distribute their biological products.

So it's industry information held by the government, and when we get it well, industry has had a chance to sit down with government lawyers and redact and white out and black out huge chunks of information, trade secrets, proprietary information, all sorts of things that they claim are confidential and privileged and protected and have to remain secret.

Now, Petitioners didn't even get a chance to look and see whether any of those claims of privilege are true. That was done again by industry lawyers and the government lawyers working together. So what we have are a couple of hundred thousand pages of heavily redacted, often blank documents largely irrelevant to the issues here.

It's a mountain, a haystack in search of a needle. There's not a needle in there as far as I can

tell. It took three years to get there too.

Finally, in talking about the discovery process and the search for information, three years ago the Petitioners realized that in England, in the United Kingdom, there was litigation going on that involved the MMR -- not thimerosal, but the MMR -- and it was litigation that had proceeded for a couple of years generating a huge amount of material and in particular generating dozens of expert reports, expert reports from both sides of the issue.

Recognizing it makes sense to not have to reinvent the wheel if you've got 50 plus expert reports from litigation that has been going on for a few years looking at some of the some fact issues we knew would present themselves in this litigation, we asked the Special Masters to subpoena from the manufacturers copies of those expert reports.

We weren't asking them to go out and generate new reports and spend a bunch of money to hire people and write summaries and interview witnesses. We were simply asking for copies of what had already been developed and produced in the U.K. litigation.

Of course, industry resisted. The Special Masters did not issue a subpoena. We never saw that

information, but we find out a couple of weeks ago that the federal government -- your federal government -- headed over to the United Kingdom. They headed over to the United Kingdom, and they asked under a new, special procedure that the British Courts have, a procedure apparently not in place when Petitioners were making their request.

Your federal government went to the U.K. and asked that selected documents over there be unsealed because all of these reports are subject to a protective order by the British Court under British law. It got to the point where less than a week before trial here apparently reports from the U.K. were coming back to the government.

Now, it wasn't all 65 reports. Apparently it wasn't an application to say let us see everything in this important litigation to really air these issues out and provide the facts that the Special Masters and the parties are going to need to make a better decision for all these kids on these important claims. What was being brought over ultimately were cherry-picked documents that are going to help supposedly the Respondent's side of the case.

Now, when those documents come in, if they ever come in, is going to be an issue and has been an

issue of debate. Petitioners obviously believe that some of these documents shouldn't even come in, at least in the Cedillo case here, because they are so late and so voluminous, and my understanding is some of them might not be introduced here, but may be introduced in other test cases down the road.

No coincidence that at the same time your federal government was applying in the U.K., one government to another, industry was over there asking for the same thing. Industry was over there asking the British Court to unseal documents, selective documents that could be used against some Petitioners who left this program following the rules and have civil cases pending in Federal Courts in the United States.

Again, industry and government, shoulder-to-shoulder, side-by-side, cherry-picking information to use to do anything they can to further their common goal of denying compensation to these children, denying compensation to these families and making sure that these folks don't have the evidence they need to move forward and put on the best possible case.

Now, a lot of people have asked why has it taken so long to get this first test case teed up here? Five years, almost five years. We're one month

short of when the general order was entered creating the omnibus.

I think there are two reasons. The first is that the science has been evolving. When these first claims were filed, individual claims back in 2000, 2001, 2002 and back when the omnibus proceeding was set up in the middle of 2002, the science was new, and there was a lot of investigation and research going on by universities, by private researchers, by the government, probably even by industry.

The government's own science, by the way, is still a work in progress. We know that there are case control studies, for example, that are looking at a possible relationship and association between thimerosal and neurological injuries. The government has been investigating that for years. We're here five years after the omnibus, and that still isn't published.

There was a study by the CDC looking at Italy, looking at unexposed and exposed cohorts of children to again investigate the hypothesis that thimerosal might be associated with neurological injuries. Haven't seen that study yet either. Still in progress.

Another case control study in the United

States looking specifically at an association between thimerosal and autism spectrum disorders. Haven't seen that study yet either.

These studies and other studies, the ongoing science, that was the main reason that the Petitioners, when we realized that there's science about to come out, have asked the Special Masters to allow that science to ripen, again so that they can make the best decision possible for this large number of very serious injury claims.

The science has been moving at pace, but science and the law I think both have a tendency to go fairly slowly, and when you combine them and you have that interface between science and the law it takes a while, but it's okay to take a while to make the best decision, and that's been the Petitioners' position all along.

It's also extremely important to understand, and I've heard Respondent make the argument well, you don't really need discovery and you don't need a lot of the things that you've been asking for because when you filed those cases you knew what your theory was, and you ought to be able to move ahead and prove your theory without waiting to get all this information from industry or from us.

Well, you need to understand that having enough information to lead you to file a case is not the same thing as meaning you have all the evidence you need to try the case, and that's especially important when you remember the statute of limitations.

These injured kids and their families had three years from the date that the very first symptom appeared to file a claim in this program, even if at that time they had no idea that it was a symptom of autism, even before sometimes autism was diagnosed, even if they were told by their doctors or other health care providers that no, the vaccines had nothing to do with it.

That clock started running for a lot of these families before they knew it, and your federal government, through the Respondent here, will look at these cases with 20/20 hindsight. They will go look at medical records, and they will go as far back in time as they can to see something that they can argue is that first symptom, and then it's gotcha. Gotcha.

That symptom happened three years and a day before you filed your claim, and you're going to be dismissed. If you're dismissed, you have nowhere to go. Nowhere to go. So of course these families filed

their claims before they were ready to try their case, and it's taken these years under that pressure of the statute of limitations with the developing science for these test cases to be ready to go.

The other reason it's taken so long I've already described. Information that would have been available as a matter of right is something that we have had to fight for for the last five years and have met resistance and obstacle at every step of the way. So that's where we are, and that's how we got here.

I want to talk about where we're going from here. I've talked a lot about industry. I've talked a lot about the Respondent and the government, but, as Special Master Hastings said in his introduction, those folks ultimately are not who are important here. The lawyers are not important, and, with all respect, the most important people are not the Special Masters.

The most important people here are the families, including folks like the Cedillos. These are families, as I said, who have played by the rules. They participated in immunization programs. They assumed the risk. They got injured for the common good, and we need to remember that.

They played by the rules by filing their claims in the program. They played by the rules

waiting for the science and the evidence to develop so that they can put on a science-based case in this omnibus proceeding, and they've played by the rules by waiting it out.

These are families that in many cases have shown incredible fortitude, and it's a privilege to represent them. Support groups, support networks, family groups, medical providers willing to go out on a limb to do what they can for their kids.

They haven't given up on this system. They have not given up on this system, and that's why they're here. As we move forward, just as they haven't given up on their own kids and they haven't given up on the system, they haven't given up on the hope that they're going to be treated fairly, that these proceedings moving forward will be open, that they'll be transparent, that they'll be fair.

They have the hope that justice will be had. They expect nothing more, and they deserve nothing less. Thank you.

SPECIAL MASTER HASTINGS: Thank you, Mr. Powers.

I now understand Ms. Chin-Caplan will make an argument specifically on behalf of the Cedillo family.

MS. CHIN-CAPLAN: Special Master Hastings, Special Master Vowell, Special Master Campbell-Smith, my name is Sylvia Chin-Caplan, and I, along with my partners, Kevin Conway and Ron Homer, represent Michelle Cedillo.

I'd like you to know who Michelle is because her life has been very short, but yet it's been fraught with health care issues and certainly not one that a normal child would ever want or that parents would ever want for their child.

Michelle was born on August 30, 1994. She weighed eight pounds roughly, and her Apgars were nine and nine. In other words, she was perfectly healthy. On day one when she was born she received a hepatitis B immunization, and it contained 12.5 micrograms of mercury. Her parents didn't know about it. The majority of the health profession didn't know about it.

Michelle went to her regular doctor's visits. Her parents, this was the first child. This was the only child. They wanted this child very badly, and they were going to give her the very best medical care that she could ever have.

They took her to her regular doctor's appointments. They gave her all her immunizations

because that was what was recommended. They took her when she was sick. They nurtured her because this was their child, and they wanted the very best that they could have for her.

So because they wanted the very best that they could have for her they took her for her other immunizations. One month after she was born, she went for hepatitis B number two, another 12.5 micrograms of mercury, so we now have 25 micrograms of mercury, a cumulative dose, in a child who is only one month old.

And because they were such good parents they took her for more immunizations. They took her for her DPT and her HiB. Her doctors were very knowledgeable. They didn't want her to get more shots than she needed to get so she got a combined shot, a DPT and HiB combined. That DPT and HiB combined also contained mercury. It contains 25 micrograms of mercury, so by the age of four months Michelle had received 50 micrograms of mercury.

Now, there were other immunizations recommended, and Michelle's parents knew this, and she took them. They took her for her immunizations. In October of 1994 she went for another series of immunizations, and then she went for her DPT and HiB again which contained another 25 micrograms of

mercury.

So by the age of approximately seven months Michelle had received three DPT immunizations, she had received three hepatitis immunizations, and each DPT immunization combined with the HiB contained 25 micrograms, and each hepatitis B immunization contained 12.5 micrograms. So you add up the math.

During this period of time Michelle seemed to be okay. She was happy. She was interacting. She was starting to walk. She was meeting her milestones. Her pediatricians didn't think there was anything wrong with her.

In December of 1995, Michelle went in for another immunization, another regular scheduled immunization. She went for her MMR. One week later Michelle developed a fever of 105. Her mother called the doctor, and she was told there's a flu going around, a very bad flu. Keep her at home. Nurse her, and she'll recover.

That fever stayed up there, 105 on December 27, 105 on December 28, 105 on December 29, 105 on December 30, and yet she was told it's the flu. Finally on December 31 it broke. It came down, and her mother thought thank God, it's finally gone because when she was having this fever she's not very

well at all. After this fever ended around December 31 Michelle wasn't her usual self, but her mother thought she's recovering from this fever so let's give her some time.

Then the fever came back. It came back in early January, around January 5, and as soon as it came back her mother was on the phone calling the doctor saying the fever has come back. They told her to bring her in, and when they brought her in they said it's sinusitis or the flu. They gave her some antibiotics, and they sent her home.

That fever lasted about two days, and after that Michelle's family noticed that she wasn't speaking. She was totally silent. Before that she had been interacting with her parents, with her grandparents. She began interacting with her cousins. She was babbling. She was reaching for her toys. She was walking practically. She was sitting up by herself.

She didn't do any of that. She suddenly became silent. She became involved in a little world of her own. She started engaging in repetitive behavior. The family would say Michelle, Michelle. She ignored them like she never heard them. Her parents got really concerned, and they told the

doctors this. What you'll see is that the doctors would say "has lost some words since the fever" and nothing else.

Now, before this, during December in the midst of these high fevers, Michelle started to vomit. You have a high fever. You have a flu. You're going to expect some nausea and vomiting and diarrhea. Michelle started vomiting. She developed diarrhea. She continued to vomit after the fever was gone. She continued to have diarrhea after the fever was gone. She had diarrhea for almost 32 weeks continuously, and on this very day Michelle still has GI problems.

So when Michelle's parents took her in once again at 18 months, because they're such good parents, she was due for her immunizations again. They brought her in, and Michelle received her fourth DPT vaccine. Now, that DPT also contained 25 micrograms of mercury.

At that time, Michelle's parents were told to just watch her. If she has hearing problems, we'll do a hearing test in the future. There's variation within each child. Not every child will progress at the same rate. Some are slower. Some are faster. She should be okay. Her parents believed the doctors because they're highly educated professionals, and

they want to take care of your children. Michelle's parents believe that then. They believe that now.

So they watched and they waited. Theresa asked everybody around here is this right? Is this right? Why doesn't she answer when I call her? Why is she playing by herself and she doesn't want to interact with anybody else? Why does she clap? Why does she engage in this repetitive behavior? Most of all, why is she not talking? She talked before. Why is she not talking now?

Finally when there didn't seem to be any answers anywhere Michelle went to another pediatrician who referred her to an adult neurologist. The adult neurologist in his medical records took down her history. He noted the high fevers, and in his notes he said, "Probably post immunization reaction." It could have affected her hearing. We don't know. She was delayed, and he recommended that she get referred for an evaluation.

In July of 1997, Michelle saw Dr. Roth approximately 18 months after her MMR. Dr. Roth did an evaluation, noted the history again of the high fevers, and Dr. Roth made the diagnosis that Michelle was autistic.

The Cedillos didn't know what autism was.

They were told that in all likelihood Michelle was never going to be able to take care of herself, that she was probably going to require institutionalization, and they were told that they should probably do it now.

Theresa and Michael Cedillo refused to institutionalize the child. They vowed that this child that they had wanted so very badly -- their one child, their only child -- was going to be cared for by them and their family at home, and they would provide as much care as she needed for as long as they could possible provide it to her.

Now, if this were the only problem that Michelle had they could potentially manage, but over the years as Michelle grew older her diarrhea persisted and she developed these eating habits. She wouldn't eat anything. She would hit herself in the chest. She would hit herself in the head. She didn't like new situations. She didn't want to go out of the house.

When her parents tried to get treatment for her -- they brought in ADA treatment -- Michelle couldn't tolerate the fact that there were new people coming into her life. Theresa started to home school Michelle.

Now, whenever Theresa asked the doctors what can I do, what can I do to make my daughter healthy, what can I do to help her maximize her potential, what can I do to ensure that she can speak, that she can at least take care of herself, maybe be a productive member of society, is that too much to ask? Her doctors inevitably said there's nothing you can do. She's autistic.

Theresa was not willing to accept that for her one child, her only child. She was determined that her child would progress as much as she could and would be able to function to the best of her ability, so she started searching on the internet.

She started searching for answers on the web. She met other families, and she heard about potential treatments coming out and doctors who were potentially making some discoveries that could help her, and then she learned that there were doctors in a group called Defeat Autism Now! who were getting together for a conference, and the public was invited to listen to what these doctors had learned and were hoping could potentially provide treatment for Michelle.

You'll hear that Theresa went to this conference, and she stood in the back of the room and

she listened to Dr. Wakefield talk. She stood in the room, and she waited for him to finish speaking so that she could catch him and try to get his attention about helping her child.

You'll hear that he was leaving the room and she's chasing him down to see if she can get answers for her child because this was her one child. This was her only child, and she was going to try and help her to the best of her ability.

In searching the net, Theresa also came across the fact that there was a secretin study going on where she lived, and she managed to get Michelle enrolled in the study. As part of the study, it was required that she undergo an endoscopy. An endoscopy is essentially you look at the GI tract from top to bottom, but in Michelle's case they only did an upper GI, so they looked at the top.

She underwent this procedure in 2000. What they found was a Grade III ulcer between the stomach and the esophagus. Her GI doctor at that point said that's why she's hitting herself. That's why she's hitting herself in the chest because that ulcer is causing her so much pain. That's why she can't eat because that ulcer is causing her so much pain.

So they treated her, and they did another

endoscopy. In that other endoscopy they found that it had healed. Then they also decided that because she was part of the study, the secretin study, they had to do both an upper and a lower GI. They had to see whether the secretin was helping or not.

At this lower GI that was performed in January of 2002 her treating doctor at that time, the gastroenterologist, took a gut biopsy. He took this gut biopsy, and he sent it off to a lab called Unigenetics in Ireland. Months later that biopsy came back positive.

It was positive, but what do we know about it? How are you going to treat it? Most of all, how do you get rid of it? Maybe there's a chance for Michelle. If you get rid of it, maybe she'll regain function. Maybe she'll be able to be a productive member of society. Maybe she'll be delayed, but maybe she can talk again.

There were no answers out there. Michelle's condition continued to worsen. She ended up in the hospital because she was unable to eat. She was unable to drink. She was admitted for dehydration, and her mother called the gastroenterologist and said she's here. They want to transfer her to your care because you're a gastroenterologist. She was told

that's a general pediatric problem. Don't come.

Her mother was stunned. All she wants is to provide care for her child, and they were not going to provide even the most basic of care. Michelle stayed in this hospital. She was treated for dehydration, and while she was in the hospital her parents noticed she didn't seem to be able to see.

You ask well, how do you determine whether a child can see or not? Her parents would approach her face and pretend that they're hitting her, and she never reacted.

A consult was put in for an ophthalmologist, and they said that she had uveitis, but it was an adult ophthalmologist because unfortunately where Theresa lives there is not a large pediatric practice for any of the subspecialties. They recommended she go and see a pediatric ophthalmologist. They stabilized her condition.

During this hospitalization also they noticed that her leg was swollen. The rheumatology people were called in, but they were adult rheumatologists. They were not pediatric rheumatologists. There wasn't any pediatric rheumatologists where they lived. They thought she had juvenile rheumatoid arthritis. It was mentioned,

but they didn't know. They recommended that she go and find a pediatric rheumatologist.

Meanwhile, Theresa continues to surf on the net, and she finds that there is a GI doctor available who has been treating people, and he was going to appear at the next DAN! conference. True to form, Theresa chased down Dr. Krigsman because she wanted help for Michelle.

Dr. Krigsman agreed to consult with her and while she was hospitalized was consulting with her treating doctors about what to do with Michelle's problems, her GI problems in particular. When Michelle was well enough she did go to New York. She traveled to New York with her family and Michelle and had her evaluated by Dr. Krigsman.

You'll hear Dr. Krigsman. He'll come in and testify on behalf of his client, his patient. You'll hear that Dr. Krigsman has had probably the most experience in treating the enterocolitis of autistic children.

You'll hear that the histories that he obtained from her, the clinical signs and presentation, the appearance on endoscopy, the pathological findings that he saw, the tests that he ran, they were all entirely consistent with a child

who had a persistent viral infection in her gut. Because they had previously obtained measles in her gut back in 2002, he believed it was more probably than not the measles that was causing the problem.

So Michelle went home. After this hospitalization for dehydration, because she couldn't eat or drink, they had to insert what's known as a PEG tube. It's a feeding tube for nutrition. Dr. Krigsman consulted on a long distance basis, but because Michelle's care was so complicated her parents decided that they needed somebody closer, and Dr. Krigsman wholeheartedly agreed with that. They needed somebody closer.

They went to San Diego Children's Hospital from Arizona, a ride of three hours, to obtain care for their child because she was their one child, their only child, and they were going to try and do the very best that they could for her. At San Diego Children's they saw a pediatric rheumatologist, and he thought that she had an arthritis that was related to her bowel disease.

While there, she also saw a pediatric ophthalmologist, and he thought that her eye problems were related to her bowel disease and her arthritis. At that pediatric ophthalmology exam she found out

that Michelle had lost 90 percent of the function of her optic nerve. Michelle was almost blind.

He ordered treatment, and luckily that has stabilized to a certain extent, and Michelle can once again engage in the few activities that give her any sort of pleasure such as watching her Sesame videos.

Now, you will hear evidence that mercury is one of the most toxic substances in the world. It doesn't matter whether it's methyl mercury, ethyl mercury or mercuric mercury. It affects all bodily tissue, including the immune system.

You'll hear evidence of how the world discovered how toxic mercury was. The first mass contamination case occurred in Minamata, Japan, where the population there ate fish that consumed a substance that was containing mercury. Their children, the children who were exposed in utero, were born with these incredible central nervous system problems. Some died. Some didn't. Those who survived didn't survive very well. So we have Minamata.

And then the world also gave us the grain contamination cases in Iraq where poor farmers were given seed grain that was coated with a preservative, whether it be methyl mercury or ethyl mercury, and not

knowing washed the seeds and made it into bread. They ate that bread that was contaminated with the methyl mercury or the ethyl mercury, and those people came down with problems, central nervous system problems, among other things, and their children who were exposed came down with problems, and their children who were exposed only through breast milk came down with central nervous system problems. Among one of the most toxic substances in the world.

Because of this, you will hear that the federal government has funded two studies, the Seychelles Islands and the Faroe Islands. The Faroe Islands, somewhere up in the North Atlantic, looked at people who ate pilot whale. The Seychelles, down someplace warmer, had people who had a steady state of fish for their diet.

The two studies were not consistent, so the White House convened a panel to look at why are these two studies not consistent, and the members of that panel, a very august body of toxicologists who had a great deal of experience with metal toxicity including mercury toxicity, came to some conclusions and made some recommendations, and when those recommendations were followed, they found that the studies were consistent with one another, that low-level mercury

exposure could cause neurological problems.

Shortly thereafter, a third study came out from New Zealand, a small study that supported that same premise, that low-level mercury can cause central nervous system problems. Now, you may wonder, what is the safe dose? Is there a safe dose? Well, EPA came out with a safe dose: 0.1 microgram per kilogram of body weight per day, over your lifetime. If you do the math, you will find that Michelle Cedillo's mercury level exceeded that from the day of birth.

You're thinking, well, why is that so dangerous, probably. It's dangerous because it's a baby, a baby who has an immature immune system, a baby who has an immature neurological system. It's growing still, it's developing, and the mercury can affect both systems. And you may wonder, why not everybody, because everybody received it, but not everybody came down with these problems.

You'll hear evidence that the immunization schedule is a schedule, is not administered at one set date and time. There is a range of time in which it's considered important. You'll hear also that neurological and immunological development has a schedule as well. There is also a range of time, and before you can have harm, you must have that exposure

occurring at this vulnerable period of time in a child's life, and the Petitioner submits that that is what happened in Michelle Cedillo's case.

You will hear evidence from scientists that the measles that was discovered in her gut has caused her persistent GI problems, the persistent diarrhea, the persistent constipation, and that, in conjunction with the mercury, has affected her ability to clear this measles from her body.

And what happens when you have persistent measles virus? Is this something new? Is this something that we don't know anything about? No. We do know that people can develop persistent measles infection that doesn't manifest itself immediately. There is a long latency period, and we do know that years after exposure, these people can come down with neurological problems, and medicine knows that and they acknowledge that it occurs.

So what about Michelle? Does her case match? Well, you've got to remember that the time of exposure will determine the type of harm that you have. So in this situation, where you have persistent measles that won't go away because the immune system has been affected by thimerosal which was given earlier. It allows the measles virus to enter the

neurons, and when it enters the neurons, it can affect the function of the brain.

It doesn't necessarily affect the appearance of the neurons, but it can affect the function of the brain. Do we know that this happens? Well, there is certainly evidence that it happens. There is a very well-known researcher who has been looking at persistent viral infections for a very long time, and he firmly believes that it can happen.

You will hear evidence in this case that in one of the doctors that Michelle's parents sought care from, that the immune panel was performed, and they looked at her immune system. You will hear evidence that that doctor indicates that her immune system was almost perfect. You will hear evidence that this physician subsequently published an article that indicates that autistic children that he saw had what is known as a skewing of Th2.

In other words, the immune system was skewed toward one particular element in the immune system, and because it was skewed in that manner, it couldn't clear infections, such as viruses. You will hear evidence that wild measles can cause both GI problems, gastrointestinal problems, as well as central nervous system problems. That's well acknowledged.

It is acknowledged also that the vaccine strain can do the same thing, albeit on a much reduced level. You will hear evidence that Michelle has both a GI problem and a central nervous system problem, and you will hear that, more probably than not, Michelle's current condition, her autism, her arthritis, her uveitis, her persistent GI problems, are probably related, and they are probably related to the fact that her immune system has been affected by the mercury that was contained in her vaccines and prevented the measles virus from being eliminated from her body.

This program that you are sitting here, and that the special masters have run for a number of years, was created by Congress as a social contract between the public and potential people who have been harmed by vaccines. Everybody knows that depending on who you are, you will react to substances that other people will not react to. That is not in dispute.

In exchange to protect the public health, the government has asked that we immunize everybody, that parents immunize their children. The Cedillos accept that, and they did that. But in exchange for this promise, Congress said that this program will take care of your children when they get harmed. The

Cedillos are here to ask these three Special Masters to honor the intent of Congress by taking care of Michelle Cedillo for the rest of her life when her parents are no longer able to do so. Thank you.

SPECIAL MASTER HASTINGS: Thank you, Ms. Chin-Caplan. We will next hear from Respondent's counsel. I understand that Respondent's counsel wants to address some of the arguments made by the Petitioners' counsel at this time and reserve the rest of his opening for the beginning of the government's case, which will be next week, but Mr. Matanoski, please go ahead.

MR. MATANOSKI: Thank you, Your Honor. First, I thank you for graciously letting me split my opening to speak briefly about the overall program issues that were raised, primarily by Mr. Powers, and then to reserve my more case-specific comments to the beginning of the government's case.

It's interesting, I know that the folks who are listening in can't see this, but the podium that I am standing before offers you a choice. You really can either turn towards the Special Masters and address them or turn towards the audience and address the audience, and I noticed that the Petitioners' counsel both addressed the audience rather than -- and

they had their backs to the Special Masters.

I would submit that this choice that you have is to direct your comments, or at least face, those who will be deciding the case, and that's not to diminish the importance of those sitting in the crowd here or listening in; it's that they are listening in, they are not deciding this case, so my comments aren't directed to you, though of course you are welcome to listen to them. My comments are directed to the bench.

First, I would like to address where Mr. Powers started, and that is with the Vaccine Program. Now, he pointed out that the Vaccine Program exists in part to divert litigation from civil proceedings to this court. Now, it's interesting, though, that at that point he professes surprise that the federal government, your federal government as he reminds you, entered a case, a civil case, it was in Oregon, and explained to the federal judge there the cases involving vaccine injuries needed to be brought before this court.

That case was proceeding under an attempt to find a loophole in the very program that Mr. Powers is here talking about today. Now, he also failed to mention that the government's position was not only

vindicated there, but was vindicated by a special master of this court. That special master, the Chief Special Master, found that cases involving such vaccine injuries needed to be brought in front of this court.

Mr. Powers tried to present the government's intervention in that federal case in Oregon as the government standing "shoulder to shoulder" -- and he used that term several times -- with vaccine manufacturers. Well, I happen to be the government attorney who appeared in Oregon, and I remember very distinctly who I was standing shoulder to shoulder with. I was sitting next to Mr. Powers and his partner Mr. Williams in the table in front of this federal judge in making my case.

And in fact, my case, in very pertinent parts, stood in opposition to several points that the vaccine manufacturers were making. I was very careful to distinguish certain cases that need not be brought in front of this court.

Mr. Powers also discussed the proceedings before this court, the long history, and I'd like to discuss that, hopefully briefly. He mentioned that short-form cases were brought. That was at the petitioners' or the PSC's insistence. He indicates

that those needed to be brought because there were time periods that were so short, he didn't have time, or the petitioners wouldn't have time to file their records before they get their cases before the court.

Now, what he doesn't mention is, did they not have time to actually make an allegation of what injury it was? These short-form petitions provide no information at all about what the theory is. In fact, every single one of them provides at least three different theories that the petitioners can proceed under. These are place holding. What the Secretary is forced to defend against is about 5,000 cases that the Secretary knows nothing about, knows nothing more in the majority of those cases than the names of the petitioners.

What he also didn't mention is that if time was of the essence and that's why short-form petitions were necessary, that they needed to be filed because there was not time to collect those records before the statute of limitations would run, what's he been doing, what's the Petitioners' Steering Committee been doing in the last five years? Those cases have sat for that time without any records being filed. If time was of the essence, I'm sure that five years would have been more than enough time to collect those

records and get them filed.

He has complained about the frustrations the PSC has had in discovery. In fact, the PSC has received more data from the government in these proceedings than in all other vaccine cases combined over the almost 20-year history of the program. He has received over 218,000 pages of government documents. He complains that the answers weren't in there. Those were the documents he requested. Those were the documents the PSC sought.

Now, it's true, they didn't seek everything they were looking for, and he says he had to fight, or the PSC had to fight, every step of the way to get this information. They had to fight and file motions to compel. All of that material that they were provided by the federal government was provided without them filing a motion to compel. Every single motion to compel that they have filed for anything that was not provided to them, they have lost.

I would submit to you that the federal government's resistance in certain instances to their broad requests was vindicated by your decisions in this case. They deposed government officials from the Centers for Disease Control, from the National Institutes of Health, from the National Center for

Birth Defects and Developmental Disabilities, from the Agency for Toxic Substances and Disease Registry, and from the National Institute of Environmental Health Sciences, and from the Food and Drug Administration.

They received all of this discovery in a program that Congress said should not involve extensive discovery. Now, listen closely to what you hear in this case. You won't hear that discovery being used in this case.

They indicated that most of the documentary evidence that they received was in the form of PLAs, Product License Applications. That's what they requested. They indicated that those applications, or that information, couldn't be given, wasn't given by the federal government until the information had been reviewed by the manufacturers that submitted it. What he failed to mention was that federal law required that.

