# 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.	)		

REVISED AND CORRECTED COPY

- Pages: 1558 through 1790
- Place: Washington, D.C.
- Date: June 19, 2007

HERITAGE REPORTING CORPORATION Official Reporters 1220 L Street, N.W., Suite 600 Washington, D.C. 20005-4018 (202) 628-4888 hrc@concentric.net IN THE UNITED STATES COURT OF FEDERAL CLAIMS THERESA CEDILLO AND MICHAEL ) CEDILLO, AS PARENTS AND ) NATURAL GUARDIANS OF ) MICHELLE CEDILLO, ) ) Petitioners, ) ) Docket No.: 98-916V v. ) ) SECRETARY OF HEALTH AND ) HUMAN SERVICES, ) ) Respondent. ) Ceremonial Courtroom National Courts Building 717 Madison Place NW Washington, D.C. Tuesday, June 19, 2007 The parties met, pursuant to notice of the Court, at 9:13 a.m. BEFORE: HONORABLE GEORGE L. HASTINGS, JR. HONORABLE PATRICIA CAMPBELL-SMITH HONORABLE DENISE VOWELL Special Masters **APPEARANCES:** For the Petitioners: SYLVIA CHIN-CAPLAN, Esquire KEVIN CONWAY, Esquire Conway, Homer & Chin-Caplan, P.C. 16 Shawmut Street Boston, Massachusetts 02116 (617) 695-1990

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1 PROCEEDINGS 2 (9:13 a.m.) SPECIAL MASTER HASTINGS: Good morning to 3 4 all. To those both in the courtroom and at home, we 5 apologize for the delay. The court reporter was a bit б late, but we're ready to go now. 7 Let me see. We were going to begin I think with the testimony of Dr. Wiznitzer. 8 9 MR. MATANOSKI: That's correct, Your Honor. 10 SPECIAL MASTER HASTINGS: Okay. MR. MATANOSKI: Before we begin, I'd just 11 12 like to say that we're going to do something a little 13 different than we did yesterday in that Dr. Wiznitzer 14 will be talking about home videos that he viewed prior to the vaccination. 15 16 Given that viewing those can be very distressing, and you know that we didn't want a public 17 forum here but the PSC demanded, and I imagine it's a 18 19 little bit even more distressing to do this in such a 20 public arena, so rather than do that Dr. Wiznitzer will talk about what he saw on the home videos, 21 22 discuss that and give you particular cites to the 23 sections in the video so that you could go back and 24 review them yourselves to match up his testimony to 25 that.

1 If you prefer, we could do this in camera 2 while he gives his testimony about the videos in 3 camera so that you can view that while he's 4 testifying. 5 SPECIAL MASTER HASTINGS: Have you talked to Petitioners' counsel about this issue? 6 7 MR. MATANOSKI: No, sir, we have not. MS. CHIN-CAPLAN: Special Master? 8 9 SPECIAL MASTER HASTINGS: Ms. Chin-Caplan? MS. CHIN-CAPLAN: There is a potential 10 rebuttal testimony by Mrs. Cedillo. Unless she is 11 12 able to see which frames Dr. Wiznitzer is referring to, we're not going to be able to comment so we prefer 13 14 a public showing. SPECIAL MASTER HASTINGS: Mr. Matanoski, let 15 16 me understand what you're concerned about. We went through Dr. Fombonne's testimony yesterday. 17 18 MR. MATANOSKI: Yes, sir. 19 SPECIAL MASTER HASTINGS: And he talked about certain behaviors of Michelle and how in his 20 view those were indications of autism that predated 21 22 the vaccination in question. 23 While certainly that wasn't probably the 24 easiest testimony in the world for the family, are we talking now about something similar to that, or are we 25 Heritage Reporting Corporation (202) 628-4888

1 talking about something different? MR. MATANOSKI: It would be similar to that, 2 sir, and I do believe that Dr. Wiznitzer will be able 3 4 to identify the particular sections of the video such 5 that it will be easy for counsel with Ms. Cedillo to 6 go back through them and talk about it and rebut, if 7 necessary, what he's saying in the video without necessarily displaying them. 8 9 SPECIAL MASTER HASTINGS: Ms. Chin-Caplan? MS. CHIN-CAPLAN: Special Master, we 10 appreciate that Mr. Matanoski is solicitous of their 11 12 feelings, but they are here. They anticipated that 13 this would happen, and they're not opposed to the 14 showing of the video. 15 SPECIAL MASTER HASTINGS: All right. Are you ready to go ahead and show them then today? 16 MR. MATANOSKI: No, sir, we're not. We did 17 18 not load them. We certainly thought the way that the 19 distress that was evident in the courtroom yesterday that we would have assumed -- we did assume -- that no 20 one would want a repeat of that so we did not load 21 22 them. 23 SPECIAL MASTER HASTINGS: Mr. Matanoski, 24 what kind of a procedure is it to load them up? How 25 long would it take?

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1 MR. MATANOSKI: I'll check with our technical representative, sir. What we could do, 2 3 however, is apparently this is at the end of the 4 direct testimony, and we could go up to that point. 5 SPECIAL MASTER HASTINGS: And then take a б break? 7 MR. MATANOSKI: And then take a break. Yes, sir. That's what I propose we do. 8 9 SPECIAL MASTER HASTINGS: That sounds like a reasonable way to proceed. Okay. Why don't we start 10 then with the first part of the direct exam. 11 12 Mr. Johnson, I understand you're going to do 13 the questioning here of Dr. Wiznitzer then. 14 MR. JOHNSON: Yes, sir. 15 SPECIAL MASTER HASTINGS: Would you please 16 raise your right hand? 17 Whereupon, MAX WIZNITZER 18 19 having been duly sworn, was called as a witness and was examined and testified as follows: 20 21 SPECIAL MASTER HASTINGS: Okay. Go ahead, Mr. Johnson. 22 23 MR. JOHNSON: And, Special Master, I just want to note that we will have handouts. They're in 24 25 the process of being copied right now, but by the time Heritage Reporting Corporation (202) 628-4888

1565 WIZNITZER - DIRECT 1 we get to the first slide they should be here. 2 SPECIAL MASTER HASTINGS: All right. Very 3 good. 4 DIRECT EXAMINATION 5 BY MR. JOHNSON: 6 Good morning, Doctor. Please introduce 0 7 yourself by stating your full name for the record. 8 Α My name is Max Wiznitzer. 9 0 Dr. Wiznitzer, are you a medical doctor? Yes, I am. 10 А 11 0 What are your specialties? 12 Α I'm a specialist in pediatrics, in pediatric 13 neurology and in neurodevelopmental disabilities with 14 board certification in those three areas. 15 Q And where did you complete your medical education? 16 17 I trained in the Honors Program in medical Δ 18 education at Northwestern University in Chicago, 19 Illinois. 20 The Honors Program is a six-year medical 21 program in which you do two years undergraduate and 22 then do four years of medical school with the first 23 two years of medical school counting towards your 24 undergraduate degree, so therefore I have a Bachelor of Science in Medicine, and then at the end of the 25 Heritage Reporting Corporation (202) 628-4888