What he failed to mention was that the manufacturers stood ready to sue the Food and Drug Administration if necessary if the Food and Drug Administration were to reveal trade secret information in the materials given to the Food and Drug Administration.

He mentions also that during the course of

the litigation, manufacturers, as he put it, intervened in these proceedings. Actually, I think you will recall that what happened was the PSC sought subpoenas against the manufacturers, and that in discovery in this program, it is discovery for your purposes. You have to, Special Masters, determine that you need the information, and it was at your invitation that the manufacturers were invited before the Court to provide their views so that you could decide whether you needed that information or not.

And what he failed to mention was that you decided that you did not need that information. What he also failed to mention is that the federal government did not oppose those subpoenas. That is because the federal government did not have a position, did not have a stake in that fight.

There has been some talk about the government's efforts to receive certain information that had been filed in litigation in the United Kingdom. This has been characterized as cherry picking on behalf of the government, that they chose only certain information that had been filed in that proceeding and presented it before you. In fact, the reports received, obtained by our efforts, in essence have balanced the scales.

The Petitioners here actually cherry-picked a few experts that had presented evidence in the United Kingdom litigation and presented them before you. You'll now have before you both. You'll have those experts and you'll also have the views of other experts who actually had the ability to take a look at the Unigenetics lab, at Dr. O'Leary's lab, to take a look at the information, the lab reports, the equipment, the lab layout, and determine whether or not measles virus could be reliably detected by their methods. I think you will find it interesting, as we did, once you review that information, that the Petitioners' experts fail to mention any of this in their reports.

Petitioners mention that it took five years to get to this point. They indicate that that was because the science was developing, that they needed that time to develop their cases. In fact, when you hear the evidence that will unfold in the next two to three weeks, you will find that nothing that you hear here could not have been presented when this file was originally scheduled to be heard in 2004. There is no new theory here. There is no new evidence that was developed in the course of the five-year wait that we have had to get to this point.

I want to depart just for a moment to talk a little bit about the notion that the government will move to dismiss untimely cases. Well, yes, the government will dismiss untimely cases, move to dismiss it. Untimely cases are cases that are barred by statute from being before you. They are not legally supposed to be here. That's why we'd move to dismiss, and if you agreed, that's why you would be compelled to dismiss that.

I listened very carefully to the PSC arguments regarding the fairness of these proceedings. The ill motives of the government, the purposes of the Vaccine Program from the PSC's view, the dangers of vaccines. What I didn't hear this morning in comments was how this case is a causation-in-fact case, and how vitally important in a causation-in-fact case it is that the result be determined by the dictates of good science.

Now, good science has been given definition and meaning by the Supreme Court of the United States. Petitioners' argument that the requirements of good science shouldn't find place here flies in the face of that Supreme Court precedent. They have argued that in their papers. Good science does apply. It has to apply here. What has no place here or in any federal

court is junk science.

What has no place here are experts at the margins of legitimate science who present untested theories, untested hypothesis, speculation, conjecture, logical fallacies based on post hoc ergo propter hoc reasoning. Nothing in the congressional history of this act suggests that the court is to accept bad science.

The PSC reminds you that the standard here is preponderance of the evidence. That's true. It's also not news. That's been the standard since the Vaccine Act began. So for almost 20 years we've been operating under that standard. In fact, that's the standard in all civil proceeding in this country. It is the standard in Daubert.

What is critically important, though, is what kind of evidence goes into meeting that standard. What is critically important is that that evidence be reliable, that it be good science in this instance, because we are going to be essentially addressing a scientific question here. What you need to consider in judging this is whether that science that they are presenting to you meets that standard. Does it meet the dictates of Daubert as reliable science?

You need tested hypotheses, you need good,

legitimate lab results, you need testimony that can withstand critical examination. You need thorough study. That's what forms the bedrock of good science. Unfortunately, after five years to prepare their case, the PSC will not present that to you. Search as you may, you will find no support for key links in their theoretical chain of causation.

You will find that their witnesses presented views that find no place in reliable science. You will find a signal lack of support for their contentions. You will find that their hypotheses are untested, or when tested, they have been shown to be false. You will even find the support they site for critical aspects of their site has been discredited.

Their experts and their expert testimony will be discredited here because their opinions are nothing more than that; they are opinions, they were developed for litigation, they are unsupported, and they are held by these experts alone. They are not science. Thank you.

SPECIAL MASTER HASTINGS: Thank you, Mr. Matanoski.

Ms. Chin-Caplan, should we start with the testimony of Dr. Aposhian, then?

MS. CHIN-CAPLAN: Yes.

SPECIAL MASTER HASTINGS: All right. Dr. Aposhian, if you could take the witness stand here. And I think Ms. Chin-Caplan will perhaps go roughly a half an hour into Dr. Aposhian's testimony and then we will take our morning break. So go ahead. Actually, let's --

Whereupon,

H. VASKEN APOSHIAN

having been duly sworn, was called as a witness and was examined and testified as follows:

SPECIAL MASTER HASTINGS: Okay. Please go ahead, Ms. Chin-Caplan.

MS. CHIN-CAPLAN: Thank you, Special Master.

DIRECT EXAMINATION

BY MS. CHIN-CAPLAN:

Q Dr. Aposhian, would you kindly state your name for the record, please?

A I'm sorry?

Q Could you kindly state your name for the record, please?

A All right, my name is H. Vasken Aposhian.

Q Dr. Aposhian, what is your current business address?

A Department of Molecular and Cellular Biology, Life Science South Building, University of

Arizona, Tucson, Arizona, 85721.

Q What is your current position?

A I am Professor of Molecular and Cellular Biology at the University of Arizona, and I am also Professor of Pharmacology in the medical school at the University of Arizona.

Q Could you kindly give a description of your educational background from undergraduate, please?

A I received my undergraduate degree, Bachelor of Science, in chemistry, at Brown University, 1948. I received a master's degree and a PhD in physiological chemistry at the University of Rochester. I did a postdoctoral with a Nobel Laureate in the department of biochemistry at Stanford University School of Medicine. I have done sabbatical scholar-in-residence at MIT and at the University of California at San Diego.

Q Doctor, are you a toxicologist?

A People call me other things, but they also call me an environmental toxicologist.

Q And what is an environmental toxicologist?

A Environmental toxicologists are interested in understanding how chemicals in the environment will affect the health of human beings.

Q And Doctor, as part of your position as an

environmental toxicologist, have you consulted to other countries or other governmental bodies on --

A Yes.

Q -- mercury?

A I've been a consultant to our government on a variety of National Institutes of Health committees, Food and Drug Administration committees, the Environmental Protection Agency commission, Administration committees, I think the Atomic Energy - - the old Atomic Energy Commission. In foreign countries, I was consultant to the governments of China, the autonomous region of Inner Mongolia, Romania, Chile, and Mexico.

Q And when you consulted to these agencies and foreign governments, was your consultation related to mercury?

A The studies in Mexico concentrated on mercury. The studies in Inner Mongolia, southwest China, Romania and Chile emphasized the exposure of the population to arsenic in their drinking water.

Q Now, the substances that you consulted on, are they considered to be heavy metals?

A Yes. That is what I deal with in the laboratory, what I deal with a great deal in my teaching, and what I deal with a great deal in the

writing that I do.

Q So have you conducted research on heavy metals?

A Oh, yes, since 1955.

Q And have you conducted research on mercury?

A We, in 1957, published the first study which showed that in experimental animals, a new drug that we developed and others helped develop would prevent the lethal effects of mercuric chloride.

Q And Doctor, forgive me, but have you published articles on the effects of mercury?

A Yes, many. I can't give you the number. There are many.

Q And do some of those publications involve the effects of mercury on the health of individuals?

A Yes.

Q And you indicated that you teach. Who do you teach?

A I am very fortunate to teach a small class of about 15 or 20 students. These are seniors who are going on to graduate school, medical school, or professional schools like law school. These are very carefully chosen students that we think are going to be the future leaders of the community. And I teach these students how the biology that they have been

taught prior to my seeing them is relevant to their everyday life, to their exposure to metals, to mercury, to arsenic, to lead, their exposure to PCBs and other toxic substances.

Q Now, Doctor, you mention that you consult to governmental agencies. Are you familiar with a group that was convened by the White House to study the situation of mercury in emissions?

A The -- ?

Q To study mercury.

A I'm sorry, I didn't understand that.

Q Are you familiar with a conference that was convened by the White House to study mercury?

A Yes, yes, I was a member of that conference. I was a member of that panel.

Q And, Doctor, the other members of the panel, did they also possess expertise in mercury?

A Many of them had such an expertise.

Q Doctor, can you describe to the Court what the purpose of this panel was?

A A number of us were very concerned that three agencies of the federal government could not agree on an RfD, that is the safe dose, the dose that if you are exposed to each day for the rest of your life of mercury, there would be no harm done to you.

We were concerned that the three agencies of the federal government could not agree on this.

We were also concerned that the government, through the National Institute of Environmental Sciences, had put millions of dollars, not just a million, but millions of dollars into two studies; one up in the Seychelles Islands -- one down in the Seychelles Islands, and one up in the Faroe Islands, as far as the influence on the intelligence of children if their mothers ate a lot of fish that contain methyl mercury.

These two studies, at the time of the White House conference, were diametrically opposed as to the results, and we felt, a number of us felt that a conference should be held to try to resolve these issues and try to advise the three government agencies that it was rather bizarre that three agencies of the federal government could not look at data and come to the same conclusion.

Q Doctor, could you generally describe to this Court what the conclusions of that panel was?

A The conclusions were, and the recommendations were, that the University of Rochester investigators who were the primary investigators of the Seychelles Islands study, and the Faroe Island

group that was the University of Odense in Denmark were the primary investigating group, that they should get together and use the same kinds of tests that could solve this mystery.

And one of the problems, the major problem was that the Faroe Islands study showed that children borne of mothers exposed to methyl mercury in the fish and seafood they ate had certain definite learning disorders. Clearly shown. They used what we called the domain study. The Seychelles Islands study said there were no effects. And, again, each group used different tests to test the intelligence of the children.

We strongly recommended that both groups used the same tests. In addition, the Seychelles Islands study examined children at age 5. The Faroe Islands study examined children at age 7. We recommended, since there were results indicating harmful effects on the intelligence of the child at 7 years of age, that the Seychelles Islands study should be done at 7 years of age also.

And this was done subsequently, and so now we know that there are also results now in the Seychelles Islands indicating that boys in the Seychelles Islands population had certain intelligence

deficits at age 7 that did not show up at age 5.

We also recommended that the three government organizations, the FDA, the EPA and the toxicology group of the NIHS, should get together and try to solve their problems and communicate better. The result of this was the FDA, about two years ago, came out with the statement they agreed with the EPA that the RfD should be 0.1 micrograms of mercury per kilogram per day.

The other group, the -- can I look at my notes? I can never remember their name. I seem to have a block. The Agency for Toxic Substances and Disease Registry, the ATSDR, they still have not changed. And they haven't changed because they are using the old Seychelles Islands data, not the new data that is now published.

Q Doctor, have you prepared an outline to assist the Court in evaluating the toxicity of mercury?

A Yes. May I go through it?

Q Certainly.

A All right. First I'd like to talk about the forms of mercury, the target organ and the sources. Then I'd like to consider the methyl mercury disastrous epidemiology studies, the estimated daily

intake and retention of mercury for the general population. Pink disease, which is due to a form of mercury, is a perfect example of the medical establishment being conservative and wrong, and we will present evidence for that.

Very important studies now show that changes in the human gene that modifies the effect of mercury on a biological process. I want to point out there is now considerable evidence that autism is a mercury efflux disorder. I want to review ethyl mercury and methyl mercury for the Court. I would like to discuss Michelle Cedillo as far as her cumulative mercury exposure is concerned, and I would like to summarize.

Q Thank you, Doctor. So, would you kindly describe to the Court the forms of mercury?

A The purpose of my making this slide was to acquaint and/or review for the Court the diversity and toxicological properties of various chemical forms or species of mercury. Next, please. First of all, we have elemental mercury. Most of you are familiar with liquid silver, as it was called. Children used to play with this.

Elemental mercury in its liquid form is relatively nontoxic, but at room temperature, it emits a vapor, and that vapor is very, very toxic. Next

slide, please. Organic mercury. Here we have enigma number one. In the case of organic mercury, I could be exposed today to a very strong dose, a very toxic dose of an organic mercury compound, and no manifestation of that toxicity, no sign or symptom, might appear, would not appear until four or five months. And we'll talk more about that in a moment.

An example of organic mercury is methyl mercury found in fish. Another example is thimerosal, and a second enigma is why it was ever included in vaccines to begin with. We'll talk about that.

We have dimethyl mercury, which is extremely toxic, so toxic it's called the super toxic form of mercury. Most toxicologists don't like the term super toxic, but it is extremely toxic.

What happened was that a very talented young woman, a professor of chemistry at Dartmouth College, about maybe five or six years ago -- actually it was 10 years ago -- was working under the hood with dimethyl mercury, which all of us have used to calibrate a certain specialized scientific instrument.

While she was working under the hood she dropped one or two drops, according to her notebook, of dimethyl mercury on her latex glove. She took the glove off and disposed of it.

My wife and I were at a conference with her in Kuala Lumpur, Malaysia, approximately five months later. We were having dinner, and she said you know, I'm not sure I'm -- in fact, I'm not feeling well. I don't know whether I'm getting the flu or not. I've never had the flu, but I just don't feel well.

That was in December 1997, I think. She went home, and she was hospitalized in February. The sign and symptoms occurred five to six months later from the time she was exposed or dropped the mercury on her glove. This wonderful woman died of severe mercury poisoning I think it was in February of that year.

This is an example of the most toxic form of mercury, and it's an example of what we didn't know at the time. It was sent through the mail. We could order it any time we wanted. We let students work with it. It wasn't until this happened that now there are very rigid federal regulations as to how dimethyl mercury should be handled.

Q Doctor, what you have described, are they considered to be organic forms of mercury?

A Yes.

Q Does organic become inorganic?

A Yes. Almost all these forms of mercury,

organic mercury, are oxidized to what we call mercuric mercury.

Mercuric mercury has a very high affinity for the self-hydro groups of enzymes, for the active senses of enzymes. Mercuric mercury is a standard enzyme inhibitor used in the laboratory and can be used in vivo also to do this.

Q And that's considered a form of inorganic mercury?

A Yes. Mercuric mercury is a form of inorganic mercury.

Q And what is the relationship between the organic mercury and the inorganic mercury?

A The organic mercury in the human body, every one of them is converted or metabolized to some extent to mercuric mercury.

Q And is there another form of inorganic mercury?

A Can I have the next slide, please? We have mercurous mercury. This is Enigma No. 4, and that is why certain children were so hypersusceptible to mercurous mercury.

They got pinks disease, and we'll talk more about pink disease later, but this is a disease in which one out of every 500 children that were exposed

to this teething powder that contained mercurous mercury, one out of 500 of them got pinks disease.

Q Doctor, what are the target organs for mercury?

A The target organs, first of all, for mercury vapor, the brain; methyl mercury, the brain; thimerosal, the brain and the kidney; mercuric mercury, the kidney. The immune system is also affected by all of these.

Q Doctor, could you kindly describe to the Court where this mercury comes from?

A Can I have the next slide, please? Let's look at the sources of brain mercury as to where they come from.

We have mercury vapor from the restoration of a cavity in your tooth or teeth. You have a dental amalgam, as we call it. That dental amalgam continuously emits mercury vapor. Even in those of you who have mercury fillings in your mouth, those mercury fillings are continuously emitting mercury vapor, which gets into the mouth, gets to the cavity and finally finds its way to the lungs.

It's absorbed very quickly into the lungs, transported very quickly to the blood-brain barrier and to other tissues, but it's able to cross the

blood-brain barrier, which the blood-brain barrier is to protect the brain from noxious substances.

The mercury vapor is lipid soluble so it can diffuse right across. Once it gets into the brain the mercury vapor is oxidized to mercuric mercury. Once that mercuric mercury is formed it attaches to proteins and, in my opinion, stays there forever. There is much evidence in the literature that shows that it can remain there for 25, 30 years.

One other form of mercury, the methyl mercury, comes from fish. My students think this is a whale, but it's supposed to be a fish. The methyl mercury combines. First of all, when you ingest fish, the methyl mercury in the fish, 95 to 99 percent of it is completely taken up by the GI tract. It's transported into the blood.

The methyl mercury, as soon as it hits the blood, the methyl mercury cysteine complex is formed. That methyl mercury cysteine complex locks to a transport system, a system that carries the amino acid methionine from the blood into the brain across the blood-brain barrier, methionine being a central amino acid.

That transport system cannot tell the difference between cysteinyl methyl mercury and

methionine, so it's transported into the cell as methyl mercury. There it's slowly demethylated to form mercuric mercury, which again stays there.

Then finally we have thimerosal from vaccine, which as soon as it enters the body is very quickly metabolized to ethyl mercury. That ethyl mercury we don't know the mechanism, but we know from experiments that have been done that the ethyl mercury gets into the cell, gets across the blood-brain barrier, gets into the brain, and we know that the ethyl mercury is deethylated to form mercuric mercury.

So from all these different forms of mercury that a human being is exposed to you're going to have this mercuric mercury remaining in the brain doing some damage, as well as the parent compound like the methyl mercury, the ethyl mercury, the mercury vapor, doing some damage also.

Q So, Doctor, the mercuric mercury cannot leave the brain?

A From all the studies that have been published we have, methyl mercury -- well, the best example I can give you was that in Mexico there was a bottle of methyl mercury fungicide in the barn and a hog tipped it over and drank it.

The family didn't know this. The next day

they killed the hog for food. They threw some of it away. There were three young children in the family that ate this meat. Two of them become very, very ill. One died. Another one survived for about 20 years.

At the time of her death she was autopsied, and at that time, 20 years after the exposure to methyl mercury, her mercuric mercury level in the brain was 100 times above normal.

Q Now, Doctor, have there been some studies done on the effects of mercury on a person's health?

A On?

Q On a person's health.

A On children's health.

Q But have there been studies done by people exposed to things such as dental amalgam?

A Yes. May I have the next slide, please? The health effects of dental amalgam mercury now are getting more and more well documented, papers published in peer reviewed journals, and summaries show that monkeys that had amalgams put into their teeth and then later were exposed for a time to the mercury emitted from these amalgams, that the bacteria in their GI tract had increased resistance to antibiotics.

This is now accepted by most of the people that I know that amalgam mercury exposure will cause resistance, an increased resistance to antibiotics.

There is a study done that actually you can get a videotape of what's happening. In vitro, the mercury from dental amalgams will destroy snail brain neurons. They weren't able to get human neurons from the brain for obvious reasons, so they used snail neurons because snail neurons are big and you can look at them.

In this video you can see the actual disintegration of a neuron after exposure to amounts of elemental mercury equivalent to what would be emitted from the amalgams in our teeth.

It's generally agreed that there is a hypersensitivity problem as far as dental amalgams in humans are concerned. There's not agreement as to what percentage. One figure is 0.5 percent of the human population is hypersensitive. Another figure is 15 percent. There just is not any agreement.

As far as the innate toxicity in humans, there are studies for it and studies against it, and we still have a lot more work to be done along these lines. The problem is that most of the signs and symptoms of mercury toxicity, actually what we call

micromercurialism, are very nonspecific. You can't say they're just due to the mercury itself, so a lot more has to be done than that.

There certainly is, and I hope to present the evidence for this or present the reference for it, now a hypersusceptibility of a certain percentage of the population to amalgam mercury.

Q Doctor, does mercury ever disappear?

A No. Mercury is an element. You can't destroy an element.

Q Doctor, when you look at this next slide, does that indicate to the Court what happens to mercury?

A Yes. This more or less shows you where the methyl mercury in fish comes from. You have elemental mercury vapor in the air. This elemental mercury vapor is always being emitted from the ground. It's being emitted from the ocean, and it's being emitted from electric utility plants that produce electricity by burning fossil fuel oil and coal.

So in the air you have elemental mercury. This soon settles down by rain and other means into the water or the lakes, oceans, et cetera, and the elemental mercury, the Hg^{0}, is oxidized to mercuric mercury.

The mercuric mercury, as you see down in the sediment, gets down in the sediment also, and that mercuric mercury is oxidized to mercuric mercury, and then there are certain bacteria found in the sediments of oceans and other places that will methylate mercuric mercury to form methyl mercury.

Unicellular organisms will eat a little bit, will constantly pull this into them from the sediment and from the ocean where it's also moved into, and it goes through a process we call biomagnification; that a unicellular organism has a little more, four or five cell organisms will have more and finally a small fish will concentrate more, so by the time it gets to the predator fish there is a tremendous increase in the concentration of methyl mercury in the predator fish as compared to what was originally in the water.

Q Doctor, have there been studies done about the health effects of exposure to mercury?

SPECIAL MASTER HASTINGS: Ms. Chin-Caplan, before we go on to that I think now would be a good time. Let's take our morning break. We'll take a 15 minute break.

I ask one particular thing. We have limited restroom capacity on this floor. Folks, if you could if you see one of the counsel or witnesses fighting

you for the next stall, please let them go first so we can get back and finish up.

We'll take a 15 minute break. You folks at home, you might get some music, but we'll take a 15 minute break, and we will be back on then.

THE WITNESS: Thank you.

(Whereupon, a short recess was taken.)

SPECIAL MASTER HASTINGS: All right. We're ready to begin again for those of you listening in.

I wanted to remind both counsel and the witness, especially for those folks at home, we need you to speak into the microphone as best you can so the folks listening in at home can hear, as well as those here in the courtroom.

With that, we are back on the record. Ms. Chin-Caplan, you can go on with the examination of Dr. Aposhian.

BY MS. CHIN-CAPLAN:

Q Doctor, before we broke I asked you if there are studies which have looked at the effects of mercury on health.

A Right. In this slide we point out the methyl mercury disasters in our epidemiology studies.

The next slide please? In Minamata, Japan, in the 1950s what was first noticed was the cats would

do a dance on the seashore. They would chase their tails. They traced this back to their eating fish. Then they began to find birds dead on the shore, again birds that had been eating fish autopsy showed.

About two years later it was found there was a factory that was dumping mercury waste into Minamata River. That river would empty into the Minamata Bay. Because of the geology involved, the bay did not empty completely when the tides changed, so the mercury buildup settled into the sediment where it was converted to methyl mercury.

The people living around Minamata Bay were primarily fishermen. Fish were their primary source of protein, and it was soon found that the people eating the fish had certain neurological signs, including movement disorders and that, more importantly, the children born of women who had eaten this contaminated fish, although the mothers did not appear to have any signs of mercury toxicity the children had severe mercury toxicity characterized by some as what we call Minamata cerebral palsy.

There were other central nervous system/ brain effects noted in these children, so this was the first methyl mercury disaster, you might say.

In Iraq in 1970 there was a famine. Because

our government looks after people all over the world, because there was a famine our government donated to Iraq bags of grain seeds so the farmers could take these seeds and plant them, get the grain and make flour, make bread, et cetera, et cetera.

The people were so hungry that they took the seed, which is always protected by a fungicide, a methyl mercury fungicide so the seeds' biological activity is not inactivated by a fungus infection. On the bags, I think 110 pounds bags of grain or seed that was sent, it said Poison, Do Not Eat in either English or in some cases in Spanish.

What the people in our government did not realize was that most Iraqi farmers are illiterate in Arabic, as well as of course being illiterate in English, so they took this contaminated seed and ground it up, made flour, made bread, and there were 6,000 cases in Iraq of methyl mercury poisoning.

This was one of the two studies that our government depended on, the Minamata and Iraq study, that made our health officials concerned about whether low levels of methyl mercury in fish that our children in this country are exposed to might be harmful to them.

Next slide, please? Therefore, the

Seychelles Islands study and the Faroe Islands study was set up, and I spoke to you about them already. The enigma was why are they so different? We now know there are a number of reasons that I'll speak to in a few minutes as to why they're different.

Originally before the White House Conference the Seychelles Islands study and the Faroe Islands study did not agree at all. However, a study done in New Zealand agreed with the Faroe Islands results, and this was very important for our EPA to switch from using the Iraqi data and the Minamata data to the Faroe Islands data as far as establishing an RfD.

Q Doctor, what is an RfD again?

A The RfD is the amount of mercury in this case, the micrograms of mercury per kilogram of body weight per day that you can be exposed to the rest of your life, every day of the rest of your life, with no harmful effects.

Q And is that a steady state of exposure?

A The RfD would indicate what a steady state exposure would be, but none of us are exposed, none of us have a steady state exposure, to methyl mercury when we eat fish, for example.

Q Doctor, what is the reference dose?

A The EPA reference dose is 0.1 micrograms of

mercury per kilogram per day.

Q Doctor, did you compare that to the dosages of mercury that Michelle Cedillo received in her vaccines?

A On her first vaccine dose when she was I believe one day old, the Cedillo child received 12.5 micrograms of mercury.

She had a body weight of approximately 3.6 kilograms, and that meant that her exposure was 3.5 micrograms of mercury per kilogram per day, which is 35 times the EPA RfD, or you might say the EPA safe dose. So this is quite high, and you'll see later on there are even higher doses that we'll point out.

What was very interesting to all of us -- I first heard about it on an airplane when I was going to a meeting with someone from Montreal. This young woman in Montreal is a professor of epidemiology studying people in the Amazon who were eating fish that were contaminated with methyl mercury.

She had two groups. One group had no signs of methyl mercury exposure. The other group had severe signs. She traced this back that the group with no signs had eaten a lot of oranges and citrus. We think this again may be one of the reasons why the Seychelles Islands study could not come up with these

effects that the Faroe Islands did.

I think the world map may be shown in the next slide. The Faroe Islands is roughly I think right there. The Seychelles Islands are roughly around here. Right there. This is a tropical or subtropical area where there's a lot of citrus grown, a lot of oranges.

Q Doctor?

A Those of us who have been to the Faroe Islands, there are hardly any trees, never mind citrus trees. The people had to cut the trees down -- it's so cold up there -- for fuel years ago, and to buy an orange? I wanted an orange one day when I was there for a week. I couldn't even find an orange for sale.

One reason for the Seychelles Islands study not showing the effects that the Faroe Islands study did was the Faroe Islands subjects did not have the protection of citrus.

Q Doctor, are children more susceptible than adults to the effects of mercury toxicity?

A Will you say that again, please?

Q Are children more susceptible to the effects of --

A Yes. May I have the next slide? I think it's on the next slide. First of all, let me just

point out -- that's all right. That's okay.

Let me first point out that everyone is exposed to mercury, and this is from the National Research Council monograph that I was involved in the writing of shows the estimated daily intake and retention of micrograms per day of mercury in the general population not occupation exposed to mercury.

The numbers in parentheses is what is retained in the body. The numbers outside the parentheses is the exposure. You can see that the greatest exposure to the American population to mercury is via dental amalgams.

Inorganic mercury is inconsequential, especially if very little is retained, 0.3, but of methyl mercury almost all of the exposure to methyl mercury is retained. The methyl mercury stays in the body.

The next slide I think will say something. Children are not small adults. Very often people just think they're smaller. We know their metabolism is different. We know that they absorb metals from their guts at a faster rate than an adult. The central nervous system, the brain of embryos and children, are the most sensitive to methyl mercury. That's been clearly shown in animal studies and in human studies.

Methyl mercury crosses the placenta. The placenta does not protect the baby or the embryo against methyl mercury, and methyl mercury and ethyl mercury have some similar properties, but their toxicokinetics are different. The rate of change in the body, the so-called toxicokinetics, are different for the two.

Q Doctor, moving from methyl mercury to ethyl mercury --

A Can I have the next slide, please? Okay. The enigma for many years has been why is thimerosal in vaccines, and this was brought up in a congressional hearing that was held a number of years ago. It must be four or five years ago.

The next slide, please? Since that time, the FDA has pointed out in the *Federal Register* of 1982. It states, "The panel concludes that thimerosal is not safe for over-the-counter topical use," for drugs sold over-the-counter for topical use, "because of its potential for cell damage if applied to broken skin and its allergy potential."

It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed. Its bacteriostatic action can be reversed wherever it is. That's 1982.

Effective October 11, 2005, and these are not my words. This is a direct quote from the *Federal Register*. The October 11, 2005, *Federal Register* stated:

"Effective April 1, 2007," a few months ago, "a number of active ingredients have been present in over-the-counter drug products for various uses as ascribed below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified use."

Thimerosal is quoted as one of these ingredients.

Q Doctor, what was the effect of this ruling in the Code of Federal Regulations?

A The net effect has been it has prevented and stopped the addition of thimerosal to a tremendous number of health products, including vaccines.

About the only vaccine that still has or the only vaccine that children are exposed to that still has thimerosal in it is probably influenza, although one can obtain now influenza vaccine free of thimerosal.

Q And that's to your knowledge currently? That's to your knowledge?

A Yes.

Q Doctor, you had mentioned earlier about pinks disease.

A Yes.

Q What is pinks disease?

A Okay. Between approximately 1890 and 1950, a disease called acrodynia -- it has other names that are here also; next slide, please -- was found in young children, very young children.

I put this first because I want you to remember this, please. The medical establishment did not accept mercurous mercury as the cause, and we'll say this again.

The next slide, please? Children with pink disease were miserable babies and toddlers. They were bright pink or red in color. They were photophobic with raw beef hands and feet. They had anorexia, peeling skin and gangrene. In other words, the blood could not get to the extremities.

Next slide, please? The mortality of children who got pink disease was 5.5 to 33 percent, a very high mortality.

Now, at the time viruses were beginning to become known. Research was showing that some diseases were caused by viruses, and also at the same time

vitamins were the scientific rage.

They were discovering new trace elements and vitamins that were required for good nutrition, so it was fashionable, and those are the words the medical literature historians use. It was fashionable at the time to call it a viral disease or a nutritional deficiency.

The next slide, please? It was found that mercurous mercury in teeth powder was the cause. What you want to remember also is that of 500 children exposed only to this teeth powder that contained mercurous mercury, only one would develop acrodynia. Only one would get pink disease, one out of 500.

So one must ask were these children hypersusceptible to the effects of mercury? The next slide, please?

Q Doctor, when you say hypersusceptible, are you referring to the fact that the individual may be more susceptible to developing this disorder because of their genetic background?

A Yes, and I'll later point out that we now have evidence of a specific gene that has now been found that is affected by mercury.

Q Thank you.

A The cause of pink disease was believed to be

a hypersusceptibility of mercury, in particular mercurous mercury. The medical establishment would not accept mercurous mercury in the teething powders as the cause.

Now, let me say the American medical establishment has always practiced excellent medicine. We're healthy for this very good reason. But, it has also been extremely conservative to new ideas. Because pink disease has never been proven by the scientific method to be mercurous mercury, but when the government prohibited the use of mercurous mercury in teething powders pink disease disappeared.

Again, we must ask were the 5.5 to 33 percent fatalities due to hypersusceptibility to mercurous mercury toxicity?

Q Doctor, you indicate that there might be a potential genetic susceptibility to developing mercury toxicity. Are there any studies that support what you're saying?

A Ma'am, yes. So the question really is is there evidence for genetic differences or hypersusceptibility in response to mercury exposure?

Professor Woods at University of Washington, who has worked with mercury for many, many years and worked with dentists, showed that for dentists with

low level occupational exposure to mercury 85 percent had the expected urinary porphyrin profile.

Now, porphyrins are chemicals in our body that are on the way to making the hem of hemoglobin, so it's a very important pathway. What happens in this pathway as far as a change in the pathway can be detected by examining the urine for porphyrins, so this is porphyrinuria or a porphyrinuria state.

Woods has found, and it's now published in one of our primary, first class, international, peer reviewed toxicology journals, that 85 percent of the dentists with a low level occupational exposure had the expected urinary profile. The expected urinary profile is different from people not exposed at all. There are certain porphyrins that appear in the urine.

Fifteen percent of these dentists with the same general exposure had atypical porphyrinuria. They had a new compound, a new porphyrin that was found in the urine. This new compound was due to what we call polymorphism or changes in the letters of the genetic code in the gene.

The matter was due to polymorphism in the human gene that modifies the effect of mercury on a biological process. This human gene is a tongue twister, the coproporphyrinogen oxidase gene. This

has been published. It was published in 2005, and there have been subsequent papers.

Now, mercury review articles do not mention this. All the articles that some of my dearest friends that I have the greatest respect for just don't mention this article because they obviously are ignorant of this article, or as we get older we get more narrow in our vision and perhaps those who write some of these articles just don't realize that genetics has become more and more important in toxicology.

So the mercury review articles do not mention this perhaps because the authors are not cognizant of genetics and genetic toxicology as an important area of human toxicology.

The genetics of mercury toxicity is just beginning, and this paper of Jim Woods is going to be a classic as a first one. This is potentially a biomarker that we can test people in the future as to whether they are going to be susceptible to mercury toxicity.

Next slide?

Q Doctor, how does this relate to autism?

A Okay. I'm going to offer you evidence to try to answer the question is autism a mercury efflux

disorder. Now let's define what a metal or mercury efflux disorder is because there is good medical evidence that we have such disorders.

Metals get into our body from our food, from the air that we breathe, gets into the blood, transported to tissues, and normally because of the homeostatic mechanisms and a large accumulation of toxic levels of those metals are prevented by a mercury efflux, a transport system that takes the mercury out of the cell or the metal out of the cell.

Could you go back, please? I'm not ready for that. So an efflux disorder is a problem with getting a metal, in this case mercury, out of a cell.

So what's the evidence for this? Let's skip the next slide. We'll come back to that much later.

Wilson's disease. All right. Wilson's disease has been known since the late 1800s. It's a genetic disorder characterized by a large amount of copper in the tissues. People with Wilson's disease, or another name for it is hepatolenticular generation. People with this disease cannot get rid of copper. The copper accumulates in the brain, in the stem in particular, and in the liver.

My first academic appointment was at Vanderbilt University School of Medicine, and a

neurologist called me one day and said hey, Vas, I hear you're making penicillamine in the lab as a possible cancer chemotherapeutic agent. I said yes, Burt, we have plenty. Why?

He said well, did you see that paper by John Walsh from Cambridge? I said yes. Why? Do you have a Wilson's disease patient? He said come to my office tomorrow morning. I went there, and in a few minutes a woman staggered in, hardly able to walk, hardly able to talk, about 24, 25 years of age.

In those days, the FDA regulations practically did not exist, so we took some penicillamine, and we very carefully prepared it, gave it to the pharmacist in our hospital, and the urologist gave the penicillamine to this woman.

A month later Burt Sprofkin called me into his office and said come and see. I walked into the office. The young woman stood up, came over and kissed me on each cheek. I was a very young man then. We just didn't do that sort of thing. She was normal.

The Wilson's efflux disease is now treatable. It's one of the few genetic diseases that you can give a chelating agent to and the signs and symptoms disappear. We now know -- this happened

maybe five or 10 years ago -- that Wilson's disease is due to a mutation in a gene called the ATP7B gene.

Next slide, please? This gene codes for the ATP7B protein, which is a copper transport protein, the protein that allows copper efflux. This is expressed primarily in the liver where it's deficient, like in Wilson's disease.

The next slide, please? There is hepatic and central nervous system copper accumulation and toxicity.

Can everyone hear me all right?

MALE VOICE: Yes.

THE WITNESS: Thank you. There are signs of hepatic and central nervous system or brain signs and symptoms.

What is unusual about Wilson's disease is it's a treatable genetic disorder, so we think other efflux diseases -- maybe even autism -- are treatable.

Next slide, please?

BY MS. CHIN-CAPLAN:

Q Doctor, before we move on, copper. Is that considered to be a heavy metal?

A Yes, copper is a heavy metal.

Q As is mercury?

A As is mercury.

Q Doctor, have there been other studies that support what your thinking is, that autism could potentially be an efflux disorder?

A Let me review some papers if I may. The first paper is entitled *Reduced Levels of Mercury in First Baby Haircuts of Autistic Children*. Amy Holmes was a practitioner, a private practitioner, not connected with a university, not connected with a research group, treating autistic children in Baton Rouge. She thought that she knew about the speculation and thimerosal being involved in autism, and she decided that one way that we may be able to show whether this is snow or not is to get baby hair.

The first haircut. Most of us who have children still have first baby haircut. My wife won't let me throw ours away anyway. So she collected this from her parents of her patients who had autism and also took some controls, and she was able to show as the next slide will show you that the mercury level in the hair of autistic children was much less than in the control group.

Now, this shocked me at first because I was not thinking about mercury efflux disorder. Now, this study has been confirmed by the MIT group. There's a very good group at MIT. This original study used a

commercial lab that used atomic absorption detection. The MIT group used a more sophisticated detection system.

So two different systems have shown that autistic children have less mercury in their hair than the control group. There have been other criticisms that Amy Holmes is a private practitioner, what do private practitioners know?

Q Doctor, before you go on, so the fact that they have less mercury in their hair than controls, what does that mean?

A It means that, well, we know that the hair is an excretory organ and that the hair is reflective of the mercury or the metal in the blood, and the blood is a reflection of the mercury in the tissues, and so the fact that the autistic children had less mercury in their hair was a hint or indication that perhaps there was mercury efflux disorder.

Q Thank you. Was there another study that supports your belief that mercury autism could potentially be an efflux disorder?

A Dr. Jeff Bradstreet was the lead author in a study entitled, *A Case Control Study of Mercury Burden in Children With Autistic Spectrum Disorders*. This group gave DMSA a chelate agent that would bind the

mercury in the cell and would not need the efflux mechanism. The DMSA mercury chelate would come out of the cell and the mercury would be excreted in the urine.

This study has shown that DMSA increased the urinary excretion of mercury three to sixfold more than found in nonautistic children. Now, this is an indication of an increased body burden of mercury in these children.

Q Now, doctor, you say it's a chelating agent. What exactly is a chelating agent?

A The word chelating comes from the word chelos from Greek which means claw, like the claw of a lobster. You can think of a chelating agent as the lobster claw that hooks up and ties up the middle. The chelating agent has a greater affinity for that metal than the protein to which the metal is attached in the cell. The metal and the chelating agent form a chelate.

The chelate is also more water soluble than the metal by itself. You must remember metals just don't float around in the body themselves. Metals are attached to proteins and other self-hydro groups. This chelating study is an indication of an increased body burden.

Q Doctor, so is this like an artificial means to remove a toxic substance that the body itself cannot remove?

A Yes. Yes. Now, there's one more critical study. When I was asked to testify before the Institute of Medicine I pointed out that it was a shame that with all the money that has been spent to study autism no one had gotten tissues that were available at various banks of autistic children to show whether there was an increased concentration of mercury in the tissues because if there is then that would be another piece of evidence for mercury efflux disorder in autistic children.

Just within the last month or so I think the next slide will show a study by Adams in 2007 where he took baby teeth. Teeth are an organ. They're a nonexcretory organ. They're one of the tissues or organs of our body.

Baby teeth were used by Nedelman at Harvard many years ago to show that children exposed to levels of lead in which there are no obvious signs of toxicity, these children with subclinical lead exposure as we called it had teeth that contained high amounts of lead in that case and their intelligence was impaired. So the use of baby teeth for detecting

mercury, or lead, or other metals is well-documented in the scientific literature.

What Adams found was baby teeth mercury in autistic children is greater than in nonautistic children. In his controls he was able to show the zinc and the lead were not different. It was just the mercury that was different. So again it appears autistic children have a greater body burden of mercury.

Q Doctor, what do these four papers tell you about the relationship between mercury and autism?

A On the next slide, please. Significance of these four papers. Next slide. Autistic children lack an effective mercury efflux system. They can't get rid of mercury in the cell. They can take mercury into the cell, but they can't get rid of it. That's true for their brain, it's true for about all the tissues in the body.

Q And, doctor, when you say it's true for all the tissues in the body does that include the immune system tissues as well?

A Absolutely. Absolutely. There are a lot of proteins with self-hydro groups that are in the immune system, as we call this huge system, and the mercury has a great affinity for self-hydro groups and when

that combination is made usually that protein cannot do what it's normally supposed to do.

Q So, doctor, what would be the danger associated with an inability to excrete mercury from say a system like the immune system?

A I'm sorry. I didn't hear you. Would you speak louder, please?

Q Sure. What would be the dangers of an increased level of mercury in a body system?

A Can we wait until we get to a later point?

Q Certainly.

A Thank you. This shows you what ethyl mercury efflux from autistic tissue -- if I have a diagram it allows me to clear my thinking. I hope it might help some people here. At the top is nonautistic tissue if you will. The blue spots are mercury. In a normal individual you're going to have the mercury moving from the tissue to the blood.

It will move from the blood to the hair or go up the other area to the urine and feces, but essentially it goes to the hair as one of the excretory organs. In an autistic child there is an inhibition of the mercury efflux system so that the mercury stays in the tissue, the blood level is low and the hair level is low.

Q And is that an indication that the autistic children are unable to excrete mercury?

A Yes. That's a very clear indication. It appears that autistic children lack an effective mercury efflux system, which will affect many body systems including the immune system.

Q And, doctor, what would be the effect of having an existing mercury load on the body system?

A Can we skip the slide? We first talk about the Pichichero study in which he took normal children and vaccinated them and followed the toxic genetics, how fast the mercury came out, how fast the thimerosal mercury came. The interpretation, these are his interpretations, administration of vaccine containing thimerosal does not seem to raise blood concentration of mercury above safe levels in infants.

Ethyl mercury seems to be eliminated from blood rap

104%104a the stools after parental administration of thimerosal in vaccines. The problem with this study is it was done with normal children, children who are not autistic, children who do not have a mercury efflux disorder. If he had also taken autistic children, children with a mercury efflux disorder, he would have found that the kinetics were entirely

different.

He would not have gotten these kinds of figures that are in his paper. The next slide, please? Thimerosal pharmacal kinetics obtained using nonautistic children are not the same as those expected for autistic children. The latter appear to have different efflux kinetics.

Q Doctor, with the different efflux kinetics, does that mean that the children retain mercury in a greater amount than control children?

A Yes. Yes.

Q Doctor, the fact that they retain mercury to a greater extent, is there harm to all the body tissues such as the immune system?

A Yes. Wait. Let me first answer your question. I many years ago resigned a tenure track position to go study enzymology with a Nobel Laureate in the Department of Biochemistry at Stanford University School of Medicine, and one thing we learned very quickly was if you wanted to inhibit an enzyme just throw in mercuric mercury. We also could show that you gave mercuric mercury to an experimental anal, that same enzyme would be inhibited in vivo.

So we know that mercury gets into all the cells, and in one form or another it will be there and

it will affect all the functions that are going on in the cell to a different extent, but certainly the immune system would be one such function. Now, I would also -- if I can have the next slide -- since we're talking about autism, everyone says well, the IOM said the epidemiology studies clearly show there's no connection between thimerosal and autism.

There's no cause, it's noneffective. I want to remind all of us that epidemiology studies cannot prove cause and effect. If you go into any medical textbook of epidemiology it will clearly say that epidemiology studies reveal statistical correlations. Now, when you correlate you're comparing one or two items or three or four items. If you don't pick the right data to compare, you don't pick the right groups to compare, then you're going to get a negative answer.

The key to being a good epidemiologist is to pick the right data. This certainly has not been done in my opinion.

Q Doctor, have there been recent studies that have looked at the differences between methyl mercury and ethyl mercury in primates?

A No. There has been a very nice study by Dr. Tom Burbacher, et al., who has been working with

methyl mercury since at least the 1990s. If I can have this next slide, please? I think it's the next slide. Here we are. Thank you. He took infant monkeys. You can't do these studies obviously in human infants, but he took infant monkeys and gave methyl mercury by oral gavage and gave thimerosal by injection, trying to replicate as much as possible the vaccine schedules in a monkey.

What he was able to show was that methyl mercury had a half life of 21.5 days in these animals whereas thimerosal had a biphasic half life, one at 2.1 days and one at 8.6 days. It's interesting to note that this -- again, these are normal animals -- 8.6 days is not too far away from the value the Pichichero study showed in humans.

What was of very great interest, especially to me and to other people that are very much interested in this sort of thing, is that even though the total mercury in the brain of the monkeys receiving thimerosal was one-third that of the total methyl mercury administered to animals the brain inorganic mercury, which many of us believe to be very, very toxic, as a percentage of the brain total mercury was 34 percent.

Thirty-four percent of the total mercury in

the brain was mercuric mercury for those animals who got thimerosal while only seven percent of the total mercury in the brains of the animals getting methyl mercury was inorganic.

Q So what is the significance of that?

A That these two agents are doing different things to the brain. That the thimerosal in particular is leaving in the brain a form of mercuric mercury that's going to stay there a very, very long time. Next, I think.

Q So, doctor, when you compared methyl mercury to ethyl mercury did you come to any conclusions at all?

A There's a tremendous amount of scientific literature dealing with methyl mercury. It's been studied a long, long, long, long time. There's not as much with ethyl mercury. Although the two molecules methyl mercury and ethyl mercury are different and many of the properties are different there are also similarities. You can't say there are no similarities.

The distribution in the blood, the compartmentalization in the blood of methyl mercury and ethyl mercury are the same. The main route of excretion for both of them is via the feces and the

bile. Now, the methyl mercury scientific literature can serve as a guide or a path for investigating ethyl mercury, and a lot of people are doing this at the present time.

Q Doctor, when you looked at this data did you come to any conclusions about autism and its relationship to mercury?

A In my opinion the scientific evidence supports the concept of mercury containing compound thimerosal triggers a response in many systems, let's say in the immune system. Later on I'll show a diagram that will pull all this together for you if I may. But I also want to point out that most complex diseases are the results of three factors: genetic susceptibility, environmental exposures and the stage of development.

I think the next slide will have that figure hopefully. Here we are. Again, you must forgive me. I have to see things more than just think about them. This is a possible path for ethyl mercury toxicity that I've tried out on some of my associates and bright students. We have thimerosal that as soon as it gets into the body it's going to be converted into ethyl mercury.

That ethyl mercury is a form of

environmental stress if you will, and the susceptibility of people to ethyl mercury, probably there is as I show you the genetic component of the dentist with the amalgams probably effective here, and the environmental stress of ethyl mercury goes on to cause immune disregulation. The immune disregulation, the result of that will be immunosuppression.

Now, if there's a measle virus in the system at the time this immune suppression should allow that measles virus to exert its pathogenic effects and this should cause encephalopathy going on to autism. Now, another way of looking at it also is that ethyl mercury causes a decrease of glutathione. Glutathione is the primary protection in the body against mercury. It transports mercury out of the cell.

It transports mercury out into the bile. It's a very essential component as far as safety of mercury or the decrease of toxicity of mercury. The decreased GSH will result in an oxidative stress and increase the amount of free radicals and both the ethyl mercury directly where we have this environmental window -- the brain as you remember is developing continuously at least until puberty and some people will say it's developing even after puberty.

So we have these processes going on in the brain and we know from the *Biology of Development Annals* that these windows are very, very narrow, they're very narrow, and that the oxidative stress or the ethyl mercury can affect one of these environmental windows at a particular time. Now, we're often asked why didn't everyone, why didn't every child that gets vaccinated get autism?

Now, I want to remind you that not every child got his second batch of vaccination at age one month. Some got it at age one month plus three days, some got it at age one month, five days, some got it at age one month minus two or three days. So this window could be a very narrow one where ethyl mercury or the oxidative stress could have this affect.

So one possible explanation as why all children didn't get autism from vaccination is that they all were not vaccinated at exactly the same time in development.

Q So, doctor, are you saying that the environmental agent has to come in at a particular point in time to cause harm?

A I didn't quite hear what you said.

Q I said are you saying that the environmental agent has to come in at a particular point in a

child's development to cause harm?

A Yes. Absolutely. We know that from studies with many, many agents. Textbooks are filled with agents that have a specific time in which they exert a toxic effect, and if the exposure is during that time you get that toxic effect, if it's after that time there will be no toxic effect, if it's before that time there will be no -- so there's a window for every process.

Q And does that include the immune system as well?

A Absolutely.

Q Now, doctor, at some point in time did you determine whether the amount of mercury that Michelle Cedillo received exceeded any reference point?

A Yes. What we're plotting here is first of all the EPA RfD down in the bottom. They should be different symbols, but all right. We'll take the symbols that we have. And then we're plotting the micrograms of mercury per kilogram body weight for Michelle Cedillo.

At the first day of her life, she received her first vaccination, and at that time, that vaccination gave her 34 times in one time, a bonus, 34 times the dose that's considered the EPA RfD for

methyl mercury, all right? At two months it was 43 times the EPA RfD. At eight months you can see 36. So these are large doses compared to what the EPA considers a safe, continuous dose of methyl mercury, and these doses of thimerosal are given at one time not every day over a period of time.

The next slide will show something about the cumulative dose. We're now plotting for the Cedillo child the cumulative mercury exposure and comparing it to the standard EPA RfD for methyl mercury. You can see that the exposure, we're not talking about body burden now we're talking about exposure, what the child was exposed to, really 10 micrograms of mercury per kilogram, which is almost 100 times more than the RfD.

Q Doctor, did you come to any sort of conclusions whether the thimerosal dose that Michelle Cedillo received was a substantial contributing factor to the development of her neurodevelopmental problems?

A Yes. Michelle Cedillo received 75 micrograms of mercury from ethyl mercury of thimerosal containing vaccines during the first four months of her life. By 18 months of age she received a total of 137.5 micrograms of mercury from her vaccines. No matter how one calculates it and compares it these are

not normal exposures of a child to a toxic agent, especially if she should have genetic hyper susceptibility to mercury species. Next slide, please? Okay.

Q Doctor, in your opinion the dosages of ethyl mercury that Michelle Cedillo received, could that be a substantial contributing factor to the onset of immune disfunction?

A Absolutely. There are papers, especially from Scandinavian countries, very good papers, that show that mercury will disturb immune function and disturb immunoregulation. No question about it.

Q And, doctor, having given all of this information to the Court would you like to summarize what your opinion is?

A All right. The chemical forms of species of mercury are different chemically and have different toxicological properties. The greatest exposure to mercury in the population is via dental amalgams. The CNS, the brain, the central nervous system of the fetus and children are most vulnerable to elemental and organic mercury. Medical ignorance and conservatism were responsible for Pink Disease being around as long as it was.

Methyl mercury from fish can accumulate in

women and be transferred across the placenta. Scientific evidence supports the occurrence of a mercury efflux disorder in autistic children. Ethyl mercury is converted to mercuric mercury faster than occurs for methyl mercury.

Mercuric mercury in the brains of ethyl mercury treated infant monkeys was 34 percent of the total mercury, but for the methyl mercury treated animals it was only seven percent as shown by Burbacher, et al. Although the two molecules methyl mercury and ethyl mercury are different in structure and many of their properties are different there are similarities.

Methyl mercury can act as a guide for understanding ethyl mercury. For some reason the next sentence did not come across here, and I have it if the Court will allow me to read it. It is plausible that Michelle Cedillo may have genetic hyper susceptibility to mercury species which would trigger unusual immune and toxic responses. I think that's the last one. Do I have the next one? Yes.

MS. CHIN-CAPLAN: Thank you, Doctor.

SPECIAL MASTER HASTINGS: Thank you, Ms. Chin-Caplan.

Did the Respondent have any cross-

examination for this witness?

MR. MATANOSKI: Actually, we do, Your Honor, but we thought in view of the time we were going to ask for a short break before we did our cross anyway, but perhaps we should just take a lunch hour now and come back and do the cross after that.

SPECIAL MASTER HASTINGS: Does that sound reasonable to you, Ms. Chin-Caplan?

MS. CHIN-CAPLAN: Yes. Do you know how long you're going to be for the cross?

MR. MATANOSKI: Probably about an hour.

SPECIAL MASTER HASTINGS: All right. With no objection, let's go ahead and take our lunch break now, and we'll start again in one hour. It's now 12:10. We'll start about 1:10.

(Whereupon, at 12:10 p.m., the hearing was recessed, to reconvene at 1:10 p.m. this same day, Monday, June 11, 2007.)

A F T E R N O O N S E S S I O N

(1:11 p.m.)

SPECIAL MASTER HASTINGS: I think we're ready to go back on the record here. If counsel are ready I think the witness will retake the stand, and I believe we were going to begin the cross-examination of Dr. Aposhian.

Ms. Renzi, go ahead when you're ready.

MS. RENZI: Thank you, Special Master.

Whereupon,

H. VASKEN APOSHIAN

having been previously duly sworn, was recalled as a witness herein and was examined and testified further as follows:

CROSS-EXAMINATION

BY MS. RENZI:

Q Good afternoon, Dr. Aposhian. Dr. Aposhian, you are not a medical doctor, are you?

A Excuse me. Could you speak louder? I can't hear you. Please?

MS. CHIN-CAPLAN: Excuse me for one minute. Special Master, could we just ask the gentleman sitting at the Respondent's counsel table to identify himself?

SPECIAL MASTER HASTINGS: Okay.

MR. MATANOSKI: This is Dr. Jeffrey Brent.

SPECIAL MASTER HASTINGS: Dr. Brent is sitting to your right?

MR. MATANOSKI: No.

SPECIAL MASTER HASTINGS: Oh, I'm sorry. Your left. Okay.

MR. MATANOSKI: Dr. Brent is sitting to my left.

SPECIAL MASTER HASTINGS: Right. Right. Okay.

Please go ahead then, Ms. Renzi.

BY MS. RENZI:

Q I'm sorry. Dr. Aposhian, are you a medical doctor?

A No, I'm not.

Q Are you a medical toxicologist?

A It depends how you define the term medical toxicologist. What is your definition?

Q My definition would be someone who has both an M.D. and an expertise in toxicology.

A I'm not a medical toxicologist.

Q Are you an immunologist?

A I'm not an immunologist.

Q So you don't do experiments on immunology in your lab?

A We don't always do experimental immunology.
Q You are not a neurologist. Is that correct?
A I'm not an M.D., so I can't be a neurologist.
Q You don't know how measles virus affects the brain?
A I spent 10 years of my research studying virology. I have papers published in *The Journal of Virology*. I was the first one to show that a virus could transfer genetic information that was not in it originally. These are published procedures in the National Academy of Sciences and other places. I have a background in virology.
Q Have you ever published anything on measles virus?
A As far as I remember I don't think I have.
Q You are not a geneticist, are you?
A I'm considered also to be a biochemical geneticist. The man I worked with for three years at Stanford University got the Nobel Prize for studying while I was with him for determining how DNA was synthesized, and was the first one to synthesize a biologically active DNA molecule. So from the years 1959 after I also went to Tufts University School of Medicine to teach to 1967 I was strictly a biochemical

geneticist.

Q Do you study the genetics of humans? Have you ever done that, sir?

A Have I done what? I'm sorry.

Q Human susceptibility? Genetic susceptibility in humans?

A Yes. We published a paper, it was the first paper of its kind, in which we showed that a mother and her son in Mexico had a polymorphism in the gene that metabolized arsenic to a more toxic form. We have permission. We have a human experimentation committee at our school, and we all must be approved by that human experimental committee or institutional review board before we can do human studies. I do have such permission.

Q Have you ever published a peer-reviewed article on autism?

A Not a peer-reviewed article.

Q I'm sorry, sir?

A Not a peer-reviewed article.

Q Have you ever published any peer-reviewed articles on genetic susceptibility to mercury toxicity?

A Now I've got to stop and think because we've got a lot of mercury papers. I'm not positive, but I

think in a symposium talk that I gave at the National Institute of Health on the toxicology of mercury and arsenic that was published in I think *The Environmental Health Perspective*. I'm not positive where it was published, but yes, we have published such an article.

Q Is that a peer-reviewed article?

A Absolutely. It's sponsored by the National Institute of Environmental Health Sciences.

Q You've published several articles on mercury. Is that correct?

A Many, and they're all in peer-reviewed journals. I think the first one was probably in 1996.

Q When is the last time you published a peer-reviewed article on mercury?

A On mercury?

Q Yes.

A I don't remember, but I want to say maybe 1999 or 2000. It would be an *Environmental Health Perspectives* article. We published so many papers I can't tell you exactly what year what we did.

Q Of the articles you had published on mercury have you ever published a peer-reviewed article on thimerosal toxicity?

A No. We've done research on it, but they're

not quite ready for publication yet.

Q On ethyl mercury toxicity?

A On thimerosal.

Q Would you agree that the majority of your research has been in the area of arsenic and lead toxicity?

A Certainly not in lead. I can't even remember a paper we've ever published in lead toxicity.

Q On arsenic toxicity?

A Arsenic toxicity in recent years. In the time between 1954 and 1959 we only published on mercury, and then we started publishing on mercury again. The last human study we did in mercury was done in Mexico where we mobilized mercury in people that were toxic to mercury. I think that was done I want to say 1997 or 1999. I don't have my CV before me, but the first author was Dr. Gonzalez.

Q You say toxic to mercury. What kind of mercury are you describing?

A I didn't hear the first part of your question.

Q You said that it was a study in Mexico regarding mercury toxicity. Is that correct?