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#### WIZNITZER - DIRECT

1 four years of medical school you get basically your 2 M.D. degree. 3 After that I attended training programs in various aspects of pediatrics. First I did a 4 pediatrics residency at the Children's Hospital 5 Medical Center in Cincinnati, Ohio. I think now they 6 call themselves Cincinnati Children's Hospital. 7 The 8 name has undergone several modifications since my 9 training approximately 30 years ago. That was a 10 three-year residency. 11 After that I did a one-year training program 12 in developmental disorders or child developmental 13 disorders at the Cincinnati Center for Developmental 14 Disorders in Cincinnati, Ohio. And on the urging of 15 my mentors at that program, I basically went into 16 child neurology doing a neurology training program 17 jointly at the University of Pennsylvania through the 18 Children's Hospital of Philadelphia and based 19 predominantly at the hospital at the University of 20 Pennsylvania, finishing after three years with 21 training in child neurology. 22 Since I've always had a major interest in 23 developmental disorders, especially disorders 24 involving learning and language, I wrote a proposal to 11 25

1	the National Institutes of Health for an additional
2	two-year fellowship, which was accepted and granted,
3	and did a two-year fellowship funded by the National
4	Institutes of Health in disorders of higher cognitive
5	function in children at the Albert Einstein College of
б	Medicine in the Bronx, New York.
7	Q Again, what was the focus of that
8	fellowship?
9	A The focus of the fellowship was
10	predominantly disorders of language and autism.
11	If I may, since I've been in medical school
12	I've had an interest in learning and language
13	disorders in children, spent time perusing the library
14	when I was a medical student reading about this and
15	finding that there was not as much material as I would
16	like, which is why I went into the field.
17	I've had an interest in child development,
18	and as I went on through it I basically honed it that
19	it went predominantly into autism, ADHD and other
20	neurodevelopmental disabilities.
21	Q Is this where your interest in autism
22	effectively began?
23	A Yes. It started basically when I was in
24	medical school.
25	Q And approximately what years were your
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1 fellowships? 2 А The last one or the first one? 3 0 Let's start with the first one. I finished medical school in 1977. I 4 Α finished my pediatrics residency in 1980. I finished 5 6 my child development training or my developmental disorders training in 1981. 7 8 I did my fellowship in child neurology from 9 1981 through 1984, and then I did my NIH fellowship in the Bronx from 1984 through 1986. 10 11 And after you finished your fellowship, what 0 12 did you do then? 13 After I finished the fellowship I took a Α 14 position at Case Western Reserve University and at 15 Rainbow Babies and Children's Hospital as a child 16 neurologist, and I have been at that institution, at 17 those two institutions, since that time. 18 And what academic and clinical positions do 0 19 you currently hold with those institutions? 20 Α My academic position is I'm an Associate 21 Professor of Pediatrics, Neurology and International 22 Health at Case Western Reserve University through the 23 School of Medicine. 24 At the hospital I have various and sundry positions. I'm basically a staff child neurologist at 25 Heritage Reporting Corporation (202) 628-4888

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#### WIZNITZER - DIRECT

1	Rainbow Babies and Children's Hospital. I wear
2	various hats within the institution because of
3	clinical responsibilities. I'm part of the epilepsy
4	team and read EEGs and evoked potentials, which are
5	electrophysiologic studies of brain and neurologic
6	function.
7	I was the head of Child Neurology for a
8	period of time. There was a transition period of time
9	during which the head of Child Neurology became the
10	chairman. I sat in his seat until someone else came
11	to take his place and to take my place.
12	I'm also affiliated with our local autism
13	center at Rainbow Babies and Children's Hospital.
14	Those are my primary affiliations and
15	responsibilities.
16	Q Describe a little about your teaching
17	responsibilities.
18	A My teaching responsibilities are split into
19	several parts. As a member of the faculty at Case
20	Western Reserve University School of Medicine, in my
21	early years I helped teach a course in epilepsy for
22	the undergraduates. When our present chief of Child
23	Neurology came to our medical center he asked to take
24	over the course, which I was happy to do because I
25	have other teaching responsibilities.

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#### WIZNITZER - DIRECT

1 At the present time my teaching 2 responsibilities include medical students who rotate 3 through pediatric and through child neurology, making 4 sure that we teach them in either area, dependent on what my responsibility is at that time; predominantly 5 6 teaching in child neurology. In individuals who have already finished 7 8 medical school and are in training, they rotate 9 through child neurology, and they may rotate through our outpatient clinic. They may rotate with us on our 10 11 inpatient service. 12 The inpatient service is basically the 13 responsibility for taking care of any child who's 14 admitted to the child neurology service at our 15 hospital, as well as doing consultations when they're 16 requested for children with suspected or known 17 neurologic disorders who are in the hospital. 18 The residents that we basically have 19 responsibility for in terms of the teaching would 20 include residents in pediatrics, in adult neurology, 21 in family medicine and in child psychiatry. I usually 22 have a child psychiatry rotator with me, and I many 23 times will have someone from one of the other 24 services, in addition to the medical student who may come join us on our service. 25

1	In addition to that, we also have
2	responsibilities, - that's the more informal
3	teaching - we also have responsibilities where we have
4	conferences in the hospital that are mental resident
5	teaching management conferences, grand rounds. I take
6	responsibility, I give a talk once every year or once
7	every two years in that format.
8	Q Okay. Doctor, are you a member of any
9	professional associations?
10	A Yes, I am.
11	Q Can you tell us which ones?
12	A I'm a member of the American Academy of
13	Neurology, I'm a member of the American Academy of
14	Pediatrics, and I'm a member of the Child Neurology
15	Society.
16	Q And do you hold any positions in those
17	organizations?
18	A Yes, I do. In the Child Neurology Society
19	it was decided a few years ago that we would form
20	what's called special interest groups where we could
21	try to hone down for the members of the Society into
22	certain areas that people had more expertise or more
23	interest than you would normally expect just to build
24	the foundation of that.
25	For instance, there was a group that dealt
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1	with epilepsy, a group that dealt with movement
2	disorders, and there was a group that dealt with
3	neurobehavioral disorders. When that group was first
4	formed, I was appointed as chair of that group.
5	SPECIAL MASTER HASTINGS: Which group?
6	THE WITNESS: Of the neurobehavioral
7	disorders. The neurobehavioral disorders group really
8	deals with both neurodevelopmental disability, ADHD,
9	autism, things of this nature.
10	Recently we actually are now working on
11	putting together by-laws and everything else. We had
12	our first election. After a few years of running the
13	group basically myself, we had elections and I was
14	elected secretary of the group, which means I keep
15	doing the paperwork that I've always been doing and
16	organizing everyone and making sure that things get
17	done with the ultimate goal that we're really going to
18	turn into a section of our Society that deals with
19	again the areas of interest in neurodevelopmental
20	disabilities and dealing with those kinds of problems.
21	BY MR. JOHNSON:
22	Q Are you involved with any other professional
23	services such as peer review or advisory groups or
24	editorial boards, anything of that nature?
25	A Yes. Yes, I am. I presently sit on the
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1	editorial board of Lancet and Neurology and of the
2	Journal of Child Neurology. I sat for three years on
3	the editorial board of Pediatric Neurology, but no
4	longer do so.
5	I review articles for multiple journals that
6	include Lancet, Pediatrics, Journal of Child
7	Neurology. There are others. I mean, those are just
8	some examples.
9	I have sat on various kinds of committees
10	and groups. Presently one of my responsibilities is
11	that I am the liaison from the American Board of
12	Psychiatry and Neurology to the American Board of
13	Pediatrics sub-board in developmental behavioral
14	pediatrics.
15	If I may explain? What this is is that the
16	American Board of Pediatrics, as the American Board of
17	Psychiatry and Neurology, are the organizations that
18	are responsible for the certification examinations
19	that are administered to individuals who have finished
20	training in the field and wish to be certified.
21	I was asked and accepted to take the
22	position of the liaison sitting for the developmental
23	behavioral pediatrics sub-board, which is an
24	examination that's given every year or every other
25	year dependent on the need through the American Board
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### WIZNITZER - DIRECT

of Pediatrics that deals with issues in developmental
 behavioral pediatrics.