A Yes. Yes.

Q What type of mercury?

A Done so long ago I don't quite remember. Give me a minute to think. These people had been exposed to high levels of mercury. I think, it's been so long ago, that it was due to their working in a fluorescent light factory. The paper is published.

Q Would that be mercury vapor? Methyl mercury?

A It was probably mercury vapor.

Q Mercury vapor. Thank you. Mercury vapor and ethyl mercury are different species of mercury. Is that correct?

A I hope you learned that from the talk I gave this morning.

Q I did. Thank you. And different species of mercury have different toxicological properties. Is that correct?

A Yes.

Q Have you ever testified as an expert witness in other litigation?

A I've been very fortunate that most of the cases that I've been involved in have been settled out of Court, and so many people think I bring a certain charm to such proceedings, but unfortunately not the case today.

Q Have you ever diagnosed or treated a person with ethyl mercury toxicity?

A I'm not a physician, so I would not treat anyone.

Q So you've never treated or diagnosed a person with any form of mercury toxicity?

A I have been asked my advice by physicians who think they may have a person who has mercury toxicity, and I have given them my opinion, but I did not do a diagnosis.

Q Have you reviewed the medical records of Michelle Cedillo?

A I have reviewed some of them, but ont all of them.

Q What records did you review?

A A notebook about that thick and that's about all I can tell you at this time. But again, I'm not a physician, and I certainly would not be expected to be expert on the various medical evaluations of such a person.

Q What types of records did you review? Did you review her immunization records? Did you review her general medical records?

A I reviewed her general medical records.

Q And how many did you review approximately?

A I don't count such things. I'm sorry.

Q More than 100?

A Again, I don't count such things. I just look at things, read them, try to store them in my mind. I don't put a number on number of papers that I read. I either read a lot or a few, and I read a lot.

Q You read a lot. Is there any evidence or allegation that Michelle Cedillo's autism was caused by exposure to mercury vapor?

A I don't know. I don't remember seeing that data if it was there.

Q Is there any evidence or allegation that Michelle Cedillo's autism was caused by exposure to methyl mercury?

A I don't know of any case where anyone would say methyl mercury per se was the cause of autism or even speculate along such lines.

Q There's no evidence, are you saying, that methyl mercury causes autism?

A I'm saying that I know of no evidence that methyl mercury will cause autism.

Q Is there any evidence or allegation that dimethyl mercury caused Michelle Cedillo's autism?

A I doubt very much that Michelle was exposed to dimethyl mercury unless she went to a dump. In the

literature there's evidence that certain dumps emit dimethyl.

Q You're saying no, sir, correct? That there's no allegation of dimethyl mercury?

A Yes. You're correct.

Q Okay. Thank you. Is there any allegation or evidence that Michelle Cedillo's autism was caused by mercuric salts?

A By thimerosal?

Q By mercuric salts.

A By mercuric salts?

Q Yes.

A I know of no evidence.

Q You know of no evidence.

A Excuse me.

Q Okay.

A Let me finish please, okay? However, the thimerosal that is in her vaccines would be expected to be converted to ethyl mercury which would be transported to the brain and in the brain the ethyl mercury would be converted to mercuric mercury.

Q Thank you. Are you familiar with the reference book *Casser and Duals*?

A Of course. Yes, I am.

Q Is it a well-regarded reference book used by

toxicologists?

A It is a reference book used in toxicology classes.

Q Would you agree with the statement from that reference that, "no other metal better illustrates the diversity of affects caused by different chemical species than does mercury"?

A I thought I said in my opening remarks that the reason I was reviewing the forms of mercury for the Court was because of the diversity.

Q So you agree with that statement?

A Yes.

Q Would you agree that the toxicity of one form or mercury does not automatically apply to other forms of mercury?

A I can't quite agree with that because all the forms of mercury that I know of, if they get into the central nervous system, in fact get in the cells, are going to be converted into mercuric mercury, and there's a standing argument as to whether the toxicity of organic mercury is due to the mercuric mercury per se, or to the let's say organic mercury per se, or a combination of both.

Q You stated earlier that people are exposed to mercury on a daily basis. Is that correct?

A I would hope to say that what form of mercury? We don't like to use the term mercury without specifying what form of mercury we're talking about. Like in that chart I gave we had a column of amalgam mercury or elemental mercury, a column for, you know, organic mercury or mercuric mercury and a column for methyl mercury.

Q So was your testimony that people are exposed to methyl mercury on a daily basis?

A People are exposed to methyl mercury if they eat fish or seafood.

Q Or live near power plants?

A Pardon?

Q Power plants?

A No. A power plant emits elemental mercury. It doesn't emit, as far as I know, methyl mercury. The elemental mercury is then spewed out into the atmosphere, and when it rains it is washed into the sea water or into the lakes and settles and there is converted to mercuric mercury again, settles down and is converted by bacteria to methyl mercury.

Q Okay. I'll rephrase my question. Would you agree that people are exposed to both organic and inorganic mercury on a daily basis?

A I think you have to be very careful now.

That's why we use species. For example, the major form of inorganic mercury is mercuric mercury. Mercuric mercury most of a general population is not exposed to to any great extent. Mercuric mercury toxicity is almost only seen in occupational setting.

Q Would you agree that any substance is either toxic or nontoxic based upon the dose?

A No. This is an ancient form of quotation that until recently we taught in medical schools, and in undergraduate school, and in graduate school. We now have to consider the hyper susceptibility of people. For example, you might be poisoned by *X* amount of some form of mercury. I might be poisoned by one-hundredth of that amount because I may have a genetic hyper susceptibility.

So the dose that I'm given will be very harmful to me, but that dose won't be harmful to you. So no longer can we use that ancient saying, and it's very ancient. This is now the year 2000, it's not the year I think 1000 B.C. or something like that when Parcellius said this. We no longer believe that the dose determines the poison. That is an antiquated belief in this modern age because now we know about genetics and hyper susceptibility of some people.

Q So toxicologists don't consider dose when

considering the toxicological effects of substances?

A That's not what you asked me originally. If we can go back to what you just asked me? I'm not certain that's the question that you asked me. Essentially, we take dose in consideration, but it's not the only thing that determines toxicity. Dose is not the only factor that determines toxicity.

Q Would you agree, though, that any substance in a sufficient dose could be toxic to humans?

A Of course. I could kill you by making you drink so much water that it would overwhelm your system.

Q But you do not agree that dose makes the poison?

A I don't agree that only dose makes a poison. I mean, that is an antiquated belief today. If I had a graduate student here answering your question he would laugh. He would laugh because students are more up to date than many of us.

Q So you disagree with that statement? You don't agree that dose is the most important and fundamental principle in the study of toxicology?

A I think I've said that in the past it was considered to be important, but today we know other things are just as important, primarily the genetics

of the individual, especially the hyper susceptibility of the individual.

Q What is the normal mercury blood level for an adult?

A I don't know what the normal one is, but I would say that if it's under five micrograms per liter is considered to be not of clinical concern. That's probably the average we usually see in an ordinary person.

Q What is the normal mercury blood level for a child?

A Again, this depends on what the child has been exposed to, and there are all sorts of ranges. I could not without consulting a reference book come up with the range and dose for a child depending on his age and sex.

Q What is a high mercury blood level?

A Again, I'm not a physician, but if someone were to ask me in class that question we would usually say that most physicians and most emergency medicine books will say that anything above 15 micrograms per liter of blood should have medical attention. Some people say even 20 micrograms per liter of blood should have medical attention.

Q You use exceedingly high in your report.

What is an exceedingly high mercury blood level?

A Where did I use the term exceedingly high? Where did I use the term exceedingly high? I may have, but I just don't remember. I like to be refreshed.

Q Okay. I will find it. Did you use the word horrendously high?

A Pardon?

Q Horrendously high?

A I don't have it in front of me. This is a Court of Law and I want to tell the truth, so I don't know until I see what you're talking about.

Q You use it on page 4 of your report.

A I don't have the report with me, so if you'd read or if someone could let me see it.

Q I can read it. When you were reporting about the dimethyl mercury exposure.

A Yes.

Q Her blood mercury levels were horrendously elevated. You used horrendously elevated.

A Yes. If I remember *The New England Journal of Medicine* article, that Karen Winterhaller had blood levels I want to say 2,000 or 20,000 micrograms per liter, but I honestly don't remember the exact number. In many review articles it says that's the largest

concentration of mercury that's been found in the blood of almost any human being.

Q Dr. Aposhian, when you discuss the several cases of mercury toxicity in your report do you mention the dose amounts of mercury or the mercury blood levels in those persons that suffered adverse effects?

A I'm sorry. I can't hear you.

Q I'm sorry. I'll stand very close to the microphone.

A You've got to speak in the microphone, please. I'm also an old man, you know, and I can't hear.

Q I will try to speak up. I apologize.

A Thank you.

Q When you discuss the several different studies of mercury toxicity you never mention the dose amounts of the mercury or the mercury blood levels in those persons that suffered the adverse effects. Is that correct?

A I don't have the report. If someone would give me a copy of the report?

Q Have you discussed the dose amounts today?

A Pardon?

Q Have you discussed any dose amounts today or

mercury blood levels today in your review?

MS. CHIN-CAPLAN: Special Master, if there's a question about a particular page of Dr. Aposhian's report could Ms. Renzi kindly give us the page number?

SPECIAL MASTER HASTINGS: Ms. Chin-Caplan, let's let her go on. She's asking a general question first.

If you get to a particular question just give us the page number.

MS. RENZI: I can hand the paralegal anything I refer to. It would probably be very difficult for me to walk over to Dr. Aposhian with anything, but I'll just ask the paralegal to --

THE WITNESS: Do you have a copy? I would appreciate it.

BY MS. RENZI:

Q Did you mention either doses or mercury blood levels in any of your discussions of mercury toxicity today?

MR. MATANOSKI: For the record, Dr. Aposhian has been handed a copy of the Exhibit P.

SPECIAL MASTER HASTINGS: Okay. Now, Dr. Aposhian, I think the last question she just asked you, you are asking now about his testimony today rather than his report?

MS. RENZI: Correct.

MS. RENZI:

Q I asked if in your discussions today with Ms. Chin-Caplan did you mention either dose amounts or mercury blood levels in the persons that suffered adverse effects from mercury toxicity?

A I don't recall, but I don't think so.

Q One of the things you mention in your report is the Fagen article. Are you familiar with that article?

A Yes.

Q In the Fagen article is a report of death in infants treated with high doses of thimerosal. It's on page 4 of your report.

A Yes. I know that. And so what is your question, please?

Q I will ask you in a moment. Please be patient. How were those children exposed to the thimerosal in the Fagen report?

A I don't recall. I want to say it may have been injected, but I haven't read that paper six, seven months.

Q Would you accept that it was a topical thimerosal tincture or would you like to look at the article?

A If you say it is I'm willing to accept your word.

Q You can look at the article. We can hand you that article, the Fagen article, which is Attachment P of your exhibit.

A Yes. Thank you.

MR. MATANOSKI: For the record, Dr. Aposhian has been handed the Fagen article previously referred to.

THE WITNESS: And what's your question, please?

BY MS. RENZI:

Q Do you know how long the children were treated with the thimerosal tincture?

A Actually, I called Dr. Fagen. He is now retired living in England, and he could not remember the answer to that question. Now, I don't remember whether it's in here or not, but we were trying to find out what some of the blood levels of these kids were, and I see there is one in Table 1 and there are some mercury concentrations. Yes. Now I recall the paper. Yes.

Q Okay. Was the exposure to the thimerosal tincture a one time dose or was it a chronic and prolonged period of time?

A I'm sorry. You've got to speak in the mic. The acoustics are very, very bad.

Q I'm speaking as loud as I can. I apologize. Was the thimerosal tincture applied over a long period of time or was it a single application?

A I'm not even certain it says, but again, I haven't read this paper six, seven months. I don't know the answer to your question.

Q Does the article report the dose of thimerosal that the children in the study were exposed to?

A I thought I asked Dr. Fagen that, and the impression I had from Dr. Fagen's answer was that he didn't remember and that the dose was not mentioned, but again, I have not read this for six or seven months, and I don't know the exact answer to your question.

Q But there is a mercury blood level in that report. Is that correct?

A There is a blood level in Table 1. Certainly.

Q And that's the mercury blood level of a child taken after his death. Is that correct?

A Yeah. One child. Yes.

Q And what is that mercury blood level?

A Three hundred and forty I think it's nanograms per milliliter.

Q Would that be about 1,340 micrograms per liter?

A It would be -- yes.

Q What is the blood mercury level of a child following the receipt of a thimerosal vaccine?

A A normal child the blood mercury level is given in the Pichichero paper I guess, but that's a normal child, it's not a child with a mercury efflux disorder.

Q And what is that level?

A Again, I don't have the paper in front of me, you have it. You probably know it better than I do.

Q Well, you also referred to the Stajich article, which is Exhibit --

A Forgive me, but you're talking down into your notebook, and I'm sorry.

Q Exhibit 2Q of your attachment is Stajich. Mr. Boxler will hand you the article. You filed it with your report.

A This is Stajich's paper. And what are you asking about this paper, please?

Q This article measured the blood level in

infants following hepatitis B vaccination. Is that correct?

A Yes.

Q And according to that article isn't the blood level of a child who received a thimerosal containing vaccine approximately 2.24 micrograms per liter?

A I have to refresh this. Yeah. One postvaccination level is 2.24, the lower level. The higher level is 7.36 of micrograms per liter.

Q And isn't the 2.24 micrograms per liter approximately 600 times less than the mercury blood level following exposure in the Fagen article?

A Probably.

Q You state in your opinion that higher doses of mercury have been shown to be toxic. Do you agree with that?

A I need to know the context that is said in. What is the rest of the paragraph, please?

Q Are higher doses of mercury known to be toxic?

A Are you asking me a question now or are you quoting me?

Q Yes. Are higher doses of mercury known to be toxic?

A What form of mercury are you talking about?
Q Methyl mercury.
A Methyl mercury in various doses is toxic.
Q Is ethyl mercury?
A Ethyl mercury in various doses is toxic.
Q What does various doses? You have specific doses at which the mercury can be toxic.
A It depends on the species of animal that the study was done on. There are studies by Magos in the rat studies and mouse. I think there are one or two studies by Suzuki from Japan. Again, I don't remember. To most of us toxicologists doses are something that we can look up. We don't have to memorize such things.
Q Does the Fagen article tell us nothing more than thimerosal at doses 600 times greater than the amount contained in the thimerosal mercury vaccine can cause an adverse reaction?
A That's what the Fagen article says. Yes.
Q Does the Fagen article tell us anything about thimerosal at low doses causing adverse effects?
A I don't think so.
Q Does that article tell us anything about thimerosal causing autism?
A Definitely not.

Q Does that article tell us anything about thimerosal administered at low doses causing immune suppression?

A This article does not deal with that subject. Would you like the references for the articles that do deal with thimerosal and mercury causing immune suppression --

Q We can get to those, sir.

A All right. Okay. I'll be glad to give them to you know if you'd like.

Q No. We can wait.

A All right.

Q I want to go back to the dimethyl mercury exposure.

A Yes.

Q And that was the chemistry professor who was exposed to the dimethyl mercury. Is that correct?

A You must forgive me. I have hearing aids I paid $4,000 for, and if you talk in the microphone I can hear you. I know it's natural for you to look down at your notebook, I just can't hear you.

Q I'm a little short and getting to the microphone means a big lean here, so I'm doing the best that I can here.

A I'm sorry. Thank you.

Q Back to the dimethyl mercury exposure.

A Yes.

Q Did the authors of that article, and that is Article LL -- would you like to see that article, sir?

A I wouldn't mind having it. I know of it, but it would help me answer any question that you might have.

MR. MATANOSKI: For the record, Exhibit LL was handed to the witness.

MS. RENZI: I think it's technically Attachment LL to Exhibit 55.

MR. MATANOSKI: Thank you.

BY MS. RENZI:

Q And that's the Nierenberg paper? Is that correct? Who is the author on that article? Who is the author on that article?

A Nierenberg.

Q Thank you. Did the authors of that article calculate the dose of dimethyl mercury?

A If they didn't calculate it here, they calculated it elsewhere, but I presume it must be here also.

Q Do you know what that dose was?

A I want to say it was something like two milligrams of dimethyl mercury.

Q Two milligrams?

A Two milligrams. That's what I sort of remember. I could be wrong, but I think that was the dose that Coxen has told me personally that they made the calculation --

Q But you rely on the article. What does the article say, sir?

A -- excuse me -- because the density of dimethyl mercury is very high, so there is a lot of mercury in that two milligrams. I'm sure they say what the dose is here. You may know where it is, since you're asking the question. You could tell me.

Q On page 1675.

A 1675. Way back down there. They say 1,344 milligrams.

Q Isn't that 1,344,000 micrograms?

A That's what most of my students would say, yes.

Q And what is the micrograms of thimerosal in the thimerosal-containing vaccine of a Hepatitis B vaccination?

A We're talking about dimethyl mercury here. We're not talking about thimerosal.

Q I understand that, but my question was --

A So to make that comparison is wrong. That's

why we emphasize, in my talk, the species of mercury.

In answer to your question, the thimerosal vaccine's total, about 180 or 200 micrograms of mercury.

Q And the Hepatitis B vaccine.

A It's either 12.5 in Hepatitis B or 25.

Q So you agree --

A Agree to what, please?

Q -- that the exposure to dimethyl mercury is not comparable. You can't compare that to an exposure in a thimerosal-containing vaccine.

A I don't know of anyone that's made that comparison. All we're saying -- I think most people would want to educated a group to know that dimethyl mercury is the most toxic form of mercury that we know of.

Q So this case study simply illustrates that different forms of mercury have different toxicological properties. Is that correct?

A I think that's what everyone knows, even before this paper.

Q You stated today that inorganic mercury is trapped in the brain and then is not eliminated. Is that correct?

A Again, slowly repeat that, please.

Q You stated today that inorganic mercury --
A Mercuric mercury.
Q -- mercuric mercury -- is that inorganic mercury?
A It is one form of inorganic mercury.
Q It is trapped in the brain --
A Yes.
Q -- and is not eliminated. Is that correct?
A It's practically not eliminated. It stays there for a long, long time.
Q And in support of that, you cited to two case studies. Is that correct?
A There are two case studies that indicate that, many years after the exposure, the amount of mercuric mercury -- in this case, inorganic mercury -- was extremely high and remained that high over a number of years.
Q And when was the family in Mexico that you discussed today that consumed a pig following the pig's ingestion of methyl mercury? Is that correct?
A Well, the case in New Mexico was a pig knocked over a bottle of a fungicide, which was methyl mercury chloride and drank it, and the next day the family killed that pig and, within a few days, used that for food. There were three children, two very

young ones. One died shortly thereafter, and the other one lived for either 20 or 21 years, and, at that time --

Q Okay. Can I just interrupt you for one minute?

A Let me finish, please?

Q Okay.

A At that time, 20 or 21 years later, everyone was astounded to see that, in a human being who had been exposed to methyl mercury 20 or 21 years previously, the brain inorganic mercury, mercuric mercury, was 100 times more than normal.

Q And I think you stated that earlier today. Do you know the approximate amount of methyl mercury that was consumed by the family members?

A I don't think anyone knows that. I don't remember the paper even trying to come to terms with that.

Q Do you know over what period of time the pig was consumed by the family?

A It was either over a six-month period or a period of one year, approximately. They didn't have freezers in those days in New Mexico.

Q But would you agree that the family's exposure to methyl mercury was at a much higher dose

than a dose of ethyl mercury that is received through the administration of the thimerosal-containing vaccine?

A Of course. Everyone knows that.

Q Were mercury blood levels reported in that case?

A I don't think so, but I'm not positive because the main emphasis of that paper was the amount of mercury in the adult's brain.

Q Did any of those family members develop autism?

A This was done, at least, 20 to 25 years ago, which would make it around 1970, I would guess. I don't think autism was a concern of any doctor or anyone making a diagnosis in those days. I don't think physicians were thinking about autism.

Q And when was that? I'm sorry. What was the date?

A My guess is it's around 1970, but I'm not positive of that.

Q Was there any reports that any family members were immune suppressed following the consumption of the pig?

A You've got to understand that this was in a very rural part of New Mexico. I don't know whether

you've ever been in New Mexico --

Q I have.

A -- but in the rural parts of New Mexico where people eat pigs that they grow, they are lucky if the physician treating them was even thinking about immune suppression.

Q But they did do a case study on this, so there had to be some sort of follow-up of this family. Is that correct?

A The only published report on this family that I know of is of the child dying 20 or 21 years later. There may have been another one, but I'm not aware of it.

Q Was the mother pregnant when she consumed the methyl mercury in that study? Would you like to see the study? We can hand you that as well.

A Pardon?

Q Would you like to see the paper by Davis that we're talking about?

A If it's that one, yeah.

MS. RENZI: That is Attachment N, for the record, of Exhibit 55.

SPECIAL MASTER HASTINGS: Okay. Thank you.

THE WITNESS: Yes. Now I remember this one, yes. What is your question about it, please?

BY MS. RENZI:

Q There was a child in that study who actually had prenatal exposure to the methyl mercury. Is that correct?

A Again, I haven't read this paper for years. If you say it's correct, I'll have to accept it.

Q Well, you cited it in your report, which you wrote on February 16, 2007. So if you haven't read this article in years --

A Which said what about a pregnant woman?

Q Well, you cited the paper, so I had assumed that you were aware of the study.

A I don't think in my paper I say there was a pregnant woman involved. I could be wrong, but, again, I have to read so many papers --

Q So you don't know, in the article that you cited, whether there was prenatal exposure to one of the family members. If you don't know, you can just answer no. That's fine.

A I didn't hear all of the question.

Q I said, So you don't know --

A I don't know what?

Q -- whether -- if you let me finish my questions, I'll try to remember to have you finish your answers.

A I'm sorry.

Q So you don't know whether, in the article that you cite, whether one of the family members was exposed to the methyl mercury through consumption of that pig prenatally.

A Since this is a court of law, I want to be absolutely truthful, and I have the sneaking suspicion one may have been, but I'm not positive.

Q Okay. So you don't know if there were any neurological symptoms of a child due to prenatal --

A I could read the paper and find out, but I don't know now.

Q We'll move on, sir.

A Yeah.

Q You also refer to, in your report, the 1994 Opitz article, and that is Attachment MM of your exhibit.

A Which attachment?

Q MM.

A MM. Thank you.

Q M like in "Mary" M.

A Okay.

Q If you would like to see it, yes.

A Thank you.

Q Have you read that article recently?

A Yes. This is from Germany.
Q When is the last time you read that article?
A If I had to make a record of every time I read an article -- I don't keep such things in my mind.
Q I didn't ask how many times you've read it. I asked, when is the last time you read it? Have you read it since --
A I have no idea. I'm trying to tell you the truth. I have no idea.
Q What was that article about?
A This is an article, if I remember correctly, of a man being exposed to mercury vapor, metallic mercury vapor, and he was treated with D penicillamine, which we were the first one to use, come up with, as far as a therapeutic agent. Our laboratory did that. They did a body -- again, they found nerve cell damage, as I remember, if I remember correctly. So what else would you like to know?
Q In your report, on page 6 --
A Page 6 of this article?
Q Of your report. I'm sorry, sir, of your report.
A Could someone get me my report? If I had known that --

Q I think we handed you your report, sir. You should have it.

A Thank you. Okay. Page 6. All right. Now, I have page 6.

Q Okay. First big paragraph, and after you cite the Davis study, six lines up --

A From the bottom?

Q Yes, from the bottom of that paragraph.

A Of that paragraph.

Q You state: "In another study, exceedingly high levels of mercury were demonstrated in a human brain and other organs 17 years after metallic mercury exposure." And my question to you is, what is "exceedingly high"?

A It's approximately 2,000 micrograms per kilogram in the brain. Does that answer your question?

Q Is that how you define "exceedingly high"?

A I would define anything high that's above what we normally see, and this is above what we would normally see.

Q But what is "exceedingly high"? Can you quantify "exceedingly high"? Is there a toxicological term that quantifies "exceedingly high"?

A No. I would just take the values reported

in the textbooks of emergency medicine and the toxicology textbook that you reported. They give normal values, and, depending on how large the number you're talking about is, compared to that base value, I would say it was high or exceedingly high.

Q Do you have the Opitz article in your hand now? Do you have the Opitz article in your hand?

A Yes.

Q Okay.

A Yes, it is. I'm looking at Table 2 on page 143.

Q And is that the mercury urine? There was a mercury urine level in that report. Is that correct?

A Certainly, Table 2 doesn't have one, so let's see what Table 3 -- it doesn't have one, so let's see what Table 1 is. Table 1 does not give a urinary value either. In the text, there is a urine value, but my guess is, since this is an autopsy, they probably did not get a urine value, but I don't know.

Q Where it says "Case Report" --

A Which one do you want, one of these?

Q No. I was looking for my glasses, to be honest with you. I'm a little blind with the small print.

On the first page of that article --

A The Opitz article?

Q -- the Opitz article under "Case Report."

A On the first page?

Q Yes, sir. A male subject, age 57 at death, had worked for 13 years in the recycling of mercury from amalgams with a mercury content of 102 percent. He suffered from an acute exposition of mercury vapor at age 41. Immediately after intoxication, he excreted 1,850 milligrams per liter of urine.

My question is, is that the equivalent of 1,850,000 micrograms?

A Yes, yes.

Q Is that how you would define, then, "exceedingly high does," when the mercury excretion --

A That certainly is not a low dose. Usually, what you see in the urine is in the order of magnitude of five micrograms per liter or less, sometimes a little more, but this would certainly be a high dose. It would be the exceedingly high dose.

Q So could you compare this article, then, to thimerosal content in vaccines, exposure through a thimerosal-containing vaccine?

A What part of this article?

Q The dose, sir.

A No, I cannot.

Q You also discussed today and in your report Minamata. Is that correct? At Minamata, there was exposure of methyl mercury through consuming of contaminated fish. Is that correct? Do you know if there were any blood -- I'm sorry. I apologize. Could you answer so your voice can be recorded? You have to answer yes or no. A nod of the head; the court reporter won't pick it up.

A I did mention Minamata in the talk to answer the questions that were asked of me earlier.

MR. MATANOSKI: I'm sorry. Just for the record, because the witness hadn't responded -- because he nodded his head in response to Ms. Renzi's last question, he nodded in the affirmative.

THE WITNESS: I apologize.

MS. RENZI: It's for the court reporter that it's important that you don't nod your head but that you answer yes or no.

THE WITNESS: I understand. I apologize.

BY MS. RENZI:

Q Thank you. Do you know if any methyl mercury blood levels were measured in any of the victims at Minamata.

A I'm certain they were. I don't know what they were, though.

Q Would you believe that they would be higher than blood levels following thimerosal-containing vaccine?

A I don't know what the data is. It's conceivable that there might have been some people there. I just don't have the data.

Q You don't have the data.

A Some people could be hypersusceptible and have a low level. I don't have the data before me on it. I'm sorry. I don't know.

Q In Minamata, there were also birth defects as a result of pregnant women who consumed fish during their pregnancy. Is that correct?

A Yes.

Q And you described a cerebral palsy-type syndrome in these children.

A Yes.

Q Do you know over what period of time the methyl mercury exposure took place in Minamata?

A At least two years and maybe even five years and then even more. You must realize that it's, at times, very difficult to get such information from Japan. The word "Minamata" in Japan is now synonymous, because of the effects on the brain, with the word "idiot." So if someone wants to insult you

in Japanese, to call you, as we would say, "You're an idiot," he would say, "You're a Minamata."

Q But my question to you is, was it a chronic exposure, or was it a short-term exposure?

A Again, you're talking about a population.

Q Is two years a chronic exposure, or is two years --

A But you're talking about a population. Some people would have one meal. It depends on how much fish they ate, but it certainly would not be expected to be a short period. It was chronic exposure.

Q So they consumed the fish over an extended period of time.

A Yes.

Q Thank you. Is there any evidence that the children at Minamata had an increased rate of autism compared to the general population?

A Again, people were not aware of autism as a disorder of children at that time, especially in Japan.

Q Do any of the neurological symptoms described in these children comport with a diagnosis of autism?

A You must realize, again, that the signs and symptoms of methyl mercury toxicity are relatively

nonspecific and that many people would have such symptoms, thinking that they were ill for some other reason. That's about the best I can say.

Q What were the symptoms? What were the neurological symptoms? You call it a cerebral palsy-type syndrome, so they must have recorded some of the symptoms. Is that correct?

A There are many symptoms. For example, there are movement-disorder symptoms. There certainly was a decrease in the intelligence of the children that were born. There is a general feeling of being ill. There is GI upsets, and there are other symptoms, of which I just don't make a point of remembering because they are things that a physician would deal with if he were doing the examination.

Q And what is the reference for those symptoms?

A Someone coughed. I didn't hear you.

Q I'm sorry. What is the reference for those symptoms described at Minamata?

A There are three or four -- there are many books written by the Minamata Research Institute. If you have any trouble getting one, I'll send you one, if you'll e-mail me.

Q I'm sure I can get one. Thank you.

A Thank you.

Q Would you agree, Dr. Aposhian, that for most of the period in utero that the blood brain barrier is not as fully formed as it is postnatally?

A Yes.

Q You state in your report, and you discuss today, Pink Disease -- correct? -- and Pink Disease was a condition that resulted from the use of mercuric salts. Is that correct?

A Mercuris, not --

Q Mercuris salts.

A In your report that I was shown, you say "mercuric," but really it was exposure to mercuris.

Q Mercuris salts. I apologize.

A Now, perhaps the mercuris was converted to mercuric in the body, but the exposure, the initial exposure, is mercuris.

Q Mercuris salts. Thank you for correcting me. And it was topically applied to the gums of infants. Correct?

A It was topically applied to the gums, but I'm not quite sure how much tissue is exposed when a tooth is beginning to bud. A simple topical application seems, to me, to be a very simple way of looking at it.

Q You described earlier the symptoms of Pink Disease, did you not?

A Yes.

Q Could you go through them again, please?

A Sure. Do you mind if I go back to give you the exact words?

Q Well, if you know them off the top of your head, that would be helpful, but if you want to go back -- if you have a list of symptoms, that would be fine.

SPECIAL MASTER HASTINGS: Doctor, do try to speak up.

THE WITNESS: I'm sorry. All right. Anyway -

SPECIAL MASTER HASTINGS: Just one moment, please. Doctor, one moment here. We're going to check your microphone to see if it's working correctly.

(Pause.)

THE WITNESS: Here we are. Mizro babies and toddlers. Bright pink or red in color, photophobic -- they are sensitive to light -- with raw beef hands and feet, anorexic, peeling of skin, gangrene in the extremities. I'm sure there are other signs and symptoms, too, but those were the most important ones

that I thought at the time that were relevant.

BY MS. RENZI:

Q Is there any evidence of an increased rate in autism in children who recovered from Pink Disease as compared to the general population?

A I'm trying to think of the best way to answer that question. We wanted to investigate that, we went back over records at the time -- nothing. I was contacted by people in Australia. Australia had a lot of Pink Disease. Australia supposedly kept their records, and when the people contacted me from Australia, knowing that we were interested in autism and mercury, they said they would be willing to cooperate.

I said, I need the medical records before we invest government money and come all the way out to Australia to do a survey and view mercury levels in you all because there is a survivor of Pink Disease society in Australia. After they looked into it, they could find no hospital records that would give us that data.

And, again, in those days of Pink Disease, 1890 to 1950, autism wasn't even considered to be a childhood disorder. I'm trying to think when the psychiatrists thought of the ridiculous statement that

autism is caused by refrigerated mothers, and that's about the time.

Q I don't mean to interrupt, but the answer is you don't know.

A I don't know what?

Q You don't know if there was any evidence of an increase in the diagnosis of autism.

A No one looked for it. No one looked for it.

Q Is there any evidence of an increased rate in immunosuppression in the children who had Pink Diseases compared to the general population?

A Again, no one looked for it.

Q So you don't know.

A No one looked for it. The absence of evidence doesn't mean that there is evidence for absence.

Q Do children with autism show signs of Pink Disease?

A I don't think so. I've never made the claim that they did.

Q And you use Pink Disease -- you state on page 9 of your report, and you said today, that the fact that the mortality of children was not 100 percent, this demonstrates a genetic hypersusceptibility of some children to mercury. It

plays a significant role with respect to the nature and extent of the injury. Is that correct?

A Yeah. One out of 500 children exposed to mercuris salts in their teething powder, and the Klausen article clearly states that one out of 500 got Pink Disease. So why didn't the others?

Q Well, do you know the amount of mercuris salts that were contained in any particular teething powder?

A No.

Q Do you know the dose of mercuric salts that were administered to any of the infants that developed Pink Disease or died.

A No, no.

Q Do you know their mercury blood levels?

A No one ever did a mercury blood level on Pink Disease that I know of. There is no published report of a blood level of mercury in pinks disease. As I said to you earlier, in the talk I gave this morning, that established medicine was not willing to admit, was not willing to agree, that Pink Disease was caused by the teething powder, and it was only after the government forbid the use of this teething powder containing mercuris chloride that Pink Disease disappeared. No one did a mercury study.

Q So you don't know the dose of the children who received the mercuric salts but did not have symptoms --

A Absolutely not.

Q -- with those who had symptoms and recovered or the doses of the children who received mercuric salts.

A I don't.

SPECIAL MASTER HASTINGS: Doctor, if you could wait until she finishes her questions --

THE WITNESS: I'm sorry.

SPECIAL MASTER HASTINGS: -- then we can get a better record.

THE WITNESS: Thank you.

BY MS. RENZI:

Q Do you know if there were any limitations to the dose amounts the parents could administer to the infants? The parents could administer the teething powder any time they thought it was needed. Is that correct?

A You'll have to repeat the question, please.

Q Were there any limitations on the application of the mercuric salts in the teething?

A Not that I know of.

Q The parents could administer the teething

powder as often as they thought it was needed. Is that correct?

A I don't know.

Q But isn't it true that unless you compare the dosages of the mercuric salts between those infants who suffered reactions and those that did not, it is just mere speculation that these adverse reactions were a result of genetic hypersusceptibility.

A "Speculation" means there is no evidence for a concept that one is trying to put forth. There certainly is evidence that there are people hypersusceptible to mercury. Whether some of these children were hypersusceptible and got Pink Disease, we have no evidence, one way or the other.

Q Doctor, I'm going to move on. Is it fair to say that you have performed a significant number of studies involving chelation?

A I have performed a number of studies on chelation for the drug that is used now for the FDA-approved treatment of children with lead poisoning. We did all of the human metabolic studies as to what happens to this drug, DMSA, in the human body, and we did much of the work showing that this compound would also chelate mercury.,

Q And you've published peer-reviewed articles on chelation. Is that correct?

A Many of them.

Q Have you ever published a peer-reviewed, experimental study on chelation where you did not take both prechelation and postchelation urine measurements?

A To my knowledge, we have never done that because we've always insisted that we do a prechelation baseline. Many of the studies that have been reported just don't do a baseline, so all they can say is the mercury is at this level. We've always done a baseline, a prechelation plus a postchelation study.

Q That's the way you assess the effect of the chelator. Is that correct? That's the way you assess the effect of the chelator. Is that correct?

A That is one of the ways you assess chelation. That's the best way.

Q And without pre- and postchelation urine levels, what would the study tell you?

A Pardon?

Q And without getting both prechelation urine and postchelation urine levels, what would a study tell you?

A What it could tell you is that we have a vast amount of literature that tells us what the normal range of human urinary mercury excretion is. That normal range, we would often say, if it's above 15 micrograms per liter, you should see a physician. Clearly, intervention is recommended.

So if someone is chelated, and he has 100 or 200 micrograms of mercury per liter, we are certainly going to say, "You'd better go see a physician and have this taken of," or the physician should do this, and if someone calls me, I tell them, "Well, wait a week or so and get a baseline again, and let's see what the baseline value is." So a baseline value is definitely the proper way of doing it.

Q You discussed today about the possible adverse effects of dental amalgams. Is that correct?

A Yes.

Q And you state in your report also that the average person with the average number of amalgam surfaces emits and retains about 10 micrograms of mercury from those amalgams. Is that correct?

A That's a figure that many people use.

Q Who is the average person?

A The average person is a person with the average number of amalgam surfaces in his mouth?

Q What is the average number of amalgam surfaces?

A It's usually considered to be about 10 in this country, but other people will give you another number.

Q Has there ever been an association between dental amalgams and autism?

A The reason why I'm hesitating is I remember reading a review article where a mention may have been made and my surprise at it. So let me say that I don't think there is a connection for dental amalgams.

Q Do you believe that dental amalgams cause Alzheimer's Disease?

A I don't think there is enough evidence to show that, one way or the other. The evidence that is available is not the best.

Q Do you believe that dental amalgams cause Parkinson's Disease?

A Again, I don't think the studies have been good studies. Whether amalgams do or do not cause Parkinson's Disease, I don't think there is enough good evidence available to make a decision.

Q You state in your report that the proposition that dental amalgams actually cause these diseases is not generally accepted. Do you agree with

that?

A Yes.

Q And when you say "not generally accepted," do you mean in the scientific and medical communities?

A My I elaborate on that? All right. There is a term that we use called "micromecurialism," and by "micromecurialism," we mean those people who have a level of mercury in them that is not excessive but will cause some sort of physiological response.

Q Sir, I hate to interrupt, but you're not answering my question.

A Pardon?

Q My question is, when you say something is not generally accepted, do you mean by the scientific and medical communities? I don't think that you're responding to my question.

A Yes.

Q Are you aware that the U.S. Public Health Service, the World Health Organization, the American Dental Association, and the National Multiple Sclerosis Association, among many, have determined that dental amalgams pose no risk to public health?

A May I take some time to clarify that point? On September 6th, 7th, and 8th, in a town near Rockville, Maryland, a meeting was held by the FDA to

discuss this question. The FDA wrote a paper, which is available on the Web, stating that dental amalgams were not dangerous, were safe. There are no harmful effects.

For the first time for the FDA, rather than just a dental committee, they had a committee made up of the Dental Committee of the FDA and the Neurology Committee of the FDA. It was the first time they have ever done this. The Neurology Committee were first-class physicians from many medical schools. In addition, they had three or four consultants that the Neurology Committee asked to attend. They had Klausen, who is a prime example of a first-class toxicologist. They had Michael Ashwood from Vanderbilt University, and they even had dentist consultants.

That committee -- I think there were 13 neurology and neurology consultants and seven dentists -- that committee voted 13-to-7 not to accept the FDA paper that said that amalgams were safe. It was the first time that's been done.

So we now have on record, by an FDA impartial committee, the statement by the majority of these two committees saying that the question is still open whether amalgams are safe or not, that more work

has to be done. You can get this off the Web. It's available. If you have any trouble getting it, I would be glad to send it to you.

Q "More work needs to be done." Is that what you said, Doctor?

A Certainly, more work has to be done.

Q But the societies I named earlier state that dental amalgams pose no health risk.

A I'm sorry?

Q The societies I read to you in my last question state that dental amalgams pose on public health risk. I did not mention FDA.

A I don't understand your question.

Q Are you aware that the U.S. Public Health Service, the World Health Organization, the American Dental Association, and the National Multiple Sclerosis Society have determined that dental amalgams --

A Would you tell me the dates of those, please?

SPECIAL MASTER HASTINGS: Doctor, please let her finish the question.

THE WITNESS: I'm sorry. I'm sorry. I get excited about this. My apology.

MS. RENZI: I do not have the dates.

THE WITNESS: I think that if you look it up, you'll find that the U.S. Public Health Service made that statement around 1996 or 1997 --

MS. RENZI: Okay. Thank you.

THE WITNESS: -- and that the other statements -- if you ask most scientists, they are not at all amazed that the American Dental Association would make such a statement.

BY MS. RENZI:

Q You're currently conducting in vitro and in vivo studies on the metabolism of arsenic. Correct?

A I think I know your question, but would you say it louder?

Q Are you currently conducting studies, both in vivo and in vitro, on the metabolism of arsenic?

A Yes.

Q What is an "in vitro study"? What is an "in vitro study"?

A An "in vitro study" usually means that you're not taking a whole organism, whole animal. You're taking either cells of that organisms or you're taking isolated enzymes of that organism. So it's not the whole animal. "In vitro" implies it's not the whole animal; it's just a part of the animal that you're isolating and studying.

Q So, in other words, they are studies carried out in isolation from a living organism. Is that correct? Are they usually done on a Petri dish?

A No. I'm sorry.

Q They are not carried out in isolation?

A I'm sorry. I didn't mean to interrupt her. The cell is indicative of a thousand other cells and a million other cells in the animal. So it's not an isolation of the individual.

Q But it's an isolation of the entire living organism. Is that correct?

A Pardon?

Q It's an isolation. It's not the same as the entire living organism. Is that correct?

A Correct. It's not like the entire organism.

Q And in vivo studies take place in living organisms. Is that correct? In vivo studies; they take place in living organisms. Is that correct?

A The living organism, but some people would say a cell, an isolated cell, a tissue culture cell is a living organism, and that's an in vitro study.

Q You're performing in vivo studies currently on mice. Is that correct?

A We're, at the present time, studying methyl mercury in mice, trying to get the mercury out of the

brain, in vivo.

Q Do you always expect the same results from in vitro and in vivo studies?

A It's difficult to say. It depends on how well the experiment is designed. Usually, historically, in medical science and biomedical science, an in vitro study will precede an in vivo study because an in vitro study can be done very inexpensively, whereas an in vivo study, whether it's done on an animal or a human being, is very expensive and more time consuming.

Q But you normally do both. Is that correct?

A We normally do both, but not all of the time.

Q But if you would expect the same results from an in vitro study as you would from an in vivo study, then you wouldn't have to do both. Is that correct?

A No, because there are always some people that are, for one reason or another, either don't believe an in vivo study or don't believe an in vitro study. So it's just easier to do both experiments so you don't have to argue at some meeting whether these studies are relevant.

Q But you can't conclude from an in vitro

study what will happen in vivo. Is that correct?

A That's incorrect.

Q You can conclude from any in vitro study what will happen when you perform that same experiment in an entire living organism in an in vivo study.

A Very often, I can predict it.

Q Very often? How often?

A Ninety-five percent of the time.

Q Then why do you do both?

A Because I've told you, I'll go to a meeting, I'll present an in vitro study, and someone who won't know very much about the basic ways of doing experiments will say, "I don't believe in vitro study. It's really an isolated part of the animal," and so it's just easier to say, "We've also done the in vivo study," so there is no sense of arguing this and taking the public's time.

We've done the in vitro study and the in vivo study. Both studies show the same thing, or both studies don't show the same thing. But most of the time, in our hands, working with arsenic and mercury, both studies will show the same thing, with one exception, and that is when we are trying to find the enzyme or the mechanism by which ethyl mercury was deethylated, and methyl mercury was demethylated in

the brain.

Q Okay.

A Then we had to take brain slices because we could not do this in the whole animal. We were looking for the enzyme.

Q So when you do an in vitro study, you can predict what will happen if you do the same study in a human.

A Very often.

Q How often?

A I just told you, I think, about 95 percent of the time, but that's because I've been doing this a long time. It depends also on what kind of a study you're doing.

Q When you do an in vivo animal study, can you use that study to conclude what will happen when you do the same experiment in a human being?

A Now, you're getting into a very difficult field. You're asking whether we can extrapolate what goes on in an animal with what goes on in a human being, and this depends on what kind of experiment you're talking about.

If you were to ask me, "What is the effective dose of an antibiotic in a mouse as compared to a human being?" it probably is quite different, so

you would have to do an in vivo study there. But if you were to ask me whether the enzyme, alcohol dehydrogenase is present in a liver slice as well as a complete animal, I would say, yes, absolutely present in both cases.

Q You said they are both present, so you know that some organisms, like both a human and an animal --

A Yes.

Q -- have present a liver. Is that what you're saying? If you perform an experiment on that liver in the mouse and in the human, do you expect to get the same results?

A Again, it depends on what you mean by "the same result." Do we expect to find an enzyme called alcohol dehydrogenase in a mouse liver and in a human liver? The answer is yes. If you say, "How much alcohol dehydrogenase do you expect to find in a mouse liver as compared to the human liver?" I would say probably different.

Q Well, let's talk about Attachment B of your report, and I think it's an article authored by you, on chelating agents. If you would like that study, we can hand that to you.

A I don't have those pages here, I don't

think. I apologize for not coming better prepared and bringing all of this paperwork.

Q That's why we have someone here to hand these things to you.

A So what page are you talking about now?

Q I'm talking about Attachment B. This is the article you authored on chelation, the chelation of mice.

A It's the Aposhian article?

Q Yes.

A My dear wife has a better brain than I have. I wish she were here. So what about this article?

Q Did you conclude from that study that the chelating agents you use on mice would have the same effect on humans from that one study?

A If you're talking about this article --

Q Yes.

A -- this is a review article. It's not an experimental article. It's not a report of an experiment. There may be an indication or a reference to such an article, but you'll have to tell me on what page you're talking about.

Q You're looking at Meso-2, 3, the DSM article.

A Which one?

Q It's Exhibit B. Could you read the title of that article? I'm sorry. Could you please read the title of that article?

A The title is "Meso-2, 3-Dimercaptosuccinic Acid: Chemical, Pharmacological, and Toxicological Properties of an Orally Effective Metal Chelating Agent." Is this the article you're talking about?

Q Yes, it is. Thank you.

A And is there some item in this article on a page that you can tell me about?

Q Yes. If you could go to page 302, please.

A 302.

Q And you state in that article that "DMSA is biotransformed into a mixed --"

A Excuse me. Could you tell me what paragraph?

Q It is the second paragraph.

A The which one?

Q The second paragraph on page 302.

A Okay. Beginning, "DMSA is biotransformed"?

Q Yes.

A Okay.

Q And you state in that article that the DMSA is biotransformed into a mixed disulfide in humans. Is that correct?

A Yes.

Q You found it in humans, but that you did not find it in rabbit, mouse, or rat urine. Is that correct?

A Correct.

Q So there is an experiment that you performed on humans and on animals where the results were different. Is that correct?

A And it really surprised us.

Q Is a mouse dendritic cell the same as an intact human immune system?

A I'm not a histologist. I really can't tell you whether they are the same or not. My guess would be that they are very, very similar.

Q A mouse dendritic cell is the same as an intact immune system --

A As far as its function is concerned, I would think that they would have a very, very similar function.

Q So human dendritic cell is the same as an intact human immune system. One cell is the same as the whole system. Is that what you're saying, sir?

A I'm not sure I understand your question.

SPECIAL MASTER HASTINGS: Doctor, I think you started to answer the question before, before you

heard the end of it.

THE WITNESS: I apologize.

SPECIAL MASTER HASTINGS: So why don't you ask your question before?

THE WITNESS: I apologize.

SPECIAL MASTER HASTINGS: It's all right.

BY MS. RENZI:

Q Is a mouse dendritic cell, one mouse cell, the same as an intact immune system in a human being?

A I don't know.

Q Is a human dendritic cell, the one cell, the same as an intact human immune system?

A I don't know.

Q You don't know. Do you know what a "dendritic cell" is?

A Pardon?

Q Do you know what a "dendritic cell" is?

A Yes.

Q What is it?

A It's a cell that is responsible for many of the immune responses where macrophages are made and come out of.

Q Are there many of them or few of them in the human body?

A I'm not an expert witness in immunology. I

don't claim at all --

Q You're not an expert witness in immunology.

A -- to be an immunologist, and I'm incompetent to answer any questions that you have about immunology, as an expert immunologist would.

Q But you state in your report that you find the in vitro studies of Gothe and Agawal highly significant. Do you recall that in your report?

A I recall that very well.

Q And although you're not an immunologist, what do you mean by "highly significant"?

A Because the concentration of thimerosal that was used in that experiment was almost equal to the concentration of thimerosal that you would expect in the cell of a child that was exposed to a vaccination.

Q And would those studies be as highly significant if the dose were higher than those found in thimerosal-containing vaccines?

A I would have to think more about that.

Q So you believe that in vitro studies on most dendritic cells and on isolated human dendritic cells can be used to conclude, more likely than not, that small doses of thimerosal will cause immune dysfunction in the human body.

A Would you mind repeating the last part of

that sentence?

Q Do those in vitro studies --

A Could you talk into the microphone, please?

Q By "highly significant," do you conclude that those in vitro studies tell you how thimerosal will act in small doses in the human body?

A I think it would be an indication, it would be a lead, as to what you should do next. What is important is that, at that dose of thimerosal, there was an effect.

Q So it helps form a hypothesis as to what will happen in the human body. Is that correct?

A Yes.

Q Are there any studies in humans that conclude that small doses of thimerosal, such as those contained in thimerosal-containing vaccines, cause immunosuppression?

A Not that I know of, but I'm not an immunologist and would not be familiar with that literature.

Q In the Agawal and Gothe studies, the dendritic cells were exposed to thimerosal and not ethyl mercury. Is that correct?

A That's correct.

Q Do you know whether in vitro -- I know

you're not an immunologist, but whether the thimerosal would metabolize into ethyl mercury the same way it would in the human body?

A I don't know the answer to the question, but I would suspect that it would metabolize very quickly, that the SH group would split off the ethyl mercury very, very rapidly in even a dendritic cell.

Q That would be your guess.

A That would be my opinion based on what I know about sulfohydro groups, disulfides bonds, and the stability of such compounds and what the literature says.

Q What literature is that?

A The literature by many people clearly -- I think Suzuki in Japan was the first to show that thimerosal, which is ethyl mercury acetal silicic acid, you might say -- he showed, and confirmed by Margolis and others, that the sulfur bond to the benzene ring is split very, very quickly, very rapidly.

Q Would you agree, sir, that in the human body ethyl mercury binds to red blood cells, proteins, and other molecules so that the entire dose of thimerosal and thimerosal-containing vaccine does not come into contact with the dendritic cells?

A I don't know, but I would be surprised if they did not come in contact because what you've got to understand --

Q I'm not asking you whether it comes into contact; I'm asking you whether a portion of that ethyl mercury binds to red blood cells, proteins, and other molecules so that the entire dose does not come into contact with the dendritic cells in the human body.

A That's reasonable.

Q Do you know what percentage of ethyl mercury binds to red blood cells in human beings?

A I would hazard a guess, but I had better not.

Q Would it surprise you if it were 90 percent?

A That would not surprise me.

Q But in the Gothe and Agawal studies, the entire amount of thimerosal is able to affect the dendritic cells. There is nothing else in there for the thimerosal to bind to. Is that correct? The entire exposure of the thimerosal is to the dendritic cell. Is that correct?

A Again, you'll have to get closer to your microphone. I'm sorry.

Q When you put the thimerosal in the in vitro

study on the dendritic cell, there is no binding to red blood cells, proteins, or other molecules. Is that correct?

A I don't know that that is correct. I would expect that there are many agents in a dendritic cell to which ethyl mercury would bind.

Q Does the Gothe or Agawal study tell you that, or are you guessing?

A I'm not guessing. I'm using 50 years of experience in research as to the properties of a thial compound and what that thial compound would react with, and it would react with many, many constituents in a cell.

Q But there is one dendritic cell, and that gets the entire exposure of the thimerosal in the in vitro studies performed by Gothe and Agawal. Is that correct?

A Again, you will have to repeat the question into the microphone. I'm sorry. The acoustics here are terrible.

Q I apologize. Then would you agree that the thimerosal in the Gothe and Agawal studies is exposed only to the dendritic cells in the in vitro studies?

A Yes.

Q Thank you. And it is your opinion that,

based on those two studies, that it is more likely than not that thimerosal-containing vaccines cause immune suppression in humans?

A I think that the amount of thimerosal in those experiments could cause immunosuppression.

Q Is it more likely than not?

A More likely?

Q More likely than not?

A I think it's more likely that it will cause immunosuppression.

Q And that's based on those two studies. Is that correct?

A I have more faith in the Agawal paper because they dealt with human cells. The other paper dealt with mouse cells.

Q Assuming that thimerosal can cause immune suppression, do these studies demonstrate how long that immune suppression will last?

A No, but papers by a Swedish group -- the author's name begins with H, and I can never pronounce it -- did point out that the immunosuppression lasts, the statement he made was, "a lengthy period."

Q A lengthy period?

A Yes. That was what the paper said.

Q You didn't file that paper with your report,

did you, sir?

A I don't remember whether it's in my report or not. It would be on the last page of the text. If I could see that, I could tell you.

Q You should have your report with you, sir.

A No. It's not in here. But it's a very well-known paper.

MS. RENZI: Well, if I ask Ms. Chin-Caplan to supply that paper, will you supply that to her?

THE WITNESS: Excuse me?

MS. RENZI: If I ask Petitioner's counsel to supply that paper, could you provide that to her?

THE WITNESS: Absolutely. In fact, when Vera, our immunologist, comes before the Court, I would suspect she will have that paper. There are two or three papers by the same author.

BY MS. RENZI:

Q You said it's a lengthy period. You stated that the immune suppression lasts for a lengthy period.

A The term I remember is "lengthy."

Q You can't quantify.

A I looked in the paper for some more of a statement, and in that one particular paper that I was reading, I could not get a more exact description at

the time.

Q Is it your point that the ethyl mercury causes a persistent immunosuppression, even after it is no longer in the blood?

A It's complicated because ethyl mercury will break down to mercuric mercury, and mercuric mercury will also cause immunosuppression.

Q Where does ethyl mercury break down into mercuric mercury?

A Pardon?

Q Does that occur in the brain, sir? Is that correct? Does ethyl mercury break down into mercuric mercury in the brain? Is that correct?

A Everywhere, in most cells. There is nothing novel about the brain. What's novel about the brain is the mercuric mercury cannot come out of the brain. We have mercuric mercury from ethyl mercury especially in the kidney.

Q The Swedish that you just cited to --

A A Scandinavian study.

Q Scandinavian -- I'm sorry -- Scandinavian study. When you say "lengthy period," that also means that, at some point, the body returns to its normal immune state, that it does not last for --

A I'm not an immunologist, so I really wasn't

reading the paper looking for that. I was reading the paper to see what I could learn about the properties of the various species of mercury, as far as immunosuppression.

Q But "lengthy period" would refer to a start and an end, whatever that length is. Is that correct?

A I don't know.

Q Is it your belief that Michelle Cedillo received thimerosal-containing vaccines that suppressed her immune system prior to the receipt of her MMR?

A It's my professional belief that thimerosal probably triggered something that caused immune suppression in Michelle. Thimerosal may have done it, per se, but I doubt that. I think the thimerosal triggered some other reaction in the body that caused immunosuppression.

Q What is your evidence for that?

A The evidence would be based on, I believe, some experiments that Ellen Silbergeld at Hopkins has done, in which she showed the immunological properties of mercury. I don't remember which species or all of the species. But I think she reported it in a paper given in Finland in 2002 or 2003. The paper is in the press. It's published in Toxicology and Applied

Pharmacology.

I believe she refers to some experiments that were done in her lab on immunosuppression caused by methyl mercury species, but I don't remember the details any more than that.

Q You don't remember the details, but you're relying on that article to form your opinion that there was a trigger.

A Because I read the paper very carefully at the time, came to a conclusion, and then went on to other things.

Q Does the amount of time between the last thimerosal-containing vaccine that Michelle received and the receipt of her MMR vaccination make a difference as to whether she was immune suppressed?

A Again, I'm not an immunologist. I would not want to -- I'm not an immunologist. I would not want to try to speculate on what I believe, in that respect.

Q Is there any evidence? You said you looked at some of the medical record. Is that correct?

A Yes.

Q And I know you're not an immunologist, but is there any evidence in the medical records that you reviewed that Michelle Cedillo was immune suppressed

between the time of her thimerosal-containing vaccines and the time she received her MMR vaccination?

A I'm a toxicologist. When I read an article, I just think about toxicological aspects of the article. If it's immunology, I usually skip over it because I'm not an immunologist.

Q Are there any studies that show that ethyl mercury in the brain can cause immune suppression?

A I don't know of any. There may be, but I don't know of any. The concept of immunosuppression and ethyl mercury is relatively new. It's not my concept. I think one of the first thoughts about this comes from Ellen Silbergeld at Hopkins.

Q You cite in your opinion to the Ashwood article, and that is Attachment C to your report. Would you like us to hand you that report so I can ask you some questions?

A I remember the statement. It was a statement that was made -- I'm sorry. May I?

Q Sure.

A It was a statement that was made just to form a liaison with the other articles, with the other reports, that were being done by the immunologists. It was trying to make a connection between thimerosal autism and immunology. That's the only reason that

was put in there. I think it's the last sentence, isn't it, practically?

Q I'm sorry?

A I'm glad I'm not the only one who can't hear. I think it's the last sentence, isn't it, in the --

Q Of your report, are you referring to the Ashwood article? I'm not sure of the last sentence that you're referring to.