3 I participated in my first meeting last 4 fall. We have our next meeting this fall. It's a 5 rigorous two and a half day process. You have to 6 write, help write new exam questions, review all the 7 exam questions that have been submitted, make sure 8 that the exam questions are fair, well balanced, and 9 obviously because it is developmental behavioral 10 pediatrics there are exam questions that deal with 11 autism.

12 In the past I've also sat on various 13 committees. There was a committee. I can't remember 14 who organized it, but there was a large group of 15 individuals with specialization and expertise in 16 autism who were brought I think it was to Washington 17 to help put together recommendations for screening, 18 diagnosis and assessment of autism.

I sat on the screening panel to do this. It was a publication that came out in the Journal of Autism and Developmental Disorders in the mid to late 1990s. It's in my CV in that regard.

In the state of Ohio I've been very active in various committees when it comes to the issue of autism. I chaired the medical committee that was part Heritage Reporting Corporation

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## WIZNITZER - DIRECT

1 of a much larger group that put together the Ohio

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# WIZNITZER - DIRECT

1	guidelines and recommendations for screening,
2	diagnosis, assessment and general outline of
3	intervention for individuals with autism ages zero to
4	21 years.
5	I've sat on various task forces through the
б	Ohio Department of Education dealing with the issue of
7	autism and the educational needs of the children and
8	how best they can be met.
9	I've worked with our local autism society.
10	I've worked with the state autism society. I've
11	worked with other parent groups again dealing with
12	issues of either recognition and identification of
13	autism or how best to try to implement interventions
14	for these children.
15	Now, interventions don't only mean
16	educational interventions. I'm a strong advocate that
17	we need to do things for these children even outside
18	the school; for instance, issues like how can we get
19	them into recreational activities, something as simple
20	as summer camp and things of this nature.
21	I presently sit on a committee through a
22	parent-based organization in Cleveland that is
23	addressing some of these issues.
24	Q Doctor, in addition to these professional
25	academic responsibilities, do you maintain an active
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1 clinical practice? 2 А Yes, I do. 3 0 And in your clinical practice do you treat 4 patients with autism and other ASDs? 5 Α Yes, I do. 6 0 How long have you been caring for children 7 with autism or ASD? 8 I've been caring for children with autism Α 9 basically since -- formally since my fellowship in the 10 Bronx and much more consistently since I joined the 11 faculty at Rainbow Babies and Children's Hospital 21 12 years ago. 13 And in relation to your treatment of ASD 0 14 patients, do you also consult with their families? 15 А Yes, I do. Just to point out, I maintain a 16 relatively busy clinical practice. I usually see 17 patients a minimum of four half-days a week, which 18 gives me approximately 200 to 250 patient visits per 19 This is only in our office. month. 20 I also run outreach clinics for the state, 21 which are just to be phased out, but we're going to 22 continue them. I run them in areas that are 23 underserved. I also see my patients with autism 24 there, as well as I go to a county where it has a large Amish population and see patients there. 25

1577A WIZNITZER - DIRECT 1 In my clinical practice you just can't see a 2 patient. You basically have to work with the entire 3 family unit making sure you get adequate history, making sure that they understand what's going on, 4 trying to get the parents to become informed consumers 5 6 and to be involved in their child's care, in their child's education and in all the issues that resolve 7 around the needs of the child. 8 9 0 Have you received any awards from family groups that are involved with autism? 10 11 Yes, I have. Α 12 0 Can you tell the Court? 13 I was named Professional of the Year by the Α 14 Autism Society of Ohio in the early 1990s. 15 0 And have you been involved in any autism 16 research? 17 А Yes, I have. 18 Describe for the Court your most recent 0 19 research endeavor. 20 Α Well, there is a project that's now ongoing 21 to look at the pharmacokinetics of various drugs in 22 children and adolescents with autism. 23 Just to quickly explain what 24 pharmacokinetics is, pharmacokinetics is basically how the body handles and metabolizes a drug, how it 25 Heritage Reporting Corporation

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1	absorbs it, how it runs it through the bloodstream and
2	how quickly is it eliminated.
3	Questions are raised in children with autism
4	how they do this. Our previous study we had done was
5	as part of the Risperidone work Risperidone is an
6	atypical antipsychotic in which my responsibility
7	was to make sure we had adequate subjects for it.
8	We're now doing a study of Memantine, which
9	is a medication that is used in Alzheimer's disease,
10	but we're also looking at it as a cognitive enhancer
11	in children with autism, and again we're looking at
12	the pharmacokinetic issues. The paperwork, just
13	literally Sunday I had to sign off on some of the
14	paperwork for patient recruitment.
15	In the past I've been involved in NIH-funded
16	research for children with autism. We had two large
17	studies that were done looking at preschoolers with
18	autism in comparison to children with language
19	disorders and with normal development looking at
20	various and sundry features.
21	My job there was as a neurologist, and to
22	some degree also there were specialized
23	electrophysiologic studies that were done on those
24	children, and I supervised the lab.
25	A second study that was done looked at these
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1	same children when they were school age, and again I
2	was the neurologist at our local center that was
3	involved in examining these children and seeing them.
4	I have done work in other NIH-funded
5	studies, but that's outside of the field of autism.
б	Q Doctor, have you given any talks or
7	presentations on the issues related to autism or ASD?
8	A Yes, I have.
9	Q When was the most recent one?
10	A Yesterday morning. The reason I wasn't here
11	was because I had already committed to giving a talk
12	to one of our local parent groups about specific
13	issues in autism in adolescents and young adulthood,
14	so therefore I gave that talk.
15	I stopped counting on my CV at 100. The
16	talks have been in my local Cleveland area, in the
17	state of Ohio, nationally and internationally.
18	Q Doctor, you mentioned earlier that you're a
19	member of the American Academy of Neurology. Did you
20	give a presentation at the meeting that was held just
21	this past May?
22	A Yes. I was named the director of a
23	breakfast seminar which was on attention deficit
24	hyperactivity disorder. That is now in its third
25	year. Hopefully it will be in its fourth year this
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1 coming year. 2 In the past I've also participated in other 3 courses as a speaker. One of the courses my specific 4 topic was autism, and I think we went to that for a few years while that course was in existence. 5 6 0 Doctor, you also mentioned earlier that 7 you've been involved in the development of guidelines 8 for intervention and treatment. Is that right? 9 А Yes. I want to bring to your attention a letter 10 0 11 that has been referenced a number of times throughout 12 these proceedings. It's a letter from an organization 13 called Autism Speaks. 14 I'm going to ask you to take a look at this 15 letter and just tell me if you're familiar with it. 16 А Yes, I am. 17 SPECIAL MASTER HASTINGS: Mr. Johnson, is 18 this in the record? 19 MR. JOHNSON: I believe it was submitted as 20 a Petitioners' trial exhibit. 21 SPECIAL MASTER HASTINGS: Yes. When you're 22 going to show us something, something that's in the 23 record, if you could let us know where it is? MR. JOHNSON: Certainly. I'm afraid I don't 24 25 have the exhibit number.