SPECIAL MASTER HASTINGS: You're right, Doctor. It's in the last sentence of your report.

MS. RENZI: Of your report. I'm sorry.

THE WITNESS: Thank you, Special Magistrate.

BY MS. RENZI:

Q Does the Ashwood article indicate that thimerosal plays a role in immune dysfunction in some autistic children?

A I don't know. I don't think so, but I don't recall.

Q You state on page 9 of your report that some children can receive 185.5 micrograms of ethyl mercury from a thimerosal-containing vaccine during the first 14 weeks of life. Is that correct?

A Just a moment, please.

SPECIAL MASTER HASTINGS: Where on the page,

Ms. Renzi?

MS. RENZI: I may have the wrong page.

SPECIAL MASTER HASTINGS: I think I see it. It's under "Thimerosal and Childhood Vaccine." It's the fifth line down.

THE WITNESS: Here it is, nine. So I have this page 9 before me now, and so what question are you asking about it, please?

BY MS. RENZI:

Q I was asking about the 185.5 micrograms of ethyl mercury received through thimerosal-containing vaccines.

A It says: "Some children can receive 185.5 micrograms of ethyl mercury from thimerosal --" that sentence?

Q Yes.

A All right. What about it?

Q Did Michelle Cedillo receive -- how much mercury? You've calculated how much ethyl mercury Michelle Cedillo received. Is that correct?

A Yes.

Q Do you have that handy?

A Sure. Let me just refer. I want to give you the exact number. On a micrograms-of-mercury-per-kilogram basis, it was --

SPECIAL MASTER HASTINGS: Doctor, please speak up a little bit. When you go down to look at that, we lose you.

THE WITNESS: I'm sorry. The data that I have with me is perhaps more relevant. It's on micrograms of mercury per kilogram body weight in the case of the Cedillo child, and the highest cumulative dose, cumulative dose, was between about 10.7, I think it is, micrograms of mercury per kilogram body weight. It's in the report that was handed to you this morning.

BY MS. RENZI:

Q Did you calculate that?

A Pardon?

Q Did you calculate that number?

A Yes. Yes, I did.

Q And what was it based upon? I'm sorry. What was it based upon?

A It was based on the amount of mercury, the cumulative amount of mercury, that Michelle was exposed to at a certain date, and then that was converted to micrograms of mercury per kilogram of body weight.

Q Could you give me the specific numbers, please?

A I'm trying to think of where they might be. She received a total of 137.5 micrograms of mercury from her vaccines. By 18 months of age, she received a total of at least 137.5 micrograms of mercury from her vaccines. During the first four months of her life, she received 75 micrograms of mercury. Does that --

Q My question to you is, she received a total of 135 micrograms over her first 18 months of life. Is that what you said?

A She received 137.5 micrograms of mercury from thimerosal during the first 18 months of her life.

Q And is that how much she accumulated in her blood at any one time?

A This is what she was exposed to. This is the total amount of mercury that was injected into her over a unit period of time.

Q But if you measured her blood levels at any one time --

A It has nothing to do with blood levels at this stage. This data is what she was injected with, the amount of mercury she was injected with, her exposure, as we call it.

Q Okay. I know I'm repeating myself. If you

could answer yes or no, at any given time, did Michelle Cedillo have 135 micrograms of ethyl mercury in her body?

A At the day of her last vaccination, which, I gather, was when she was 18 months of age, if you added up all of the mercury that she had received in her vaccinations up until the age of 18 months, it came to 137.5 micrograms of mercury. That is what she literally was injected with, was exposed to, over this period of time.

Q You believe that autism is caused by an efflux disorder. Is that correct?

A I believe that, first of all, autism is not a single disorder. You have autistic spectrum disorders. At one end of this "spectrum," as it's called, is Asperger's Disease. At the other end is a very severe autism.

Now, when a chemist looks at a spectrum, the chemist looks for individual bands. This has not been done with the autism spectral disorders. So the autism spectral disorders are probably made up of a different group of diseases with similar signs and symptoms. All right?

Now, one of those probably is due to one of these specific diseases that fall into the autism

spectral disorder definition is probably due to children having a mercury efflux disorder.

Q I may not be understanding you, so correct me if I'm wrong. Can you identify those children, based on their symptoms or based on where they are in the spectrum, whether it was caused by an efflux disorder?

A We can, on the basis of the Adams work -- can you hear me all right? -- on the basis of the Adams paper, which just came out in 2007, we can identify those children who have more mercury in their teeth than other children.

What we want to do eventually, and it's a territorial nightmare, is to get the brain tissue of deceased autistic children and to get other tissues from deceased autistic children and analyze them and compare them to a proper control to see if the mercury level in them is excessive.

Q But you don't have those brain tissues. Is that correct?

A I don't have them.

Q No one has done the experiments on those brain tissues, so you have the tooth study. Is that the basis for your conclusion that autism is caused by a mercury efflux disorder?

A No. You've got to take into consideration the hair experiment by Holmes, which was confirmed by the MIT group, number one. You have to take into consideration the Bradstreet experiment, which showed that DMSA indicated there was a greater body burden of mercury in autistic children, and you have to take into consideration the Adams experiments on the teeth.

So when you put those together, collectively, they support the idea of a mercury efflux disorder. There is no question that many more experiments have to be done.

Q You didn't mention two other studies that I will mention today. One is the Ip study from 2004, and the other is the Kern study from 2007. Are you familiar with those studies?

A I'm familiar with one of the latter studies. Who was the first one?

Q Ip, I-P.

A And what was that study about?

Q These studies failed to replicate the hair study and the Holmes study.

A I'm not surprised because hair studies are probably the most difficult studies to replicate. There is no question about the fact that if hair studies are not done in an experienced laboratory who

had experience doing them, that the values are meaningless.

Q So it's your point that the Holmes study was done right, but that the Ips study was not. Is that correct?

A The Holmes study was done at the Doctor's Data, which probably analyzes more mercury samples than any other laboratory in the world. All right? They have been certified, they have been approved, by the FDA for doing hair analysis.

Q What do you know about the Kern paper?

A There are two, so you've got to tell me which Kern paper you're talking about. Is this the Sohago Group?

Q The 2007.

A Pardon?

Q 2007?

A You've got to tell the title, please.

Q I'll have to get it. It's the Kern hair study. Is there more than one?

A I thought that the Kern was also the Adams paper because I thought Kern was an author on the Adams study. Kern, I remember, is a psychiatrist from Dallas or someplace in Texas, I think, and I think what they did was look at the sulfohydro groups in

autistic children versus nonautistic children.

Now, I don't think it was a very good study, and when I do a quick read on the study, if I don't think it's very good, I just don't bother with it anymore.

Q Are you familiar with the Ips study?

A Pardon?

Q Ip, I-P.

A What about it?

Q Are you familiar with it?

A Yes. Actually, they gave me a copy of the Ip paper.

Q And what is that study about?

A I think they, more or less, could not repeat some results.

There are other papers I should tell you about, in case you don't know about them, and that is there is a paper that came out of Missouri which claimed that autistic children did not, when given DMSA, did not excrete an increase in mercury. But if you quote that paper, the answer to it is almost none of their subjects, normal or autistic children, excreted very much, if any, mercury.

So my guess is that whoever did their mercury analysis don't know what they are doing. This

is from a clinical toxicology or emergency medicine group, I think, at the University of Missouri, and when you look at that paper, you just have to say, "Wow. How could anyone get those results?"

So not all scientific papers, even in peer-reviewed journals, are good.

Is it all right if I just stand up and stretch for a minute?

SPECIAL MASTER HASTINGS: Go ahead.

MS. RENZI: I'm almost done, but we can take a break, if you would like to.

THE WITNESS: Thank you.

SPECIAL MASTER HASTINGS: Doctor, let me take this time to apologize to you, too. Here we are trying to get you to speak up, and it turns out your microphone wasn't in proper working order, so I apologize.

Go ahead, Ms. Renzi.

BY MS. RENZI:

Q Doctor, you stated earlier today that not everyone who gets vaccinated gets autism. Is that correct?

A Of course, as you know.

Q And you said that it's the timing that is critical as to why some children develop autism, and

some children do not.

A That's what I would think.

Q So they have to receive an immunization during a very specific window in order to develop autism. Was that your testimony today?

A That is a possibility that, to me, seems reasonable.

Q Is it more likely than not?

A Pardon?

Q Is it more likely than not that this theory -- has this theory been proven by anyone else? I'll start with that.

A In science, we get some experimental results, or we get some data, and we try to understand the data, and then when we try to understand the data, we set up a hypothesis. The hypothesis eventually will be proven correct or incorrect. The hypothesis that I've offered is that perhaps there is a very narrow window for children who are vaccinated to have an effect on their developmental system and, therefore, causing autism, and that some children may not get vaccinated in that window, and other children may. So there is a variability here, and this is a hypothesis.

Q So, in your hypothesis, let's assume that

Michelle Cedillo got vaccinated at two months and one day, and she developed autism following her MMR vaccine. She received thimerosal-containing vaccines at two months and one day, and then went on to get an MMR vaccine at 15 months and developed autism.

A But she also got a vaccination -- I think it was seven months before. I think the MMR is what, at 12? I've forgotten what month the MMR is given.

Q She received her first MMR at 15 months.

A At 15 months? Okay. I think she got her last mercury-containing vaccination -- the MMR does not have mercury in it -- probably around seven months. Am I correct or not? I don't have the figures in front of me.

Q I think you are correct about nine months earlier. That is correct.

A So it is possible that that window, at that time, was very narrow, enough to cause some kind of immunosuppression.

Q Which window are you talking about? Is this the window when she received her thimerosal-containing vaccine or the window that is between the time of her receipt of her thimerosal-containing vaccine and the exact day she received her MMR vaccine?

A I have hypothesized that it is the window

when she received that last, seven-month dose of vaccine, thimerosal-containing vaccine.

Q The Pichichero paper found a half life of mercury in the blood of seven days. Is that correct?

A Of what kind of mercury?

Q Ethyl mercury in the blood.

A You're talking about when thimerosal was injected.

Q Yes.

A And are you talking about the humans, or are you talking about the monkeys?

Q I am talking about the Pichichero paper with the humans.

A Okay. All right. Now I know what you're talking about.

SPECIAL MASTER HASTINGS: Now which paper is that, the Pichichero paper?

MS. RENZI: Yes.

SPECIAL MASTER HASTINGS: Okay.

THE WITNESS: What's your question? May I ask?

BY MS. RENZI:

Q You said that there was a flaw with that study, that you can't compare that to the autistic children who receive vaccines as to the half life of

ethyl mercury in their blood. Is that correct?

A What I did say, I believe, was that autistic children, if they have a mercury efflux disorder, would have different toxicokinetics and that that data, in normal children, may not be applicable at all to a child who cannot get rid of mercury his or herself.

Q Is there any evidence? Are there any papers that confirm your hypotheses on that?

A I think, if you're talking about the hypothesis of mercury efflux disorder?

Q Whether autistic children have a longer half life of ethyl mercury in the blood. Are there any peer-reviewed articles that state that autistic children --

A I don't know if that's been done. I don't think any mother would want more ethyl mercury injected into her autistic child, knowing what has happened before. So I doubt that that experiment can be done in humans.

Q You also stated in your testimony today that immune suppression is significant in the development of autism. Is that correct?

A I think I may have said that in that figure that I showed that one of the possible pathways for

ethyl mercury triggering something was it would first trigger immune disregulation, and this would lead to immunosuppression. Again, that was a model that I had up on the screen, and, again, it's a hypothesis.

Q Do any papers or peer-reviewed articles confirm your hypothesis?

A The hypothesis was made less than three or four weeks ago, so the answer is no.

Q You also stated, in your testimony today, that there are genes involved in the handling of mercury in the body.

A Yes.

Q Are these genes polymorphic?

A Yes. Let me clarify something. At the present time, we only have proof for one such gene that is affected by mercury. There probably are others, but there is no paper published about those others as yet.

Q Has anyone tested Michelle Cedillo for this gene?

A There are certain rules and regulations that must be followed before an academic institution or an academic person can do something with a human, especially a child. I would not be surprised if those experiments have been done at the University of

Washington, but, at the present time, I don't know whether they have or not.

A study was published in 2005, two years ago, maybe a year and a half ago. Those studies, in order to get through a human subjects committee, it would take a while. But I would be amazed if those studies are not ongoing at the present time.

Q So could any of the 5,000 children that now have claims before this Court get that genetic test, be identified with that gene, and then we could determine that that particular person's autism was caused by the handling of the mercury due to that gene defect?

A First of all, one must realize, there are many genes involved with mercury toxicity. There are different genes that convert elemental mercury to mercuric mercury. There are different genes that convert ethyl mercury to mercuric mercury.

Let's say Autistic Child X has a faulty gene that will cause a different porphyrin-urine profile. It's another case to be able to prove that the defect in that gene causes autism. Just because a child has it, and a normal child doesn't, doesn't mean that that is the cause.

What has to be done, believe it or not, when

you talk about in vitro experiments, what has been done with other diseases in similar genes is you take that gene and put it into a yeast, and the yeast -- you can reproduce many of the effects that you find in a human being by a gene. You can produce many of the transport efflux disorders found in humans in the yeast cell, which still amazes me, but it's true.

Q Now, you stated earlier that, even if there is a genetic susceptibility in autistic children to retain mercury, does every child who has autism have that efflux disorder?

A As I said earlier, we have autism spectrum disorder, a group of diseases, and I don't think any physician that I know of would say that the autism spectrum disorder diseases are just one disease or one disorder. There is Asperger's. Do you know what Asperger's is?

Q Yes, I do.

A Okay. These are the infant savant, very unusually gifted children. So these are very, very gifted children, and then we have the very, very severe autism children at the other end. In between, we have all sorts of variations. So one cannot say that all of these autism kids have the same disorder, the same genetic disorder at this stage of the game.

Q Is there any way you can determine whether a child has this genetic susceptibility to autism?

A There are papers about his, actually, one from Rutgers. There is an excellent review article on the genetics of autism from the Mass. General Hospital. I know you're down here in Washington, but Mass. General and Harvard Hospitals are considered to be the meccas of American medicine, as Hopkins is.

There is a very good review article that came out two or three, maybe two years ago. It was so good that I stopped and sent an e-mail to someone I didn't even know saying what a wonderful article it was, and she was shocked to receive such compliments, and I was shocked that I gave it, too.

Q Now, did you cite it in your report?

A Pardon?

Q Did you cite that article in your report?

A No, because I didn't see any need of citing that article at the time. It was just a review.

Q But it talks about genetic susceptibility. It's an excellent article about genetic susceptibility in autism.

A That was an article pointing out the theory of the month, as far as which gene causes autism. We really don't have any specific data, but there is one

paper coming out of Rutgers that is highly thought of. I don't remember the names of the authors or even what they did.

MS. RENZI: I have no further questions. Thank you, Doctor.

THE WITNESS: Thank you. I'm sorry that I interrupted you when you were asking questions.

MS. RENZI: And I'm sorry if I interrupted you, sir.

SPECIAL MASTER HASTINGS: Let's take a restroom break at this time, and we'll be back in 15 minutes.

(Whereupon, a short recess was taken.)

SPECIAL MASTER HASTINGS: All right, folks. We'll be starting again here if everyone will take their positions.

Dr. Aposhian, you're still in the hot seat, I'm afraid.

THE WITNESS: Still?

SPECIAL MASTER HASTINGS: We have maybe a couple of questions for you here, and if you would take the witness stand again, hopefully, we'll get you through it soon.

THE WITNESS: Thank you, sir.

SPECIAL MASTER HASTINGS: Thank you very

much. Just for the benefit of those individuals who are listening in here or are here in person and have not witnessed a hearing in the Vaccine Act, I note that it is quite common -- it's basically the rule in these cases that the special master, generally after both parties have asked questions of the witness, the special master often does ask questions. I have one or two for Dr. Aposhian myself, and I'm going to be asking my colleagues if they have any, so this is not an unusual practice.

I meant to say, this morning, that the three of us have spent many, many, many hours, weeks, and months, actually, studying the medical literature that you've heard Dr. Aposhian talk about, and you'll hear many witnesses talk about.

There are many hundreds of articles put in about 18 or 19 expert reports. We've studied all of those, and we've done our best to learn as much as we can ahead of this trial so we can understand what the experts are talking about, and sometimes, in the course of doing that, we come up with some questions that we would like to hear the witnesses answer.

Now, it turns out, as in most cases, as was the case today, both the fine counsel for both sides have already asked most of the questions that I had

for Dr. Aposhian, but a couple of more were raised today, so I'll go ahead and ask those, and then we'll give the Petitioners' counsel a chance to ask any more redirect questions of Dr. Aposhian.

Doctor, one thing I was interested in: You mentioned, just toward the end of your testimony, talking about what was referred to as the "window of vulnerability," and you were describing that as a hypothesis and that it's plausible based on everything you know.

I guess what I'm asking is for you to tell us, as best you can, how sure you are of that. Is it something you're absolutely sure about, or is it just sort of an initial hypothesis? Is it something you can say you think it's probably correct? Can you help me on that?

THE WITNESS: Sir, if I were able to do the experiments, I know what experiments I would do, and so let me say that, at the present time, it is an initial hypothesis. It is an initial hypothesis, based on what we know about other toxic agents and the windows that they act in, the very narrow windows. The idea of a narrow window made sense to me because of the question: Why don't all children who got vaccinated get autism?

The answer to your question, I hope will satisfy you, is that this is an initial hypothesis.

SPECIAL MASTER HASTINGS: All right. Let me ask the same question about your general view. You testified here today, in great detail, about the effects of mercury in its many forms, and you suggested that another hypothesis you have is that the thimeric to mercury in the form of thimerosal can cause immune suppression in these individuals and that thereby, I guess, ultimately leading to their autism.

The theory that I understand you're talking about is immune suppression, that mercury causes immune suppression. Again, is that a hypothesis? How strongly can you support that?

THE WITNESS: It is not my hypothesis originally. There may have been other people, but the paper that I know is a paper by Ellen Silbergeld, who is a professor at Hopkins. She is a McArthur Fellow, which is a "genius award," if you will. She is the only toxicologist that ever received the McArthur "genius award," and, knowing her, I have a great deal of confidence in her papers, and there is a paper that she published that was the result of a talk she gave at the International Congress of Toxicology in Finland, which, I think, was about four years ago,

2002, I think.

So I have a great deal of confidence that there is immunosuppression caused by ethyl mercury, based on the work of others. Is there anything else?

SPECIAL MASTER HASTINGS: All right. So you say "a great deal of confidence."

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Do you think it's probable?

THE WITNESS: It's very plausible, in my opinion, very, very plausible.

SPECIAL MASTER HASTINGS: Can I follow that up? When you say "very plausible," can you go so far as to say "probable"?

THE WITNESS: I thought "probable" was less, but I think it was probable. Highly probable.

SPECIAL MASTER HASTINGS: All right.

THE WITNESS: I believe it happens.

SPECIAL MASTER HASTINGS: That answers my question. That's all the questions I have for this witness. Special Master Vowell?

SPECIAL MASTER VOWELL: Yes. I have a couple of clarification questions, Dr. Aposhian. You referred earlier in direct examination to a Mexico study and they you referred in cross-examination

specifically to a New Mexico study. Is there one study or are there two studies?

THE WITNESS: There are two entirely different studies.

SPECIAL MASTER VOWELL: Okay.

THE WITNESS: Would you like me to define what they --

SPECIAL MASTER VOWELL: Please explain the difference to me.

THE WITNESS: Okay. The New Mexico study involved the pig, who drank a bottle of methyl mercury and the family in rural New Mexico slaughtered that pig within a couple of days and that pig was fed to children and the rest of the family. The children got ill, very ill. I think one of them died. Another one lived until -- for another 20 or 21 years. And that one that lived for 20-21 years, when they autopsied her, they did a brain mercury analysis and they found her brain mercury, which would be inorganic mercury, was 100 times above normal. So, that's the New Mexico study.

The Mexico study is one that my group did -- I don't remember what it was. In Mexico, we were called in to determine the following. There was a lotion, a cosmetic lotion that was used to lighten the

skin, to bleach the skin of people with dark skin. And this contained --

SPECIAL MASTER VOWELL: Calomel?

THE WITNESS: Pardon?

SPECIAL MASTER VOWELL: Calomel?

THE WITNESS: I don't remember --

SPECIAL MASTER VOWELL: Or mercurous mercury.

THE WITNESS: There are a number of names of it. Anyway --

SPECIAL MASTER VOWELL: Mercurous chloride?

THE WITNESS: -- we were called in to examine the fact there were workers, who made it, and a number of people, including a 90-year old grandmother, who had -- great grandmother, who had put it on her skin for years. And we gave them a chelating agent to determine their body burden. We had -- we did a baseline on them and then gave a chelating agent. So, the Mexico study that we did was to determine how much mercury, what was the body burden of mercury in these workers and people, who had been exposed to a lotion that contained mercurous mercury, actually. Does that clarify your question?

SPECIAL MASTER VOWELL: Yes. And I -- did you cite both of those studies in your report, do you

recall?

THE WITNESS: I don't think I -- I'm not certain whether I cited the Mexico study. It may not have been relevant. It would be -- if we did, it would be in the bibliography. The first author is Gonzalez.

SPECIAL MASTER VOWELL: Okay. There is an article in your bibliography, and I want to make sure that I'm not confusing --

THE WITNESS: No.

SPECIAL MASTER VOWELL: -- your testimony in the studies. It's at Tab GG of your attachments. Could I prevail upon the Department of Justice paralegal to hand that to Dr. Aposhian, please? It's a study by McRill and Boyer from 2000 and it involves Arizona in a cosmetic claim. Are you talking about a similar study you did?

THE WITNESS: Oh, I know this paper.

SPECIAL MASTER VOWELL: Okay.

THE WITNESS: Let me -- would you like me to explain that paper?

SPECIAL MASTER VOWELL: No. I think I understand the paper, Dr. Aposhian. I just wanted to make sure that you were referring to a study you were involved in, not this particular one.

THE WITNESS: Our paper is not this paper. Our paper is a different one. This is a -- I think it appeared in the Journal of Emergency Medical. Ours appeared, I think it was in the Journal of Pharmacology and Experimental Therapeutics.

SPECIAL MASTER VOWELL: Did you come up with any different results than this study?

THE WITNESS: Yes.

SPECIAL MASTER VOWELL: Okay.

THE WITNESS: We were amazed to find out how much mercury was in some of these people. We had -- until some of the figures were given to me today, we were amazed at the milligram amounts of mercury that we found in some of these people. And they were exposed to both elemental mercury in the synthesis of the mercurous mercury compound and the assembly of the lotion with the mercurous mercury.

SPECIAL MASTER VOWELL: Okay. And my second question has to do with page nine of your report. And at page nine, in the first paragraph, you talk about the mortality rate from Pink disease as being between 5.5 and 33-1/3 percent.

THE WITNESS: Yes.

SPECIAL MASTER VOWELL: Can you tell me where those figures came from? The article you cite,

the Dally article, doesn't contain those figures and I am just trying to find out whether that is something commonly known to toxicologists.

THE WITNESS: I believe it went into one of Clarkson's review articles. Clarkson is one of the senior, probably the most experienced mercury investigator before he retired. He retired about four or five years ago. And he's written maybe probably four or five review articles since he's retired. And I think in one of those papers, that figure is given. That's why I say, certainly the figure 1/500th is from one of his articles.

SPECIAL MASTER VOWELL: I did find that one. I'm sorry, I just didn't find the other one and I was hoping you could --

THE WITNESS: When I get back to my lab, can I send it to you?

SPECIAL MASTER VOWELL: Certainly send it to counsel for Petitioners and they will file it with us, I'm confident. Those are all the questions I have, Dr. Aposhian. Thank you, very much.

THE WITNESS: Thank you.

SPECIAL MASTER HASTINGS: Special Maser Campbell-Smith, did you have any questions?

SPECIAL MASTER CAMPBELL-SMITH: No questions

at this time.

SPECIAL MASTER HASTINGS: All right. That's all the questions we have. Ms. Chin-Caplan, did you have any redirect?

MS. CHIN-CAPLAN: No redirect.

SPECIAL MASTER HASTINGS: All right. I understand from our discussion earlier that you would -- you were next going to go with the testimony of Theresa Cedillo. And before you come up over here, Dr. Aposhian, you are off the hot seat, at this point. We thank you, very much.

(Witness excused.)

SPECIAL MASTER HASTINGS: While both of you are here, earlier today, as we started the hearing, I made some remarks of thanks about your family and thanks and you were out of the room with Michelle at that point. So, I just wanted to perhaps reiterate those and say to both of you, as I said this morning, that we certainly, the three of us here and all the members of the Court, are very grateful for the fact that your family was willing to have Michelle's case designated as the first test case in the Omnibus Proceeding. We thank you and all the members of your family, which, as we mentioned this morning, for coming here to be with us today. And we, also, wanted

to say that certainly having read all of the medical records of what you folks have gone through with Michelle, we wanted to extend our sympathy to you folks, but also to say that we certainly feel a lot of admiration for the way you've dealt with Michelle, with her illness and taking care of her. And we enjoyed meeting you here this morning before we started and we thank you, very much, your whole family, for your participation --

Mrs. Cedillo: Thank you, very much.

SPECIAL MASTER HASTINGS: -- today and throughout the rest. So with that, Mrs. Cedillo, as a reward, we are going to grill you. So, if you would come and take a seat.

Whereupon,

THERESA CEDILLO,

having been first duly sworn, was called as a witness herein and was examined and testified as follows:

SPECIAL MASTER HASTINGS: Please have a seat and Ms. Chin-Caplan, go ahead, please.

MS. CHIN-CAPLAN: Thank you, very much.

DIRECT EXAMINATION

BY MS. CHIN-CAPLAN:

Q Could you kindly state your full name for the record, please?

A Okay. My name is Theresa Cedillo.
Q And are you married?
A Yes, I am.
Q And what is your husband's name?
A My husband's name is Michael.
Q Do you have any children?
A Yes, I have one child, Michelle.
Q And is Michelle the subject of this hearing today?
A Yes, she is.
Q Can you describe to the Court what Michelle was like when she was first born?
A Michelle was a happy, robust baby, very loving.
Q And was she responsive to you and your family members?
A Very responsive, very normal, very happy, a good baby.
Q When you say 'very normal,' what do you mean by that?
A She -- well, starting from birth, you know, I breast fed her. She breast fed normally. Everything about her was normal, her sleeping habits, her play habits. She became very -- she had a lot of attention to grandparents, my husband, myself, being

the only child. So, she was very responsive to all of us.

Q And as Michelle grew older, did you take her for regularly scheduled doctor appointments?

A Yes, I did.

Q At these doctor appointments, did any of the pediatricians indicate that they thought that Michelle was not developing normally?

A No, they did not.

Q At some point in time -- well, prior to that, can you tell the Court when Michelle sat up?

A Michelle sat up -- unassisted, you're asking me? Unassisted, probably about seven or eight months.

Q And was she -- can you tell the Court when she started to babble?

A She started to babble close to -- well, actually earlier than that. I'm going to say approximately -- well, ask me again. Just baby babble or closer towards just babble in general?

Q Yes.

A She made happy sounds very young, maybe three and four months, like the cooing sounds.

Q And did she smile at you --

A Yes.

Q -- and your husband?

A Yes, she did.

Q Did she, at some point in time, start to develop words?

A Yes, she did.

Q And what words did -- was Michelle able to say?

A Well, she was able to say, baby, mommy or mama, daddy, addy was daddy, juice, apple -- I'm probably leaving some out -- words supposed to be kitty versus key; turtle was turt-turt, like that. And she said Jesus, because my mom had shown her a crucifix in her house everyday, she said, Jesus loves you, there's Jesus, and she'd go Jesus, and a few other words.

Q But, you understood what she was saying to you?

A Oh, yes.

Q Did Michelle play with toys --

A Yes.

Q -- when she was younger?

A Yes, she did.

Q And did she react when other people came into the homes?

A Yes, she did.

Q Did she play with other children?

A Yes, she did.

Q And about the time of Christmas 1995, when she was about 15 months old, can you tell the Court what Michelle was able to do at that time?

A At that time, she was beginning to walk. I can't recall exactly at the 15-month point if she was walking completely independently. But, she could push the little baby shopping cart unassisted. She played with her toys. She played with us. She interacted with all of us, her family. We took her everywhere. Like I said, being the only grandchild in town, my mom and I, we went to lunch with her -- I mean, we took her to lunch with us. She went to church with us, to the park, to the grocery store. You know, she was on regular outings, to visit family and family gatherings. She was happy. She ate normal. Her health was normal, you know. And she was a happy, well baby.