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WIZNITZER - DIRECT 1 SPECIAL MASTER HASTINGS: Okay. I'm 2 notified that this has been filed as Petitioners' 3 Trial Exhibit 6. 4 MR. JOHNSON: Thank you. 5 SPECIAL MASTER HASTINGS: Go ahead, Mr. 6 Johnson. 7 BY MR. JOHNSON: 8 All right, Dr. Wiznitzer. We're looking at Q 9 Petitioners' Trial Exhibit 6, which is the letter, and I had asked if you were familiar with this letter. 10 11 Yes, I am. I remember receiving this letter Δ 12 earlier this year, if I'm not mistaken, at my office. 13 And can you just tell the Court what your 0 14 understanding is of this letter? My understanding of this letter is to 15 А 16 increase the recognition by individuals who care for 17 children with autism, that children with autism have 18 GI symptoms and complaints. That's basically the 19 purpose of the letter. 20 0 And what does the letter actually say about 21 the clinical significance of GI disorders and ILNH in 22 particular in ASD patients? 23 Α On the page that's in front of you, and if I 24 may read to the Court? 25 SPECIAL MASTER HASTINGS: Is that on page 4? Heritage Reporting Corporation (202) 628-4888

1 THE WITNESS: Yes, sir. 2 SPECIAL MASTER HASTINGS: Okay. Go ahead. 3 THE WITNESS: "The clinical significance of LNH in children with autism is unclear given that 4 similar findings have also been reported in children 5 6 with typical development, as well as children with food allergies and immune deficiencies." 7 BY MR. JOHNSON: 8 9 0 As a clinician, what does this mean to you? 10 Α Not much. It does not really raise or 11 heighten my worries about this kind of a problem in 12 children with autism because there's no clear data 13 telling us that it's an issue that's specific in this 14 population. 15 0 Does the content of this letter, or did it 16 when you received it, cause you to change the way that 17 you would treat your ASD patients or any other patient 18 with a neurological disorder? 19 No. All this letter basically says is if a Α 20 child, and let's leave out the word autism. If a 21 child shows up with GI complaints that an evaluation 22 should be done, which any prudent physician would do. 23 And that if there are issues that can't be 24 remedied by simple interventions you should refer the children to a pediatric gastroenterologist, which is 25 Heritage Reporting Corporation

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1583A WIZNITZER - DIRECT 1 again what any prudent physician would do, which is 2 again what I do in my clinical practice. 3 When I read this letter I said this does not alter my clinical practice. This is what we've always 4 5 done as good physicians. б 0 And I believe you heard Dr. Krigsman testify 7 last week. Is that correct? 8 Yes, I did. Α 9 SPECIAL MASTER HASTINGS: Now, before we 10 move on I may have mis-spoken. Just to make the 11 record clear, that was Petitioners' Trial Exhibit 6. 12 MR. JOHNSON: Yes, sir. 13 SPECIAL MASTER HASTINGS: Thank you. 14 BY MR. JOHNSON: 15 And based on your reading of the letter, Q 16 does the letter endorse Dr. Krigsman's model? 17 Α No, it does not. 18 Why not? 0 19 If we can just show? First of all, the Α 20 letter does not state specifically that there is an 21 MMR-related enterocolitis that occurs in children with 22 autism and is not only the cause of the enterocolitis, 23 the MMR, but the MMR vaccination is also the cause of 24 the autism. 25 I did not read that anywhere in the letter. Heritage Reporting Corporation

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1584A WIZNITZER - DIRECT 1 In fact, in the letter it says, "The clinical 2 significance and therapeutic implications of 3 inflammatory changes in the intestine requires further investigation," again on page 4, the first paragraph. 4 And again you said you actually received 5 0 6 this letter in the course of your practice? 7 А Yes, I did. 8 0 Doctor, you have obviously done some 9 litigation consulting. You're testifying today. Is that correct? 10 11 А Yes. 12 0 In fact, you've testified in vaccine cases 13 before this Court before. Is that right? 14 А Yes, I have. 15 Approximately how much of your professional Q 16 time is spent on litigation consulting? 17 None of my professional time is usually Α 18 spent on that. May I explain? 19 Certainly. 0 20 Α I want to just make sure that everyone 21 understands. Basically my primary responsibility is 22 as a clinician and as a faculty member at Rainbow 23 Babies and Children's Hospital and at Case Western 24 Reserve University. That is my job. 25 Therefore, should I have to be out of town, Heritage Reporting Corporation (202) 628-4888

1	as I am today, because of the need to testify in a
2	legal proceeding I basically will never take my
3	patients and just cancel them out and say that's it.
4	I basically reschedule them and increase my patient
5	burden for the days right before or right afterwards.
6	For instance, yesterday morning I ran a
7	clinic to make up for this morning when I would
8	normally have a clinic so that I always make sure that
9	I do not take away from my professional time in order
10	to do this work.
11	In my average week I may spend five to 10
12	percent of my time doing some sort of medical/legal
13	work, usually in evenings and weekends, in terms of
14	reviews. Obviously because legal proceedings do not
15	occur on evenings and weekends on the days when I have
16	to be in a courtroom I will basically show up again,
17	never trying to inconvenience my patients, always
18	rescheduling them and making sure that their needs are
19	first taken care of.
20	Q Would it be fair to say that the majority of
21	your time is spent treating patients, teaching,
22	lecturing, publishing?
23	A The vast majority of my time is spent doing
24	that type of work.
25	Q All right. Doctor, I'd like to now turn to
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1	the opinions that you have given in this case. Based
2	on your education, training, experience and knowledge
3	in the field of pediatric neurology, do you have an
4	opinion as to whether the receipt of an MMR
5	vaccination, combined with the administration of
6	thimerosal-containing vaccines, more likely than not
7	causes autism?
8	A Yes, I have an opinion.
9	Q What is that opinion?
10	A It does not.
11	Q And specifically in this case did the MMR
12	vaccine, either alone or in combination with the
13	receipt of thimerosal-containing vaccines, cause
14	Michelle Cedillo to develop autism?
15	A No, it did not.
16	Q Doctor, approximately how many children do
17	you see in your clinical practice each month?
18	A Between 200 and 250.
19	Q And if you can approximate, how many of
20	those children are diagnosed with autism or ASD?
21	A Probably a quarter of those children have
22	the diagnosis within the autistic spectrum. I think
23	we also have to qualify that I run days in my clinic,
24	at least one day a week in my clinic, what we'll call
25	an autism day in which I see new patients.
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1	Those are new patients in which the parents
2	or clinicians, whether they're medical professionals,
3	educational professionals or psychologists or such,
4	have concerns that the child may have autistic
5	features and wants further evaluation. Sometimes
б	those children do have the diagnosis. Sometimes they
7	don't.
8	For just an example, yesterday I saw a girl
9	where the mother had the concern that her child had
10	autistic features, but she clearly did not on
11	examination. She had other developmental issues, but
12	it had nothing to do with autism.
13	Q Yesterday we heard Dr. Fombonne give a
14	detailed presentation on ASD, but can you just briefly
15	describe for the Court autistic spectrum disorder from
16	your perspective as a pediatric neurologist?
17	A I would be happy to. If I may, we'll say
18	this is my first cover slide, which is What is an
19	Autism Spectrum Disorder? May I have my next slide?
20	Q Sure. That for the record was Slide No. 2,
21	and we're now moving to Slide 3.
22	SPECIAL MASTER HASTINGS: Have you got the
23	handout yet? Not yet?
24	MR. MATANOSKI: Sir, a handout has been
25	given to counsel for the Petitioners.
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WIZNITZER - DIRECT

1 SPECIAL MASTER HASTINGS: Okav. 2 MR. MATANOSKI: We expect to have handouts 3 for the Court itself momentarily. 4 SPECIAL MASTER HASTINGS: All right. Fine. THE WITNESS: As probably was explained to 5 6 the Court before, when you're looking at this field 7 the title that was originally given to this group of 8 conditions was pervasive developmental disorders, 9 which from the beginning many of us did not like 10 because it's too vaque a term. 11 Probably more recently people have come 12 around to the thinking that we should call it autism 13 spectrum disorder or autistic spectrum disorder. 14 That's probably a better descriptive title to give us 15 an idea. 16 Using the model that is probably accepted in 17 the United States, when we look within that group 18 we're talking about individuals with a spectrum of 19 severity. The most severe and the classic model 20 within there is autistic disorder. The least severe, 21 but still representative of the condition, is Asperger 22 disorder or Asperger syndrome, and in between for 23 individuals, and I'll show you a little bit more on my 24 next slide, is pervasive developmental disorder not otherwise specialized. 25

1 In addition to this there's a group of 2 children who between age two and 10 years of age have 3 a change in their functioning from totally normal 4 development to a regression that has autistic features known as childhood disintegrative disorder, and then 5 6 there is a group of children, girls with a known genetic disorder affecting on the X chromosome a gene 7 8 called MECP2 called Rett syndrome. 9 The Retts girls have a slightly different phenotype, which means a different appearance than the 10 11 rest of the individuals within this category, but 12 they're still put into this category according to the 13 accepted classification schema. 14 May I have the next slide? 15 BY MR. JOHNSON: 16 And what do you look for in order to 0 17 diagnose a child with ASD? 18 There are core features irrespective of Δ 19 which diagnosis we're talking about. 20 Whether you're talking about a diagnosis of 21 autistic disorder, whether you're talking about a 22 diagnosis of Asperger disorder, whether you're talking 23 about a diagnosis of PDD-NOS, there are some core 24 features that need to be present. 25 One is a significant qualitative impairment Heritage Reporting Corporation (202) 628-4888

1	in socialization. There are important words here.
2	Significant means it's big time. When the diagnosis
3	is made it's obvious that there is a problem with
4	socialization, but it's not a socialization delay.
5	It's a deviation from the normal course of social
б	development. We'll get into some more of the fine
7	points of this criterion later.
8	Second, there's a significant qualitative
9	impairment in communication. This is not a problem
10	specifically with language, but it's more use of
11	language, which means communication. We're talking
12	about verbal communication. We're talking about
13	nonverbal communication.
14	It's not that the children have a delay.
15	It's not they're behind in their language. It's that
16	again there's a deviation or a change in the normal
17	development of how their language progresses.
18	SPECIAL MASTER HASTINGS: Before you go to
19	number three, we're now on Slide 4. As you move from
20	one slide to the other, if one of the two of you could
21	mention that for the record it would be helpful.
22	THE WITNESS: I'd be very happy to, Special
23	Master.
24	In the classification schema, qualitative
25	impairment in play is subsumed within communication,
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1	but from a thinking standpoint it's easier to say that
2	these children have a change in how their play occurs,
3	which we'll address in a little bit about the
4	specifics of that. Again, it's not that their play is
5	immature for age. It's that their play is different.
б	How they utilize the objects is different.
7	Lastly, the children have areas of
8	restricted interest or repetitive behaviors that again
9	we'll delineate in just a short time.
10	By definition classic autism or autistic
11	disorder has to be symptomatic prior to age 36 months.
12	Even children with Asperger syndrome, in my clinical
13	experience, are symptomatic prior to age 36 months. A
14	diagnosis might not be made until close to school age
15	or afterwards, but they clearly are symptomatic.
16	Again, by definition childhood
17	disintegrative disorder is diagnosed between age two
18	and 10 years.
19	BY MR. JOHNSON:
20	Q Doctor, do you have a diagram that shows the
21	relationship between these core features?
22	A Yes, I do, and if I may just have Slide No.
23	5?
24	If we look at the three core areas of
25	dysfunction in the autistic spectrum disorder
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1	dysfunction of socialization, dysfunction of
2	communication and dysfunction of behavior as shown
3	in this slide, if you meet criteria for all of those
4	by definition it's an autistic disorder.
5	However, there are some individuals that may
6	clearly meet criteria in two of these three, like
7	socialization and communication or socialization and
8	repetitive behaviors or restricted interests, and
9	while they may have dysfunction in the third category
10	it's not sufficient to meet the diagnostic criteria as
11	they've been defined.
12	Those are the individuals who are put in the
13	category of PDD-NOS. NOS stands for not otherwise
14	specified, and it's a category where basically the
15	central thinking of it is when you know they have the
16	condition, but you may not have enough formal criteria
17	in front of you to put them in there. That is the
18	category in which they fit.
19	Q Doctor, let me ask you. In terms of
20	clinical presentation, do all kids with ASDs look
21	exactly the same?
22	A No, they do not. While they have
23	dysfunction in these three core areas, in
24	socialization, communication and behaviors, the level
25	of dysfunction may vary by the severity of the
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### WIZNITZER - DIRECT

1 condition, by age and exactly by which subgroup you 2 fall within in autistic spectrum disorders. 3 0 And even within say the same subgroup, would two children within that subgroup necessarily exhibit 4 the same signs and symptoms? 5 6 Α No, they do not. Again, you have the core features that are there. Exactly how it manifests may 7 8 be different. 9 If I may just give a very simple example, when we look at issues such as restricted interests 10 11 and repetitive behaviors let's just take an issue of 12 fascination, which I know has been mentioned to the 13 Court before. 14 I may have one individual who has a 15 fascination with space, another individual who has a 16 fascination and a major interest in Star Trek, another 17 individual who has a major fascination with numbers 18 and letters, the idea here being that there's a 19 fascination or a restricted interest, not necessarily 20 specifically what the restricted interest is. 21 Dr. Fombonne mentioned yesterday and you 0 22 discussed today some diagnostic criteria. I assume 23 you use diagnostic criteria in your practice? 24 Α Yes, I do. And which ones do you use? 25 0 Heritage Reporting Corporation

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1 We are now on Slide 6 for the Court. Α 2 Basically accepted within the United States is the use 3 of the DSM-IV criteria for autistic disorder. If I 4 may? 5 Q Certainly. 6 Α There's much more discussion about whether 7 the DSM-IV criteria for Asperger disorder really 8 captures the group, and many of us will use other 9 diagnostic criteria that have been formulated that 10 probably better capture that group. 11 But let's just stick with the classics, the 12 classic ASD, which is autistic disorder. People agree 13 that the DSM-IV criteria are the ones that we use. 14 And please tell the Court what the first 0 15 DSM-IV criterion is. 16 Α The first criterion is the qualitative 17 impairment in social interaction, and really within 18 that group there's four subgroups. Within that column 19 there's four subgroups of areas of dysfunction that if 20 you meet at least two of them it puts you on the path 21 to potentially be diagnosed as having an autistic 22 disorder. 23 When we look at these, the first one is 24 marked impairment in the use of multiple nonverbal 25 behaviors to regulate social interaction and people Heritage Reporting Corporation (202) 628-4888

1 talk.