Q Now prior to December 20, 1995, had Michelle received all of her immunizations as scheduled?

A Yes, she did.

Q And on December 20, 1995, did Michelle receive another immunization?

A Yes, she did.

Q What immunization did she receive?

A The measles-mumps-rubella vaccination.

Q Can you describe to the Court what Michelle was like after she received the MMR?

A Six days -- for the six days following the vaccination, she was okay. On the seventh day, she developed a fever that lasted approximately four to five days, that would spike up to 105 or over and then come back down with Tylenol and then go back up, come back down.

Q And when she spiked the fever, did you call the doctor's office?

A Yes, I did. I called the doctor's office and also the ER when it continued on into the weekend.

Q And what did they tell you?

A They told me there was a very bad flu going around, a lot of babies were in that were sick. If she had any symptoms of vomiting, which she did, it was probably the flu. It was probably -- just treat her with Tylenol and cool baths and keep her hydrated.

Q Now, you indicated that you called both your doctor's office and the ER. Who told you that there was a bad flu going around?

A They both did. The first call was to the doctor's office and I don't know if I remember the day of the week correctly, but I think it was like a

Wednesday or Thursday. But then by Friday night, I could see that the fever was not coming down, so then I called the ER real quick and she said, oh, honey, you're better off treating her at home. We have a roomful of kids here and you're just going to expose her and, you know, just go ahead and treat her with Tylenol and cool baths and fluids again.

Q So, aside from the fever, was Michelle exhibiting any other symptoms?

A Well, she was vomiting. She was crying. She was very hot with the fever. We had -- just had her -- it was December, but in Yuma, Arizona, our winters are like everyone else's summer or spring. But, we just had her either with no little shirt or just like the little baby undershirt. We had to work pretty hard to keep her happy during those times. She was very irritable.

Q So, at some point in time did the fever come down?

A Yes, it did, about, I think, the 31st, which was, I think, on a Sunday. I think that was the last day of the fever.

Q And what happened after the 31st?

A After the 31st, she was -- she did not have any fever for two to three days and then the fever

returned on either the third or fourth day, around that time frame.

Q And what did you do when the fever returned?

A I called the doctor's office and made an appointment. I can't remember if I made the appointment or I just went in, but I -- the next day. But, I had an appointment within the next one or two days. I did call, though.

Q And when you took her to the doctor's office, what did they tell you was wrong with Michelle?

A They were unsure, except for they thought it was probably like a sinusitis or viral, like the flu. They noted -- I had just given her Tylenol, but her fever was still, I think, 100.3 or 100.7, in that range. And I had told them she was very irritable and I thought she was sick. So, they thought it was sinusitis or the flu.

Q And did they order something for Michelle?

A They ordered antibiotics and fluids, for me to give her fluids.

Q So, did that fever go away, as well?

A Yes, it did. I think that day was the last day of the fever.

Q After that fever, that second fever, what

was Michelle like?

A She was very irritable. She cried easily. She vomited frequently, many times a day, and up to where we had a little bucket and everything in a couple of other rooms where she was at, because we was always having -- I mean, it was so frequent, we were cleaning it all day. She didn't want to eat anything by mouth and she just wanted to drink a lot of fluids. She -- I thought she was still have effects from the flu or whatever it was that I thought she had -- or they thought she had.

Q So, how long did the vomiting last this time?

A The vomiting lasted quite a while. It lasted, I believe, about six to eight weeks, not -- the frequency was greater at the beginning and then it decreased, but she was still vomiting.

Q So, you say that she vomited six to eight weeks. How many times a day would she vomit?

A At the beginning, it was a lot. It was like maybe eight times a day and then the frequency decreased. But, it was still frequent, like maybe two to four times a day.

SPECIAL MASTER HASTINGS: Mrs. Cedillo, we want to make sure that the people listening can get

this. So, if you can get maybe a little closer to the microphone --

THE WITNESS: Okay, sure.

SPECIAL MASTER HASTINGS: -- that would be great.

THE WITNESS: Here we go. Okay. Let me just move it forward.

SPECIAL MASTER HASTINGS: Thank you, very much.

THE WITNESS: Okay.

BY MS. CHIN-CAPLAN:

Q Did you notify anybody about the vomiting?

A I did. I called the doctor's office and they thought it was just kind of like a leftover thing, at the beginning, from the fever -- or from the flu, I mean. And then after that, they really didn't have an answer why. They thought maybe she was allergic to milk or maybe I needed to change her diet. But, she wasn't eating my mouth. So, there was really no conclusion made.

Q Was Michelle eating at this time?

A No, she was only drinking liquids at that time.

Q No solid food?

A No solid food.

Q Around this time, was Michelle exhibiting any other gastrointestinal problems?

A She began having diarrhea, which we thought was because she was only drinking fluids. But, we didn't know, even -- we just didn't know. She was -- the vomiting and diarrhea.

Q And you said she started to have diarrhea. Can you date approximately when the diarrhea began?

A Around the time of the fever, which is what originally led us to believe it was the flu.

Q When you say 'the fever,' are you referring to the first fever or the second fever?

A The first fever.

Q So sometime within the time frame of December 27th --

A Twenty-seventh.

Q -- through the 31st?

A Yes.

Q That's when the diarrhea started?

A Yes.

Q And during this time frame immediately afterwards, did the diarrhea persist?

A Yes, it did.

Q Now, when you say 'diarrhea,' are you referring to the frequency of her stools?

A To to the consistency and the frequency, both.

Q Okay. How many times a day did Michelle have diarrhea?

A Thinking back, it was frequent, maybe four to six times a day, she would have a stool, watery stool.

Q And did that stop at any point?

A It did stop at some point, yes.

Q And did she develop any other gastrointestinal symptoms?

A She did. She became constipated.

Q So once the diarrhea stopped, she developed constipation?

A Yes.

Q And do you know approximately when that occurred?

A It would a rough approximate. I can't exactly remember. But, it was probably, if you go from the 27th, maybe eight to 12 weeks after, maybe more like the 12-week mark.

Q So, she had diarrhea for approximately eight to 12 weeks after the first fever; is that it?

A Yes.

Q And then after the eight to 12 weeks had passed, her diarrhea turned into constipation?

A Yes.

Q And did you notify her doctors about that?

A Yes, I did.

Q And what did they tell you?

A They didn't have any conclusion. Well, when I did notify them, it was at a well baby check and they said I could try getting her, I think it was Babylax or mineral oil, I think was the name of the product -- I mean, the Babylax name. Mineral oil is just mineral oil.

Q And was that for the constipation?

A That was for the constipation, yes.

Q Now, after the high fever disappeared the second time, what was Michelle like behaviorally?

A She was different. She seemed withdrawn. I thought her hearing had been affected. She was no longer talking. In fact, she was completely quiet. She didn't make any sound, which is why we thought it was her hearing. We thought maybe she couldn't hear, so that's why she wasn't responding or making her own sounds. She pushed away, when previously we could hold her. She would either push away with two hands or just lean away from us. We had difficulty taking her out anywhere. Over time, you know, we quite taking her to church or we still tried to take her for

stroller rides, that kind of thing. But, it was hard for her to be in public settings.

Q So, were you able to take her to church any longer?

A No -- well, not without causing a commotion. We tried.

Q Were you able to take her out to lunch with your mother any longer?

A We tried. We made several attempts; but, no, eventually, we stopped. It was too upsetting for everybody, for her, for the people in the restaurant, for us. So, we stopped.

Q Now, you mentioned that prior to the MMR immunization, Theresa was playing with people?

A Yes.

Q Did that continue after the high fevers ended?

A No; no, it did not.

Q Did Theresa play with her toys?

A Michelle. You said, 'Theresa.' It's okay. Michelle no longer -- Michelle was not playing. She was -- she had her toys, but she wasn't playing with them the same.

Q What do you mean by that?

A She would want to line them up or instead of

-- if it was something with like a push button, she would rather study it than push the buttons. You know, she wouldn't push the buttons any longer. She seemed to be preoccupied with certain toys and lining them up a certain way, instead of just sitting down and playing with them like she did before.

Q Did she respond to her name when you called her?

A No.

Q Did you tell your doctor that Michelle wasn't responding to her name when you called her?

A Yes, I did.

Q Did you tell your doctors that she was lining up her toys and that she had not done that before the high fevers?

A I can't remember if it told them about the toys until a much later time, because it seemed -- it seemed unusual, but at the time, I didn't realize it was the symptom of anything. So, my main focus always was on that she had quit talking.

Q And did you tell your doctors that Michelle wasn't talking any longer?

A Yes, I did.

Q And what did they tell you?

A They told me that sometimes, sometimes

children will do that, sometimes an only child will go through a phase and not -- you know, and then regain -- not regain, but resume, resume speaking later. They said she looked okay; you know, was she bumping into walls, could she still pick up things, in which she could. But -- so, they said at a later time, we can test her hearing, if we wanted to. But, they thought she would be okay.

Q So, did they have any recommendations for you at all?

A Other than a later hearing test, no.

Q And did Michelle, at some point, have a hearing test done?

A Yes, she did.

Q And what was the results of that hearing test?

A She had to -- one was just the regular hearing test, where you're in the closed room and they tried to mark her response. And it was normal. What they measured was normal. It was hard, because she wasn't talking. The other one was a brain step auditory evoked response test and that was to see whether or not the brain is processing the sound properly and that was normal.

Q And when was that done?

A The brain stem test was probably done in 1997, maybe late 1997. It was after we -- it was probably around that time, after she was diagnosed.

Q Now, you indicated that you told your doctors about these behaviors of Michelle's, that she wasn't responding to her name, that she was lining up her toys, and she couldn't speak. How long did that continue before you decided that you needed to see somebody?

A That continued for probably about until April of 1997, so maybe about a year's -- a year's time or how long will they go back -- from the fever, then it was over a year. It was probably a year and three months.

Q And what were you doing in that one-year period when Michelle was exhibiting these behaviors?

A I would ask other family members or other friends that I knew that had only children, you know, did your child talk late and somebody would give you a book on the late talking child. And there was -- I think that was around that time frame, I spoke to other doctors. One was a friend of mine, who is also a surgeon and she said she didn't talk until she was five. Michelle would probably be okay. So, you know, I tried to reassure myself that everything was okay.

And so, but at some point, you know, then it was like I don't think everything is okay.

Q And when did you decide that you needed to seek more medical care?

A It was following a pediatric visit for a diaper rash, a real severe diaper rash that she had and I inquired with that pediatrician, you know, Michelle never started talking again and she had these fevers and she doesn't really seem the same. So, then she made a referral for me.

Q And who did she make the referral to?

A To a neurologist, who was an adult neurologist.

Q An adult neurologist?

A Yuma is small, so we don't have a lot of pediatric specialists, especially back then. I think now, we have a couple. But back then, we did not. So, some of the adults would do consults.

Q And did you see this adult neurologist?

A Yes, we did.

Q What did he say to you?

A He said that he thought -- he thought she had some form of auditory problem.

Q And was that the reason that the hearing test was done?

A Actually, no. The hearing test was done later, at the recommendation of another doctor.

Q Okay. So, he thought she had an auditory problem?

A I don't believe he even ordered a hearing -- an auditory test. I think we had that done on our own later. But, he thought it was possibly auditory based. She was not responsive to her name, not responding normally.

Q And did he make any recommendations?

A He -- I think -- I can't remember for certain what he recommended, other than that he was thinking it was an auditory problem.

Q And did you seek further medical care?

A Yes, we did.

Q And who did you see next?

A We saw a child psychologist.

Q And who was that?

A That was Dr. Karlsson Roth.

Q And what did Dr. Roth tell you?

A She had told us that Michelle -- she diagnosed her with autism.

Q At that time that Michelle was diagnosed as autistic, did you know what that was?

A Vaguely, not in-depth. I knew a little bit

about what it was.

Q Did Dr. Roth tell you what Michelle's future would be?

A She did. She said that although she was very young, she was still -- still two almost three. She said that at some point, she would be uncontrollable, probably not too far from the age she was now, and that one of our -- and that probably one of our only options would be to institutionalize her.

Q And when Dr. Roth told you that, what did you -- did you and your husband have a discussion?

A After probably three days of not being able to speak, because we were completely overwhelmed and devastated by hearing that, especially being so little, then we did talk about it and we both agreed that we didn't ever want to do that. We didn't ever want to put her away somewhere and both decided that we would try to concentrate on finding out what was wrong and more about what her diagnosis was and to see what form of help we could get for her.

Q Did you seek other medical care?

A Yes, we did.

Q And where did you go?

A We went to -- shortly after the diagnosis the same year in 1997, it was August, we went to UC-

Irvine, to see Dr. Sudhir Gupta.

Q What was the reason you went to see Dr. Gupta?

A Because, I had read -- I read on-line about another mother, Cindy Goldenberg, who had a similar situation as Michelle, and her son received IVIG treatment and he got better. So, we went -- you know, I found out where he was and it was in driving distance and I said, oh, maybe we can see him and he can tell us something.

Q When you say within driving distance, how far away was he?

A He's in UC-Irvine, so it's Orange County, so it's about a five- to six-hour one-way drive. That's about 12 hours -- 10 to 12 hours round trip.

Q That's drivable?

A That's drivable, yes. It was drivable for us, right.

Q So after Dr. Gupta saw Michelle, was she a candidate for IVIG?

A Not under the -- no, she wasn't.

Q And after you saw Dr. Gupta, did you seek other medical care?

A We did. He actually referred us to a pediatric neurologist.

Q And who was that?
A That was Dr. Ira Lott.
Q And where was Dr. Lott located?
A He is, also, at UC-Irvine.
Q Okay. And when you saw Dr. Lott, did he tell you what he thought Michelle's diagnosis was?
A Yes, he did. He had diagnosed her as moderate severe autism.
Q And did he recommend any treatment?
A He recommended applied behavioral analysis and any early intervention programs that we could get in town.
Q Were you able to get BA therapy for Michelle?
A Not at that time, we were not. We didn't have any therapist or any agencies in town that provided. So, it was quite a while before we got to that point.
Q And when you say 'quite a while,' how long was it before Michelle started receiving this therapy?
A Probably about two years, maybe one to two years.
Q After you saw Dr. Lott?
A After we saw Dr. Lott, right.
Q Now, Dr. Lott is a pediatric neurologist; is

that true?

A Yes.

Q Now, you testified earlier that Michelle had had diarrhea for approximately eight to 12 weeks after the first fever and then it turned to constipation.

A Yes.

Q Did Michelle continue to have GI problems?

A Yes, she did.

Q And do those GI problems persist to this very day?

A Yes, they do.

Q When Michelle has GI problems, what types of symptoms does she manifest?

A They've changed over time, because, now, she's somewhat partially better. But, she displays by her behaviors abdominal pain, lower abdominal pain, discomfort. She sometimes -- well, actually, it's just abdominal. Sometimes, she'll hit herself, because she's very -- has a lot of pain or very uncomfortable. Or she'll stay awake until she passes a stool, which could be 18 or 20 hours. I mean, you know, and then she'll pass a stool and go right to sleep and then we know that -- over time, we've learned that that's why she keeps staying awake, even though she looks like she'd nod off and go to sleep.

So --

Q You indicated that Michelle would hit herself when she was having pain?

A Yes.

Q Any particular spot that she would hit herself?

A It's changed. She used to first hit herself on her thighs and her chest. Now, she hits herself more on her face.

Q And did that behavior continue?

A Yes, it did.

Q Now, you indicated also that Michelle had sleep problems?

A Yes.

Q Could you tell the Court what the sleep problems consisted of?

A She would be awake for many hours, maybe 18 hours straight and then maybe sleep for two to three hours and then wake up and then stay up. Sometimes, she would sleep for eight hours straight. It was very erratic. There was no pattern. She had a lot of, while you would stay night waking, but, sometimes, she would sleep in the day. But, she would just wake up frequently while sleeping.

Q With all Michelle's problems, did you try to

find medical help for her?

A Yes, I did.

Q After Dr. Lott, who did you see?

A After Dr. Lott, I believe that's when we had the BAER, the brain stem auditory evoked response, if I said that in the right order. And then, we tried to get an MRI, but we couldn't, because they couldn't sedate her with the chlorohydrate. They weren't able to get her to drink it and the suppository didn't work. So, after those two visits, then we -- I read on-line about a study in Phoenix, which is driving distance, just three hours one-way, six hours round trip, because that's around the time all the news had come out about secretin and some of the kids stomach problems felt better and some of their behaviors got better and a few other children had completely seemed to get better all the way. So, we made arrangements to be evaluated and then we had her enrolled in the study.

Q So, Michelle was accepted into the study?

A Yes.

Q And as part of the acceptance into the study, was she required to undergo any diagnostic procedures?

A Yes, she was. She was evaluated by a

pediatric gastroenterologist and it was his -- part of his treatment plan and diagnosis was to do an upper GI endoscopy.

Q And did he tell you why he thought Michelle needed an upper GI?

A He said because of her behaviors, she had a lot of saliva that she would either spit on her hands or either lick her hands or lick everything, bath books mostly, lick her hands. She would always -- you know, that was one of the signs. She would hit her chest and then she still had diarrhea. Well, at that point, she has -- was having diarrhea, had gone from constipation to diarrhea again. So, those were the three.

Q So, based on those symptoms, Dr. -- who was the doctor?

A Dr. Montez.

Q He indicated that Michelle would require an upper GI for diagnostic purposes?

A Yes.

Q And was that performed?

A Yes, it was.

Q And do you know what the results of that upper GI was?

A Yes, I do.

Q What were the results?

A She had a grade three ulcerated esophagus, meaning there were ulcers for nearly the entire length of the esophagus.

Q Throughout the entire length of the esophagus?

A Just about.

Q And did Dr. Montez indicated to you whether the ulcers that he saw in Michelle was any indication of the symptoms that she was exhibiting?

A He said that he thought that that's why she was hitting her chest, because it was a very -- it is a very painful condition. He actually diagnosed her with GERD, which gastroesophageal reflux disease and he said that it's very painful. And by the time that she was diagnosed, the ulcers were very bad. The next stage -- well, one of the other doctors said the next stage was forming strictures, which is like scar tissue from the ulcers, which would then mean that it would start to close. So, it was -- then, it would have to be surgically opened. So, it was all a very painful condition for her to happen. So, he attributed her hitting her chest and crying and waking to the pain that she was having from that.

Q And did Dr. Montez order any treatment for

Michelle?

A Yes, he did. He ordered her to be treated with Prilosec.

Q To your knowledge, did the Prilosec work?

A Yes, it did; to my knowledge, yes.

Q And after that, after the Prilosec, did Michelle undergo another diagnostic procedure with Dr. Montez?

A Yes, she did.

Q And do you know approximately when that occurred?

A That would be December 2000.

Q And December 2000, you said?

A Yes.

Q And do you know what the results of that diagnostic procedure was?

A That showed that the ulcers -- the esophagus had healed. She still had gastritis. She still had GERD, but the medication had healed the ulcers.

Q And did Dr. Montez recommend any other treatment for Michelle?

A At that time, no, he did not.

Q And those were her GI problems, is that true?

A Yes.

Q Now, you indicated that Michelle had to go for diagnostic work-up to enter the secretin study; is that true?

A Yes.

Q Did you ever find out whether Michelle was actually -- actually received secretin?

A I did find out.

Q You did find out?

A Uh-huh.

Q And had she?

A No, she had not.

Q So, she received placebo?

A Yes.

Q Mrs. Cedillo, did Michelle's GI symptoms continue after the second endoscopy by Dr. Montez?

A The upper seemed resolved, but she still had diarrhea.

Q So because she had continued diarrhea, was another procedure done?

A Yes.

Q And when was that procedure done?

A That was done on January 31, 2002.

Q And do you know what the results of that study was?

A That was an upper and lower endoscopy-

colonoscopy that showed that the ulcers were still healed, but she still had gastritis ad she had lymphoid nodular hyperglagia. And I believe his diagnosis was colitis. But, I'm not sure what else he found, other than, you know, the lymphoid nodular hyperglagia.

Q Aside from the secretin study, did you try to find other medical care for Michelle?

A Yes, I did.

Q And what did you do?

A We had -- we paid to have the ABA people come in and train us on how to work with Michelle, so we could try to teach her self-help skills. We had speech therapy. We tried to get occupational therapy, but we didn't have one in town. Then, when we got one, there is a waiting list. The other -- let's see, I tried to enroll her in a few early intervention programs. She was almost too old by that age, because I think she was about five years old by then. Early intervention, I think, is three to five.

Q And at some point in time, did you start doing some research on the Internet to look for explanations about what Michelle's condition was about?

A Yes, I did.

Q And in your searches, what did you find?
A On the Autism Research Institute website, I found that they had a good bit of doctors, referred to as DAN doctors, which is defeat autism now doctors, and that they held conferences and that they were -- at that time, they were almost always in San Diego, which is, again, driving distance, two-and-a-half hours one-way. So, we -- and that was a whole conference of nothing but doctors dealing with children with similar symptoms as what Michelle had.
Q And did you attend one of these conferences?
A Yes, I did.
Q Which conference was it?
A We attended many, but this one was -- this would have been in late 2002, I think it was October 2002, where we attended -- we attended several, but --
Q And at these conferences, did you learn anything about what could be the cause of Michelle's symptoms?
A I heard several presentations by several doctors describing Michelle to a tee with her -- the regression, her bowel problems, how her bowel problems had persisted and what was wrong.
Q And did these presentations indicate that there was potential treatment for Michelle's symptoms?

A Yes.

Q And were they particular individuals, who you sought the attention of after these conferences?

A Yes, I did.

Q Whose attention did you seek?

A There was two actually in 2001 at that conference. It was Dr. Andrew Wakefield. And later in 2002, it was Dr. Arthur Krigsman.

Q And did you go up to speak to both of these doctors?

A Yes. After they spoke, I approached them both -- well, I mean, at different times, but at their -- each of their conferences.

Q Now, you indicated that when Michelle's bowel symptoms persisted, that she underwent another endoscopy with Dr. Montez. And this would be the third endoscopy with Dr. Montez, is that it?

A Yes.

Q And was that both an upper and a lower GI?

A Yes, it was.

Q When Dr. Montez did the lower GI, did he also do a biopsy of Michelle's gut tissue?

A Yes, he did. He did two sets of biopsies.

Q And do you know where those biopsies went?

A One went to the pathology department at the

hospital and the other set was sent to Ireland to Dr. John O'Leary's lab.

Q And did you get the results of that biopsy from the Irish lab?

A Yes, we did.

Q And do you know what those results were?

A Yes, I do.

Q And what were they?

A She tested positive for measles virus RNA in her colon tissue.

Q When you got this information, what did you do with it?

A Well, I was overwhelmed again, because it was confirming -- confirming to us what we thought we had seen in her. I faxed it over to Dr. Montez and asked him, you know, if there was anything we could do to help her.

Q And what did Dr. Montez say to you?

A He said that he did not think there was an antiviral treatment for measles virus of this type, at that -- I mean, for measles virus at this time. And he said that we could try similar medication to what they were using in England, which was Pentasa, which he ordered, of course, Pentasa for her.

Q And was Michelle able to tolerate the

Pentasa?

A No, she wasn't -- she wasn't able to swallow the capsules, so she was getting the beads -- there are beads in the capsules, so we were putting it in her food. But, it's not delivered the way it is supposed to be when you take it that way. It needs to go in the capsule and then dissolve in the stomach and she just couldn't swallow the capsules.

Q So, at some point in time, did you just stop with Pentasa?

A She couldn't tolerate it probably because she -- it wasn't -- she wasn't taking it the proper way. So, it was probably both things, she wasn't taking it the proper way and then she probably could not tolerate it. She had other symptoms. She didn't look well and was vomiting.

Q So, she was -- the vomiting had resumed again?

A Yes.

Q And approximately when did the vomiting resume?

A Approximately in late 2001.

Q And at that time, was Michelle continuing to have diarrhea?

A Yes.

Q So, she was vomiting and she had diarrhea?
A Yes.
Q Was she able to tolerate any foods at all?
A Very little, very select -- she was very self-limiting to what she would eat. And she would go maybe three days without eating and then eat a lot in one day and then not eat and like that, that pattern.
Q Now, you indicated that you had spoken to Dr. Krigsman?
A Yes.
Q Who is Dr. Krigsman?
A He's a pediatric gastroenterologist in New York.
Q And how did you find Dr. Krigsman?
A When I heard him speak at the DAN conference, which would have been in October of 2002.
Q And at some point in time, did you contact Dr. Krigsman after the meeting?
A Yes, I did.
Q And what was the purpose of contacting Dr. Krigsman?
A Because Michelle was not getting any better. She -- the diarrhea was a ridiculous amount and she would eat and have a stool and drink and have a stool and, you know, it was like she wasn't keeping anything

in. So, my purpose was to see if there was anything that could be done to help her.

Q So, essentially, whatever went out, just ran right out again?

A Sometimes immediately. If not, then it was maybe within an hour or so.

Q And did Dr. Krigsman agree to see Michelle?

A Yes, he did.

Q And as part of -- did you have an understanding of what Dr. Krigsman wanted to do when he saw Michelle?

A Yes, I did.

Q And what was your understanding?

A My understanding is that it would require a lab work-up prior to her going to see him and then upper and lower endoscopy-colonoscopy.

Q And did you have that lab work done?

A Yes, we did.

Q Was it done locally?

A Yes, it was.

Q And do you know what that lab work consisted of?

A Not all of it. I don't remember. He looked for markers of inflammation, the set rate or ESR. Like a CVC, the chemistry, I think, is what measures

the albium and the protein in her body. I believe he looked for markers of Crohn's disease and/or inflammatory bowel disease. I don't know if there's a differentiation on that.

Q Was this done all before Michelle went to see him?

A I think it was. I'm not certain. It might have been -- I can't remember. I think it was done prior to us seeing him.

Q Now, at some point in time, did Michelle develop some black and blue marks on her body?

A Yes, she did.

Q And did you have those evaluated?

A Yes, we did.

Q And did anybody tell you what the cause of those black and blue marks were?

A Yes, they did.

Q And what was the cause of it?

A That she was malnourished and had developed a secondary coagulating disorder.

Q From the malnutrition?

A Yes.

Q Now, Mrs. Cedillo, at one point in time, was Michelle hospitalized because she was unable to eat?

A Yes, she was.

Q And approximately when was that?
A There were two times. One was May of 2003 and then again in late July of 2003.
Q In late July of 2003. During one of these hospitalizations, did Michelle develop additional problems?
A Yes, she did.
Q Could you tell the Court what other problems Michelle developed?
A She, at one point, after being in the hospital maybe one week, she seemed to have lost her vision. And when we -- and we went completely by behaviors, but we noticed that she was letting her videotape run to where it was all snow, which she never did. And then we would reverse it and she would just want to hear the sound. She wasn't looking at it. She actually had it covered up with a towel and then when we would do this motion in front of her hand or like this, she wouldn't flinch. And a few times, she would -- she was doing this movement, like she couldn't see at all.
Q And you were the ones, who noticed this?
A It was my husband and myself, my mom, my aunt --
Q Okay. And --

A -- and my father.
Q And you told the doctors about this?
A I did. And she had -- also, her eyes looked real dry, like the eyeball, itself, was very dry.
Q And did the doctors order a consult?
A They did. Again, she was in the hospital locally and we didn't have any local pediatric ophthalmologists, but they ordered a consult with an adult ophthalmologist.
Q And do you know what the evaluation by the adult ophthalmologist was?
A He was uncertain, but he said she did not need to be on antibiotic drugs. He said she did need to be evaluated. The hospital that we have didn't have the ophthalmology equipment for him to do a full evaluation there at the hospital, so his only option, other than just looking, you know, like we're looking at each other, was to -- he didn't have an equipment, so we would have to take her into his office, which we couldn't do, because she was hospitalized at the time. So, he recommended that we stop all the antibiotic drops and begin with re-wetting drops, which we did.
Q And did he indicate to you that she should be followed-up further?
A Yes; yes, he did.

Q And did you make an appointment to have that followed-up after she was discharged from the hospital?

A Yes; at that point, we did, yes.

Q And who did you see?

A We saw Dr. Henry O'Halloran.

Q And where is Dr. O'Halloran?

A I'm sorry?

Q Where is Dr. O'Halloran?

A Oh, Dr. O'Halloran is at San Diego Children's Hospital.

Q And how did you find Dr. O'Halloran?

A He was the closest eye specialist. I looked on their website under pediatric ophthalmology and --

Q And, again --

A -- that was the one we could get into the soonest.