2	What that really means is that we don't use
3	nonverbal cues adequately. These individuals have
4	problems with what's called pragmatics, which is the
5	nonverbal aspect of language, gesture, pointing with
6	their eyes, eye contact, the use of body language,
7	reading body language, things of that nature.
8	Number two is failure to develop peer
9	relations appropriate to developmental level. It's an
10	important criterion because it says developmental
11	level, which means if you have a cognitive impairment
12	and you're 10 years old but functioning at a five-
13	year-old level, you should socialize at a five-year-
14	old level. It's good that this criterion is there.
15	Therefore, you're not making peer relations
16	appropriately. You're not interacting with your peers
17	appropriate to the developmental level, and there's
18	actually even other subgroups within there about what
19	do we mean by failure to develop peer relations
20	because there may be various and several different
21	kinds of conditions that can interfere with your
22	ability to adequately interact with your peers that
23	have nothing to do with autism.
24	Number three is marked impairment in
25	expression of pleasure in other people's happiness,

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1	which is the empathy category. Really it's sharing
2	with other people what they do, reading the other
3	people, taking pleasure from what they're doing and
4	how they're doing things and reacting to it in an
5	appropriate matter.
б	Then lastly is lack of social or emotional
7	reciprocity, which is two categories. One is
8	responding to a social or emotional input from a
9	person, but the second thing is initiating social and
10	emotional contact because the word here is
11	reciprocity. It's a two-way street in terms of how
12	you're interacting with people.
13	Q Doctor, what are some of the different
14	clinical presentations you see with respect to social
15	interaction?
16	A Well, on Slide 7 here I have taken a
17	modification of criteria that were developed probably
18	over 20 to 30 years ago.
19	Basically this was an approach to social
20	recognition and socialization in autistic disorder
21	that was taught to me by my mentors at the Albert
22	Einstein College of Medicine, and it's a good
23	functional categorization to try to get a mental
24	picture of the range of social deficits that can occur
25	in this population.

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1	What we have here on this timeline is the
2	social deficits that we see in this population running
3	from children who are socially unavailable, which I
4	will define in a little bit, to children who we call
5	pseudosocial, which means they have some superficial
б	social skills, but down deep they still lack that
7	innate ability to really do socialization in the way
8	that other individuals in the environment do it.
9	The importance of this slide is that
10	children with autistic disorder don't stay necessarily
11	at one social level; in other words, one level of
12	social impairment. The natural history is that we see
13	some improvement in socialization as time continues,
14	although the improvement may be variable.
15	Some children show a significant amount of
16	improvement, and other children only show small
17	amounts of improvement. That's what the slide says
18	here with the two points underneath showing increasing
19	age and decreasing severity.
20	If I may have the next slide? When we look
21	at the greatest impairment in socialization
22	Q And this is Slide No. 8, correct?
23	A This is Slide No. 8. These are children who
24	we consider them to be socially unavailable. They're
25	relatively oblivious to their surroundings.
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1	If they fall and hurt themselves they don't
2	seek consolation from a parent. Basically they don't
3	show the parent the boo-boo, if you want to think of
4	it in that manner, or where they were hurt. They act
5	like they're isolated and out of contact, and many
б	times they will just do some purposeless wandering in
7	the environment. They walk around and really don't
8	make too much social contact.
9	In my clinical experience, this is the
10	picture that I tend to see in children when they are
11	at about two years of age. If they're going to show
12	this, it's at approximately a year and a half to two
13	and a half years of age as a round number.
14	Now if we move to Slide 9, a less impaired
15	but still significant dysfunction. You can consider
16	children to be what's called socially remote. These
17	are children who basically do not initiate social
18	interaction within an adult, yet if an adult makes a
19	contact with the child the child may follow through on
20	it, but once the adult stops the contact the child
21	will not wish to continue it, does not go seeking
22	after the adult in order to say let's keep doing this.
23	An example would be playing ball. If I roll
24	a ball to a toddler and the toddler rolls it back to
25	me and we make a big stink about it and they giggle
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1	and laugh and we keep going back and forth, but if I
2	walk away and quit and the toddler is not ready to
3	quit the toddler will basically yell or scream or
4	throw the ball or come after me in order to continue
5	the activity.
6	We don't see that in the child who's more
7	socially remote. They usually do more of their
8	solitary activity. They may look at their peers, but
9	they don't approach them. When they do an activity,
10	most of the time their interest is more in the
11	activity than in effect of doing it with the person.
12	In fact, a question that I frequently ask
13	the parents in my practice is if the child walks into
14	the room and there's a group of children playing with
15	toys in one area and then there's just a pile of toys
16	in another area, which way does your child prefer to
17	go?
18	The children with this kind of dysfunction
19	will go towards the toys and not to join their peers
20	playing with the toys, which is what the typical child
21	would do. Of course, if you ask me there are other
22	conditions that can also do this. For example, social
23	anxiety is a big one, but we're not talking about a
24	child with social anxiety here.
25	Slide 10, please? There are some children,

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1	especially as they get older, who are more socially
2	inappropriately interactive. These are children who
3	basically have some desire to interact, but just don't
4	know how to do it. It's not that they're socially
5	immature. They just don't get how to do it.
6	They interact better with adults than with
7	their peers simply because we as adults can guide that
8	interaction, and we can give them cues and clues in
9	order to stay on target for that.
10	When they do interact with their peers they
11	may do it in inappropriate fashion. One of my
12	patients I remember clearly would go up to his peers
13	and push them repeatedly and would get punished by the
14	teacher for pushing them repeatedly.
15	It turns out that he was modeling to some
16	degree the behavior of his peers on the playground,
17	which if you think about children, especially little
18	children, a lot of times they'll go up to their peers
19	and push them. He thought that was the way to
20	socially interact.
21	We basically took him back, made sure he was
22	trained in a more appropriate social greeting, which
23	was either a handshake or saying hello, and that
24	behavior disappeared. But if you stress them, they
25	then will retreat into an isolation.
	Hanitana Danantina Gamanatian

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1601

# WIZNITZER - DIRECT

1	Slide 11? There are also children,
2	especially higher functioning children, which means
3	children with normal intelligence, who have some
4	social skills. They've learned and memorized social
5	skills, but their social interaction is mechanical and
6	pedantic, pedantic meaning that they talk to you
7	rather than with you.
8	It's almost like as if they're repeating a
9	social script in terms of how they're supposed to
10	interact with you. They have problems maintaining the
11	interaction if it's not following the script that
12	they've been taught.
13	An example that I have is a child who came
14	into my office who when I was talking with them I'd
15	say where do you live, and I would get no answer.
16	After I asked it two more times the parents said to me
17	you need to ask him what's your address.
18	When I asked that question I was able to get
19	the answer correctly, but again the child basically
20	was taught a social script, and these kids are very
21	good at learning some social scripts. Not all of
22	them, but these kids, the higher functioning kids who
23	are capable of doing it.
24	Many times when they do talk to you they
25	talk to you regarding their areas of fascination about
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1 certain topics or themes, and these kids may be verbal 2 enough that if you catch them within this area that it 3 may initially mask a social deficit, although it will 4 become apparent over time. 5 Therefore, what we have here is again it's a 6 spectrum of social dysfunction from all of it being significant, but it runs from the most severe to we'll 7 8 say the much less severe, from one that is not 9 functional to one that has a potential for being functional. 10 11 All right, Doctor. We've looked at some 0 12 different presentations in the area of socialization. 13 What is the next diagnostic criterion? 14 А The next diagnostic criterion basically 15 deals with the qualitative impairment in 16 communication, and when we look at this again we have 17 to remember the word is not language. It's not 18 speech. It's communication. It's getting your 19 message across to other people. 20 For us to get our message across to other 21 people we not only use our words; we use our body. We 22 use our intonation. We use a lot of nonverbal cues 23 and clues that are given. 24 There are again four criteria within this category, and you'd have to meet at least one of them 25 Heritage Reporting Corporation (202) 628-4888

1602A

1603

# WIZNITZER - DIRECT

1	in order to basically qualify for potentially being
2	diagnosed with autistic disorder.
3	SPECIAL MASTER HASTINGS: And we're now on
4	Slide 12. Is that right?
5	THE WITNESS: Yes, sir. I'm sorry, sir.
б	This is Slide 12.
7	The first one is a delay or the total lack
8	of development of spoken language, which basically
9	does not have associated with it gesture language.
10	One of the reasons this is there is to exclude
11	children, for instance, with hearing impairment or
12	children with a predominantly expressive developmental
13	language disorder who will gesture or mime, point and
14	do things of this nature in order to get their
15	messages across, which again means the child is not
16	really having any true communicative intent in this
17	manner.
18	Number two is children with adequate speech.
19	They have problems initiating or sustaining
20	conversation with others. Again, it's not because of
21	lack of practice. It's not because of not paying
22	attention to what other people are doing. It's not
23	because of being overall delayed in your development.
24	It's that you just don't know how to use the language.
25	And really if you think about the deficit in
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1	communication, and we always talk about it. We always
2	talk about how they talk. It's really social
3	communication. How do you use your communicative
4	ability in order to interact with another person?
5	It's the use of communication. Here the person is
6	unable to use it in a functional manner.
7	Number three is stereotype or repetitive use
8	of language or idiosyncratic language, and that just
9	means things just as repeating what other people have
10	said, repeating scripts that they may have heard.
11	Traditionally we will have in these children that
12	they'll come in and they will be repeating scripts
13	from videos that they enjoy watching. They'll repeat
14	scripts from commercials they have seen.
15	Patients of mine, when they drive by
16	McDonalds, will sing the McDonalds jingle in order to
17	communicate that they've seen the sign, and maybe
18	that's their signal for I want to go to McDonalds, but
19	they're unable to verbalize in a perfect manner. They
20	may also use language in a somewhat inappropriate or
21	stilted fashion, but that's really the category there.
22	Then the fourth part of that category is a
23	problem with good imaginative play. The word make-
24	believe is here. Spontaneous make-believe or social
25	imitative play. It's important, the word spontaneous.
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1 It's not quided by an adult. It's not scripted where 2 you follow the same script over and over again. 3 There are higher functioning children whose play can be scripted, but if you watch them you'll see 4 that their play looks very similar from session to 5 6 session to session, or it needs to be initiated by an 7 adult. They do not do it at their own spontaneous 8 level. 9 Of course, again it's where they act cognitively. It has to be at their cognitive level so 10 11 a child who's 10 years old with the intelligence of a 12 10-year-old should play like a 10-year-old. A child 13 who's 10 years old but has the intelligence of a two-14 year-old should play like a two-year-old. 15 If I may move on to the next slide, to give 16 some further explanation of the impairment in 17 communication again there is a spectrum of dysfunction 18 that occurs in the use of communication in this 19 population. You've got some children who really have 20 no communicative intent whatsoever, which is one far 21 side of this curve that I have here. 22 Most of the children, the vast majority of 23 these children, will develop communicative skills to 24 get their basic needs meet. Again, that's not social communication. I'll call it existence communication, 25 Heritage Reporting Corporation

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1606A

# WIZNITZER - DIRECT

1	life communication. They will basically ask for
2	drinks, ask for juice. If they want something from
3	the parents they will do that, but the impairment
4	there is that they still don't communicate for social
5	purposes.
6	When I ask parents, I ask does your child
7	gossip or schmooze with you? The parents will say no.
8	The child does not share things like here's a little
9	bug I found on the ground, here's a tree limb, look at
10	these pictures I drew today, unless the parent
11	initiates that type of an interaction.
12	Individuals may actually develop more
13	language that's there, but again the language, as was
14	mentioned before, is idiosyncratic. They have speech,
15	but there's tangential comments. If you listen
16	carefully, many times those tangential comments deal
17	with some of their fascinations or scripts that
18	they're pulling in from TV shows and from other areas
19	that they've been interested in or they watch or may
20	repeat lines that parents have used.
21	For instance, some of my patients, when
22	they've acted out in my office or had some
23	inappropriate actions, you hear them actually in
24	almost their parents' voice reprimanding themselves.
25	You're not supposed to behave that way and using those
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kinds of words. That's one of the tangential 1 2 comments. 3 Then the best use of language we'll call a cocktail speech, and the reason we call it a cocktail 4 5 speech or I use that as an explanation is that when we 6 go to cocktail parties we say a lot, but there's not 7 much content in it. It's basically social talk and 8 gossip that's there, and these kids outside their 9 areas of fascination have difficulties in terms of the social communication. 10 11 Irrespective of the problem with 12 communication that occurs in this population, we know 13 that in children with autistic disorder they have 14 impairments in three areas that really interferes with 15 their ability to really use communication adequately. 16 Number one is they have problems with joint 17 attention. Joint attention is the concept or the 18 understanding that I can do an action or activity with 19 someone else and, by the way, the someone else doesn't

have to be a person -- it could be an animal or it could be something on that level -- revolving around a theme. In other words, there's a triangle of activity, the two individuals plus a common area of interest.