Q And, again, San Diego Children's is roughly --

A They're about close to three hours one-way, one-way drive.

Q Now, when you went to see Dr. O'Halloran, was it?

A Yes.

Q What did he tell you about Michelle's eyes?

A At that point, he said she had paling in the optic nerve, but he thought, at that point, that she had good potential to continue to see. But, she needed to be continued to be rechecked and he -- because he was guessing, because he hadn't seen her in the hospital, that she probably had had uveitis.

Q That she had what?

A Uveitis.

Q And did he indicate to you what the cause of the uveitis was?

A Secondary to inflammatory bowel disease.

Q And did Dr. O'Halloran order any treatment for Michelle, for her uveitis?

A At that point, no, he did not. He said by treating her bowel disease, you will be treating the eyes.

Q Okay. Now, when Michelle was hospitalized during this time frame and you noticed that she was not able to see, did she develop any other problems?

A She -- towards -- well, she was unable to eat, so they had to place a feeding tube during that time. And she lost a large amount of weight. And she, also, developed arthritis; but, at the time, we didn't realize it was arthritis until a later time. She had swelling -- I guess you could say she

developed swelling in her ankle, the one ankle.

Q Did the swelling just remain in her ankles?

A Yes, it did. It was very -- it was very limited at the beginning, then it got worse.

Q And when it got worse, what do you mean by that?

A Once she was released and then back at home, it swelled. Like in a month's time, it swelled -- her legs swelled up to her knee. So from her toes on the left foot all the way up to her knee on the left leg, she was swelling big.

Q And did you seek treatment for that?

A We did. We couldn't get in though until about a couple of months later.

Q How much later?

A A couple of months later. Well, let's see, that was the end of September, so -- October, November -- it was like two-and-a-half months later, December 2003.

Q And who did she see in December 2003?

A We saw Robert Sheets, who is a pediatric rheumatologist at San Diego Children's Hospital.

Q And what did Dr. Sheets tell you about Michelle's ankle swelling?

A He felt that it was arthritis secondary to

inflammatory bowel disease.

Q Mrs. Cedillo, when Michelle was hospitalized for the dehydration, where was she hospitalized?

A In Yuma.

Q And did you attempt to have her transferred anywhere?

A Yes, I did.

Q And where did you try to get her transferred to?

A To Phoenix Children's Hospital.

Q And what happened when you tried to transfer her?

A The doctor refused to have her transferred. The ER doctor was trying to get her transferred, but the doctor they were trying to transfer her to did not want to have her sent there.

Q So, by December 2003, Michelle had a diagnosis of autism. She had a diagnosis of inflammatory bowel disease. She had a diagnosis of uveitis. And she had a diagnosis of arthritis.

A Yes.

Q And did anybody tell you whether those problems were all connected?

A Well, separately, all the specialists said that they were connected to the bowel disease.

Q They were -- I'm sorry, I didn't hear you.

A I mean, each specialist that we saw -- I mean like for the rheumatology and for the eyes, they told me those were connected to her bowel disease. So, does that answer? Okay.

Q So after Michelle started seeing the rheumatology people and the ophthalmology people at the University of San Diego, is that right?

A San Diego Children's.

Q San Diego Children's, did she develop any other medical problems?

A She did. About -- well, let's see, well, she developed seizures.

Q And could you tell the Court how those seizures first began?

A They first began, she had only one that we thought was related to Demerol, which would have been in 2004, and then she didn't have another one for a long period of time, until early 2005. And I'm kind of approximating on the dates here. When I say 'early,' probably within the first three months or so. And then she had what we weren't sure if they were seizures, and I'm still not sure to this day, it looked like she was staring, but she would still blink her eyes if you went like this. But, then it would go

away. But then later she started having what would be termed grand mal seizures.

Q Now, you indicated that you thought at first it was reaction to Demerol?

A She had one seizure following IV administration of Demerol.

Q And what was the reason she had to get IV Demerol?

A She was in the hospital to be treated for pancreatitis.

Q And when did the pancreatitis began?

A That began in early -- well, let's see. In early 2004.

Q And what was the cause of the pancreatitis?

A At the time, they thought it was related to her medication.

Q And what medication was that?

A 6-mercaptopurine.

Q And what was she on the 6-mercaptopurine for?

A To treat her bowel disease, bowel inflammation.

Q So the treatment that she was given for her inflammatory bowel disease caused her to develop pancreatitis, is that true?

A Yes.

Q And when she was in the hospital for the pancreatitis, she was undergoing a procedure; was that it?

A No, she was having pain.

Q She was having pain?

A They said that she was allowed so much pain medication; did I want them to give her something? Because they couldn't judge what her pain level was, so they were depending on us to tell them what her pain level was.

Q So the IV Demerol was for the pain that she was having from the pancreatitis.

A From the pancreatitis, yes.

Q And the thinking was that she developed a seizure disorder from the Demerol?

A No, they think that was an isolated incident.

Q Did she subsequently see a neurologist for these seizures?

A Yes, she did.

Q When was the first neurologist that she saw?

A The first neurologist -- okay, other than Dr. Masland when she was real little, and I feel like I'm leaving somebody out -- I think the first

neurologist was a consult with an adult neurologist, which would have been October 1st, 2005; because of that day, she had a grand maul seizure and fell and broke her leg.

So up until then, her seizures, she wasn't having that many. They were pretty far apart; maybe months apart, and I wasn't certain that it was really a seizure that I was seeing. So after she had the grand mal seizure and fell, then I knew that they were actually seizures. So they did a consult with that neurologist, who placed her on medication. So that was Dr. O'Malley. That was his name.

Q Did you say that she had a seizure, fell, and broke her leg?

A Yes.

Q And when she saw the neurologist, what did he say?

A Well, that was when they did the consult. He said we needed to get her on medication.

Q And was she placed on medication?

A Yes.

Q What medication was she placed on?

A Topomax.

Q Did she stay on the Topomax?

A Yes, she did.

Q Did it control her seizures?

A Yes, it did, for awhile.

Q At some point in time, did the Topomax get discontinued?

A Yes, it did. We ended up seeing another neurologist before it got discontinued. So that would have been Dr. Allen Kaplan at Phoenix Children's Hospital.

Q Was he a pediatric neurologist?

A Yes.

Q And what did Dr. Kaplan recommend?

A What did he recommend?

Q Yes.

A He recommended to continue with the Topomax at that time. Later, he was also the one who discontinued it. Wait a minute; you know what, that's not right. He did recommend to discontinue it. But he thought that they were under control, and that she wouldn't need that much medication. He said let her go a little while and see how she does without it.

Q How did she do?

A She did bad. She started having seizures with more and more frequency, and then she began having them almost every other day.

Q Did you continue with Dr. Kaplan?

A No, we went to see a neurologist at San Diego Children's Hospital.

Q Three hours away.

A Three hours away, yes.

Q You indicated that she had a seizure, fell and broke her leg.

A Yes.

Q Did anybody indicate to you what why she would break her leg just by falling?

A Well, she had osteopenia.

Q And what is osteopenia?

A Osteopenia is not osteoporosis; as in, it's not a progressive disease like osteoporosis is. But it is an indication that your bones are not as dense as they should be for her age. So it's osteopenia versus osteoporosis, which would be like an older person with a progressively worsening disease. But it's still a serious problem.

Q Did they tell you what the cause of the osteopenia was?

A They said it was probably from malnutrition and from steroid therapy or prednisone therapy.

Q What was the prednisone therapy for?

A That was to treat the bowel disease and the arthritis.

Q So if I understand correctly, Mrs. Cedillo, Michelle's bowel problems required that she be placed on prednisone and 6MP. Is that what you told us?

A Yes.

Q And as a result of the prednisone, she developed osteopenia?

A And the malnutrition, also.

Q And the malnutrition?

A Yes.

Q When she had a seizure, she fractured her leg --

A Yes.

Q -- because of the osteopenia?

A Yes.

Q The 6MP that she was also receiving for her bowel disease, it cause a pancreatitis?

A At the time, that was the conclusion, that it was --

Q Because she had pancreatitis, she had to get IV Demerol for the pain?

A Yes.

Q And it was initially thought that the seizures that she developed were related to the Demerol that she received?

A That first one, yes.

Q So when you took her to San Diego Children's Hospital for pediatric neurology consult, what did they tell you?

A She said that Michelle had epilepsy, which I believe there's a distinction between just seizure disorder and epilepsy. I believe epilepsy is worse. I could be wrong. I don't know all the terms exactly. She said that Michelle had developed epilepsy because of everything going on with her body.

We already had the MRI, and her brain showed to be normal. So it wasn't like she had a structural problem causing the seizures. So she said it's everything else -- that's her words -- everything else that she has going on combined to where she has developed epilepsy.

Q Did the doctor at San Diego Children's order any treatment for Michelle's seizures?

A She ordered Keppra.

Q Is Keppra an anti-convulsant medication?

A Yes, it is.

Q What is Michelle's current dosage of Keppra?

A She's on 2000 milligrams a day of Keppra.

Q Does it control her seizures?

A Not completely, no.

Q So she continues to have seizures, this

present day?

A Yes, she does.

Q Approximately how often does she have seizures?

A About two times a months; about every two to three weeks.

Q When she has these seizures, do you give her additional medication?

A We can give her Valium, a two milligram dose, if she -- she's never done this yet, and I hope she never does. But if she develops a seizure pattern where she can't stop seizing, we can give her 20 milligrams of Valium to stop the seizure as an emergency treatment.

Q How do you care for Michelle?

A She requires a lot of care. It's around the clock care with, if you want to call it, two people on at one time. Because somebody has to watch her all the time, and then the other person is getting medication ready, or if she needs to be changed, her diaper changes, those kind of things, it takes two people.

Q You indicated earlier that Michelle had a feeding tube inserted; is that it?

A Yes.

Q To this present day, is she continuing to be fed with a feeding tube?

A Yes, she is.

Q Does she take anything by mouth?

A She eats gluten and casing-free crackers and water by mouth.

Q And nothing else?

A No, nothing else.

Q So Mrs. Cedillo, if I'm clear, Michelle currently suffers from autism; and with her autism symptoms, does she continue to hit herself?

A Yes, she does.

Q And where does she hit herself right now?

A Now she hits herself on her face.

SPECIAL MASTER HASTINGS: Mrs. Cedillo, can you talk a little bit louder?

THE WITNESS: Yes, let me move this.

SPECIAL MASTER HASTINGS: Thank you.

THE WITNESS: Which one is the one that's on? There's two here. Are they both on?

SPECIAL MASTER HASTINGS: I believe they both are

THE WITNESS: Okay, is that better?

SPECIAL MASTER HASTINGS: I believe so; thank you.

THE WITNESS: You're welcome. Okay, she hits herself on her face.

BY MS. CHIN-CAPLAN:

Q Is it any particular spot on her face?

A Usually, it's right in here, on the eye socket area; sometimes right here, in between; sometimes on her chin.

Q Has anybody indicated to you why she hits herself?

A It's likely due to pain. She also, in 2006, was diagnosed with a 90 percent optic nerve damage. Again, with uveitis and open angled glaucoma, both of those things and especially the uveitis can cause eye pain and pain to the eye socket area.

But that is now being treated, and she still hits that area. So I'm not sure if she still has symptoms, or if that is caused from pain from other areas. But it is this behavioral thing to keep hitting in this area. I'm uncertain. I don't know. It can also cause headaches; uveitis can cause headaches.

Q Now earlier you had indicated that you were told that the UVA was related to the her bowel disease. Are the current eye problems that she had also related to her bowel disease?

A They believe it's related to chronic inflammation from the bowel disease.

Q So she's autistic. Her behaviors continue, and she hits herself on her forehead and in around the eye socket.

A Yes.

Q And she continues to have GI problems?

A Yes, she does.

Q She's fed by a feeding tube?

A Yes.

Q She eats gluten-free, casing-free crackers, and water by mouth, only?

A Yes.

Q Does she continue to have diarrhea?

A Yes.

Q Does she continue to vomit?

A She doesn't vomit as frequently as before.

Q But she still has occasional episodes?

A Occasionally, yes.

Q She's under treatment for a seizure disorder?

A Yes.

Q And she's currently receiving Keppra, 200 milligrams?

A Yes.

Q And she has break-through seizures?
A Yes.
Q When she has the break-through seizures, you give her Valium to control the seizures?
A Right, yes.
Q Does she still have arthritis?
A Yes, she does.
Q We saw that Michelle was in a wheelchair today. Is she able to walk?
A She's able to walk with assistance. But she needs a lot of help walking. She'd be a real high risk to fall and break something else if we were to let her go on her own. So on some days, it's very painful for her to walk.
Q She is under treatment for all these problems?
A Yes, she is.
Q Has anybody told you what Michelle's prognosis is?
A No, nobody has.
MS. CHIN-CAPLAN: I have no further questions, Special Master.
SPECIAL MASTER HASTINGS: Thank you. Thank you very much. We had discussed earlier that Ms. Chin-Caplan -- would you stay there just for a minute,

Mrs. Cedillo -- that Ms. Chin-Caplan will have some additional questions for Mrs. Cedillo tomorrow concerning the video, is that correct? So we decided we would take the rest of her testimony, and then she'll testify again concerning some video.

I think I'm going to take the opportunity right now. I just had a few clarifying questions for you, Mrs. Cedillo.

THE WITNESS: Sure.

SPECIAL MASTER HASTINGS: I understand there's a problem with the microphone.

THE WITNESS: The light went off awhile ago, but I thought --

SPECIAL MASTER HASTINGS: Is it back on?

THE WITNESS: No, here, hold on, it says, "push," Here it goes. Is that better?

SPECIAL MASTER HASTINGS: Yes.

THE WITNESS: Okay, here you go.

SPECIAL MASTER HASTINGS: Is that better there?

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: I just wanted to ask you, Mrs. Cedillo, a very few questions here to clarify some points in the record.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: Obviously, you've been through a great deal here, and we hate to force you to talk about such difficult topics. But we appreciate you being here and being willing to talk with us. So I just have a few more questions.

You have made a number of statements in the record here, and I just wanted to ask you a few questions about them, just to find out exactly under what circumstances those statements were made.

So perhaps it would be helpful if somebody could put in from of Mrs. Cedillo a copy of Exhibit 18. I don't know if you've got it there. I'm going to be talking about Exhibits 18, 21, and 54, which are three documents that contain statements by Mrs. Cedillo.

MR. HOMER: Exhibits 19, 54, and what was the third one, sir?

SPECIAL MASTER HASTINGS: Exhibits 18, 21, and 54 -- you've got 18. We'll start with that one.

THE WITNESS: Thank you.

SPECIAL MASTER HASTINGS: If you'll look at 18, on 18, the first page of it, is a vaccine administration record. I'm looking at the second page.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: It says, "Michelle, observations."

THE WITNESS: Observations, okay.

SPECIAL MASTER HASTINGS: Can you tell me about how you came to make these observations; or if someone asked you to, or when did you start doing this?

THE WITNESS: These were made after this time had gone by. I was asked to make chronology of her behaviors prior and following the vaccination.

SPECIAL MASTER HASTINGS: Okay, so when it says 3/18/97 --

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: -- this record was made by you on March 18, 1997. Is that correct?

THE WITNESS: Let me look at it for a minute.

SPECIAL MASTER HASTINGS: Okay, sure.

THE WITNESS: Because I've actually made several narratives.

SPECIAL MASTER HASTINGS: Right.

THE WITNESS: And I want to make sure that I'm telling you about the right one.

SPECIAL MASTER HASTINGS: Go ahead and take your time.

THE WITNESS: Okay, if she was two and-a-half, then, yes, 3/18, that's my first statement. She's two and-a-half years old. So this would have been made on or close to that 3/18/97 date.

SPECIAL MASTER HASTINGS: Okay, then if you flip over to page three.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: That's the third page of those observations.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: It's toward the bottom. It says, "4/24/97".

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Then it says, "Today I am writing additional comments."

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: Are you with me there?

THE WITNESS: Yes, I am.

SPECIAL MASTER HASTINGS: Then it says, "I am writing additional comments, observations for any doctors, psychologists, or therapists that want a history of her development."

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Then you provide a

history of Michelle's condition, up to that time.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: So if I understand, you made this. You wrote these out on April 24, 1997.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: All right, now let me see, the next one then, and you can close that one up.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: This won't be long.

THE WITNESS: That's okay.

SPECIAL MASTER HASTINGS: Exhibit 21, do you have that in front of you?

THE WITNESS: Let me see -- yes, for Good Samaritan?

SPECIAL MASTER HASTINGS: Yes, correct.

THE WITNESS: Okay, yes.

SPECIAL MASTER HASTINGS: Now turn through that to page eight. There are big page numbers at the bottom.

THE WITNESS: Okay, there are numbers, okay.

SPECIAL MASTER HASTINGS: There are big page numbers at the bottom middle of the page.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Then on page eight at the top, it says "narrative."

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Okay, and it gives your name as the author of this. I didn't see here where there was anywhere on here as to when you wrote this narrative. Do you have any idea?

THE WITNESS: Okay, let me look at it for a minute and see.

SPECIAL MASTER HASTINGS: Okay, yes, take your time, please.

THE WITNESS: No, I don't have. I'm going to take a guess that it might have been early after I first filed; and the attorney prior to this, I think was Phil Fleming, before we went with Kevin.

SPECIAL MASTER HASTINGS: Okay.

THE WITNESS: He may have asked. I think usually when this happened at this date, someone had asked me for a brief narrative of what had happened. All I can think of at this time, who would have wanted to know about this particular timeframe may have been when we first filed.

SPECIAL MASTER HASTINGS: Okay.

THE WITNESS: But I'm guessing, and I don't

know why. I usually dated everything, but there is no date on here.

SPECIAL MASTER HASTINGS: Now if you flip over then, the narrative goes pages eight, nine, ten, eleven, and twelve.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Page 12 being additional notes.

THE WITNESS: Additional notes -- this might help me. I'm sorry, go ahead.

SPECIAL MASTER HASTINGS: Go ahead. Take your time and take a look at that.

THE WITNESS: Because this might give me an idea of when exactly.

SPECIAL MASTER HASTINGS: Yes.

THE WITNESS: Okay, see, I refer to the upper endoscopy in 2000.

SPECIAL MASTER HASTINGS: Yes.

THE WITNESS: So this was probably written around that time. Maybe it was written for the study that she was in, the secretin study.

SPECIAL MASTER HASTINGS: Yes.

THE WITNESS: But generally, when someone asked me for a narrative, that's when I would write something like this, because the old ones were really

old, so I had to re-do then. The only things I can think of would have been for the filing or maybe for a study. Usually I was specifically asked to write it.

SPECIAL MASTER HASTINGS: Okay, thank you, then if you flip to the next page.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Pages 13, 14, and 15.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: At page 13, it says these are records of dosages, giving Tylenol to Michelle Cedillo.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Then there are three pages of notations of medications. Is that your handwriting?

THE WITNESS: Yes, it is.

SPECIAL MASTER HASTINGS: Okay, so are these notes that were actually made on the dates in question?

THE WITNESS: These were made on those dates, and I found them at a later date.

SPECIAL MASTER HASTINGS: Okay.

THE WITNESS: I didn't even realize I had then until a later date.

SPECIAL MASTER HASTINGS: All right, so you used these notes, these little three pages of notes -- 13, 14, and 15 -- to help you write the narrative.

THE WITNESS: Yes, I did.

SPECIAL MASTER HASTINGS: Now did you have anything else that helped you write the narrative? Because obviously, you are doing this after the year 2000 or later, and there's a lot of detail about each of these days from December 28th through January 6th.

THE WITNESS: Yes, I did. I relied on my old calendars from that time.

SPECIAL MASTER HASTINGS: Okay, so you had written notes on the calendar?

THE WITNESS: Yes, I did; and, in fact, there's the narrative part that we just looked at prior to this one. I actually made an error, and when I went back and looked, I think I said she got the fever on the fourteenth day. She actually got it on the seventh day.

But once I looked, then I always wrote the seventh day. I don't even think at that point I realized I had the calendar. Then when I went back and tried to find it, then I realized it was the seventh day. So if you see that, that's why that's there.

SPECIAL MASTER HASTINGS: So flipping over then to page 16, that seems to refer to that, back here.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: It looked like this narrative was done, probably this last page, 16, was done shortly after you did the other pages.

THE WITNESS: Okay, let me see.

SPECIAL MASTER HASTINGS: But take a look at that, because it mentions the calendar there.

THE WITNESS: Yes, I see that. But I actually had forgotten about that; on page 16?

SPECIAL MASTER HASTINGS: Right, it mentions the calendar there.

THE WITNESS: It mentions the calendar, and I had forgotten about the event on the 23rd, which would have been the third day after the vaccination.

SPECIAL MASTER HASTINGS: Okay, now I wanted to ask you about that calendar, and I hadn't found a copy of that calendar anywhere in the record. We asked your counsel to talk to you about that and see if you could bring it.

THE WITNESS: Yes, I made copies and they have them.

SPECIAL MASTER HASTINGS: Okay, we'd like to

take a brief look at when we're done here --

THE WITNESS: Yes, that's fine.

SPECIAL MASTER HASTINGS: -- along with the counsel for both sides.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: The third document I wanted to ask you about is Exhibit 54.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: Have they given you a copy of that, Mrs. Cedillo?

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: That one does give us a date of when you swore to this, and this was 2001.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: I guess the only question I was going to ask you, and it's got a date, so that's obvious, when you signed this --

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: -- when you signed this, do you have any idea whether this one we just talked about, Exhibit 21, which is not dated but clearly was done in 2000 or thereafter because of the notation of the 2000 incident -- I guess the endoscopy in 2000 -- do you have any idea whether you did this

statement that was Exhibit 21 before the affidavit that's Exhibit 54?

THE WITNESS: Let me look at it real quick, okay, because I can probably tell by what she had wrong with her. Let me look at this one real quick.

SPECIAL MASTER HASTINGS: Okay, yes, take your time, please.

THE WITNESS: Okay, this looks like it's just of that short timeframe following the vaccine. Let me look at this one. It was page eight, right, on 21? I think it was page eight.

SPECIAL MASTER HASTINGS: Well, I'm not sure what you're asking me, Mrs. Cedillo.

THE WITNESS: Oh, I'm sorry. We're comparing Exhibit 21, page eight, to Exhibit 54.

SPECIAL MASTER HASTINGS: Right, yes.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: Yes, page eight of the exhibit. That's correct.

THE WITNESS: Okay, let me see.

SPECIAL MASTER HASTINGS: David, do you have a copy of this for Mrs. Cedillo, as well? Do you have the other copy of this? Why don't you come and take one of ours? We can look together here.

THE WITNESS: Special Master Hastings?

SPECIAL MASTER HASTINGS: Yes.

THE WITNESS: I'm not certain. I still can't pinpoint the timeframe of this.

SPECIAL MASTER HASTINGS: Okay.

THE WITNESS: I think they were very close, though.

SPECIAL MASTER HASTINGS: Okay.

THE WITNESS: Because I mentioned the 2000 scope being in this Exhibit 21. But then this Exhibit 54, it only goes up to that certain point.

SPECIAL MASTER HASTINGS: Okay, well, that's fine. That's all I need to know. I want to ask you one more question then.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: I guess my law clerk just put in front of you some xerox pages off the calendar.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: He photocopied those.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Can you look at those?

THE WITNESS: Yes, I can.

SPECIAL MASTER HASTINGS: So is that an

accurate photocopy of the data on your calendar --

THE WITNESS: Yes, it is.

SPECIAL MASTER HASTINGS: -- that you relied upon this to make that first narrative?

THE WITNESS: Yes, it is.

SPECIAL MASTER HASTINGS: Okay, the other set of notes, we already saw about the medication, plus these notes, those were the notes you made contemporaneously at the time of the incident?

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: And the rest of what was in the first narrative came from your memory.

THE WITNESS: That's correct, as far as I know. I mean, I'm trying to think what else I would have relied on. But it would have been these notes showing the times, and these notes showing the dates -- the handwritten, the little ones.

SPECIAL MASTER HASTINGS: Right, okay, that's all I need.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: I think it would be helpful, counsel, for the Petitioners -- the notes of the medication are already in the record, as I just went over. The notes from the calendar were not. I know Cedillo family would want to keep that calendar

and take it back with them, and not get it out of their hands.

But if you could place a photocopy of this calendar into the record, it might be helpful if we need clarification on the chronology. Then let me see, I think I just had one more question.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: Ms. Chin-Caplan did a very good job going over Michelle's medical history with you. I wanted to ask about one thing.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: We talked today a little bit certainly about the two incidents of high fever after the MMR vaccination, and we have in the record of when you took Michelle to the pediatrician on January 6th.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Then we had another record where you went back to the pediatrician two months later in March of 1996. On that one, it notes that Michelle was talking less.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: Now I noticed in the medical record that that was the last medication record that we were able to find; and of course, we

had thousands of pages of them.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: But that was the last one we could find for about year. The next one was March of 1997.

THE WITNESS: Yes.

SPECIAL MASTER HASTINGS: I just wanted to make clear that there weren't any medical visits during that year.

THE WITNESS: That's correct; not until I think it's April of the next year. That's correct.

SPECIAL MASTER HASTINGS: I just wanted to clarify that.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: So that's all that I have.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: Again, I want to thank you for testifying about this really terrible time in your life. We appreciate it very much.

With that counsel, should we adjourn for the day, and then take up tomorrow with your direct examination of Mrs. Cedillo about the video?

MS. CHIN-CAPLAN: Yes, Special Master.

SPECIAL MASTER HASTINGS: Is that okay, Mr. Matanoski?

MR. MATANOSKI: Yes, sir.

SPECIAL MASTER HASTINGS: Is there anything we should talk about before we adjourn today?

MR. HOMER: Yes, sir, this is Mr. Homer. Special Master Vowell, we had a question for Dr. Aposhian regarding the mortality rate. It's at Petitioner's Exhibit L, the Dali (phonetic) article. It's on page 292, the first paragraph.

SPECIAL MASTER VOWELL: Great, thank you very much.

MR. HOMER: You're welcome.

SPECIAL MASTER HASTINGS: There's one more item then, Ms. Cedillo, that we'll go back over with your husband.

THE WITNESS: Okay.

SPECIAL MASTER HASTINGS: And we thank you again.

THE WITNESS: Okay, thank you.

SPECIAL MASTER HASTINGS: There is one more housekeeping matter. I wanted to go over this before we adjourn for the day. We had had requests from other counsel who were following the case today by e-mail, to get the list of the witnesses, for information for those who were following along with this case.

The list of the witnesses and the actual reports were filed into the file of the Cedillo case itself long ago, or at least several months ago in both cases. But they have not yet been made a matter of public record. Neither side wanted to make those witness lists available up until now.

We have now got agreement today to put the list of the witnesses with their specialties. We'll put some kind of an order onto the autism master file and the web site, listing the names and the specialties of those witnesses.

I won't go over them now, but for those of you who are following along, tomorrow we are going to be having more testimony from Mrs. Cedillo, and then we're going to have the testimony of Dr. Arthur Krigsman, the gastroenterologist who was mentioned today. We will get, tonight or tomorrow, for purposes of anyone who wants to follow along, the list of the expert witnesses for both sides.

The plan again, as we mentioned before, was that the Petitioner's experts will be testifying this week, and then we'll begin with the Respondent's experts next week.

We have a rough order that was provided for those witnesses today, and we're not holding anyone to

this in stone. But I believe the Petitioners anticipate that Dr. Kennedy and/or Hepner will be testifying on Wednesday, Dr. Byers on Thursday of this week, and Dr. Kinsbourne on Friday of this week. Is that right, Ms. Chin-Caplan? Did I get that right?

MS. CHIN-CAPLAN: That's correct, Special Master.

SPECIAL MASTER HASTINGS: And then next week, if we get through all the Petitioners experts this week, the Respondent will be meeting with Dr. Fombonne on Monday, and perhaps Dr. Wiznitzer on Tuesday.

We will be getting more word from the Respondent tomorrow on the order of their expert witnesses. But I wanted to get that information out to whoever is interested in it, if they want to plan when they will listen in or when they'll visit us, et cetera.

With that, I want to thank everyone who participated in a long day today. It's one day down and 14 to go, I guess. But everyone did a fine job today, and I thank everyone for being here. We're going to start again tomorrow at 9:00 a.m. We will see you all then; good day.

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(Whereupon, at 5:20 p.m., the hearing in the above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

DOCKET NO.: 98-916V
CASE TITLE: Cedillo v. Sec., HHS
HEARING DATE: June 11, 2007
LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Court of Federal Claims.

Date: June 11, 2007

Christina Chesley
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