25 It could be something as simple as having a Heritage Reporting Corporation (202) 628-4888

1	conversation where the conversation is the common area
2	of interest. It could be playing ball where that's
3	the common area of interest. It could be, for
4	instance, a child coming along and showing the
5	caterpillar that he just found on the ground. That's
6	the common area of interest. Joint attention is one
7	of the core areas of impairment in autistic disorder
8	and within the entire autistic spectrum.
9	Number two is they have problems with
10	metalinguistic skills. Metalinguistic skills are
11	higher order language skills that deal not just with
12	how we talk; in other words, not how you articulate
13	the words, not how you grammatically put your
14	sentences together, but actually the meaning of what
15	you say and the nonverbal activities that you use in
16	order to say what you mean.
17	We can say the same sentence in three
18	different ways by varying our tone of voice and it
19	will come across as interpreted as meaning three
20	different things.
21	We can identify in these individuals they
22	have problems with issues such as humor, especially
23	verbal humor. My patients have much easier times with
24	visual humor. I always say the anvil falling on the
25	coyote's head in the cartoons is easier for them to
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1 understand than if a joke is told to them. 2 Number two, they have problems with sarcasm, 3 cynicism and other uses of higher order language which 4 is much more abstract. In fact, these children are somewhat literal and concrete and we have to be 5 6 careful what we say to them. 7 If we say to a child hop to it, if the child 8 was ASD the child may start hopping across the room 9 because the child does not understand the 10 colloquialism or the slang that we're using. In fact, 11 one of the interventions that are used in terms of 12 addressing this issue is the text on English as a 13 second language, which actually contains a lot of the 14 typical slang we use in our language. 15 I warn teachers when I give presentations to 16 teachers to say what you mean because if you don't say 17 what you mean it may be misinterpreted. 18 Thirdly, it's how they use their language. 19 As I stated before, use of language is primarily for 20 getting their needs met. Many times it may be for 21 interaction around one of their areas of fascination or restricted interest. But the use of language in 22 23 the true social sense that we would expect is very 24 limited or lacking in this population. 11 25

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WIZNITZER - DIRECT 1 BY MR. JOHNSON: 2 And, Doctor, I believe you said issues 0 3 related to play also fall under the criterion related 4 to communication deficits? 5 Δ Yes. When we look at play in this 6 population --7 SPECIAL MASTER HASTINGS: And now we're 8 going to move to Slide No. 14? 9 THE WITNESS: Yes. Thank you, sir. On Slide 14, when we look at play, we know that children 10 11 with autism have an impairment in play, and we need to 12 differentiate this impairment in play from just the 13 play issues that we may see in children who are just 14 generally delayed in their development. 15 This is important in terms of paying 16 attention to it because initially these children, what 17 they do is they'll have oral behaviors, but we can 18 argue all kids have oral behaviors. There are certain 19 developmental levels that will have oral behaviors, 20 but their oral behaviors tend to be more so than we 21 would normally expect for that developmental level. 22 And they may have cause/effect play. I push 23 a key on a piano. The piano makes music. I push a 24 button. Mickey Mouse pops up. I flick a light The light goes on. That's more of a cause/ 25 switch. Heritage Reporting Corporation (202) 628-4888

1 effect play.

2 After that though there's a serious 3 deficiency in terms of how we see play development 4 because the children have difficulties, impairment in imitation, which is the second thing that interferes 5 6 with their ability to learn. The first is joint attention. The second is imitation. 7 8 You don't pay attention to the person, and 9 then when you do it's difficult to really follow 10 through on a regular basis as to what they're showing 11 you to do. Notice I said on a regular basis. There 12 may be some sporadic breakthroughs here and there, but 13 it's not a consistent pattern of behavior such as we 14 would expect in otherwise typical children. 15 Because they have problems with imitation, 16 there are delays. We find that these kids in the 17 second half of the second year of life between 18 and 18 24 months, their parents don't report that these kids 19 have good imitative play. 20 They don't have what we call good 21 representational play, which means I take a little 22 teacup and pretend to drink from it. I feed a doll. 23 I put my teddy bear to bed, behaviors of this nature 24 that we normally would expect children to show them. 25 Instead, after a while they may develop some

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1	imitation, but it becomes somewhat mechanical. It
2	almost seems to be scripted, just like their words are
3	scripted. Their play may be scripted where it looks
4	the same from session to session. The child will take
5	an object and play with it the same way. If I teach a
б	child to play restaurant, the child cooks the same
7	menu, serves the same food every single time. There's
8	little to no variation on the theme.
9	Then as you get on in time people believe
10	there's probably a deficit in true symbolic play,
11	which means taking an object and having it represent
12	something else. A stick represents a wand. A stick
13	represents a microphone. A stick represents a sword,
14	or in today's context a Star Wars light saber, things
15	of this nature.
16	The children have great difficulties in
17	this. We tend to see a stagnation where the play
18	freezes if it develops that far.
19	BY MR. JOHNSON:
20	Q All right, Doctor. We've talked about
21	impairment in socialization and impairment in
22	communication. What is the third diagnostic
23	criterion?
24	A The third diagnostic criterion is
25	restricted, repetitive and stereotype patterns of
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1613A

#### WIZNITZER - DIRECT

1 behavior, interest and activities. 2 SPECIAL MASTER HASTINGS: And we're now on 3 Slide 15. 4 MR. JOHNSON: Slide 15. THE WITNESS: Out of this category you need 5 6 to have at least one of these features in order to meet the criteria for autistic disorder, and really 7 8 there's four things within this category. 9 One is, I'm not going to read verbatim because I 10 know people can do this, but it says a preoccupation 11 with a pattern of interest that's abnormal in 12 intensity or focus. That can be a variety of 13 behaviors. It could be that I repeatedly do things 14 such as spin a plate or spin a wheel in a mechanical, 15 nonfunctional manner, or I sit and watch a fan 16 spinning in one of the home improvement stores or at 17 home. 18 It may be that you have an area of 19 fascination or interest. As I had mentioned before, 20 my preschool patients will have interest in Thomas the 21 Tank engine where it's an overwhelming interest that 22 really pervades their lives. It may be Mickey Mouse. 23 It may be Dora the Explorer. 24 It may be with other ones things like the Yugi-Oh cartoon show or Pokemon. Pokemon is not as 25 Heritage Reporting Corporation (202) 628-4888

1 popular now as it used to be, just to mention. I'm 2 seeing phases go through as we see things on 3 television. As they're older we may see areas of 4 interest or fascination. I had mentioned things 5 6 before such as Star Trek, Star Wars, biology. I 7 remember one boy clearly knew everything there was to 8 know about crustacea. I mean, everything. Dinosaurs. 9 You name it, but the idea being they almost 10 turn into walking encyclopedias of this. They may 11 have a fascination with numbers and letters and they 12 seek them out all over, but that's what they mean by 13 this restricted pattern of interest. 14 Number two is an adherence to specific 15 nonfunctional routines or rituals. In a way what this 16 means is it's a desire for sameness. You want things 17 to be done a certain way. You sit in the same seat 18 every time you eat. Chairs have to be arranged around 19 the table a certain way. I always eat from the blue 20 plate. If I'm walking with my family, we need to take 21 the same route. If I'm driving to grandma's house, we should drive the same way. Otherwise I get upset. 22 23 If I walk in and I greet the doctor, the 24 doctor should return the greeting to me in the way that I normally expect. Otherwise I've been prompted 25 Heritage Reporting Corporation

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1	by my parents sometimes. I need to go back, start all
2	over again in order to allow the transition to occur,
3	although the individual may be bothered by the fact
4	that there was not this adherence.
5	The third category is stereotype to
6	repetitive motor mannerisms. Really what it is is a
7	lot of different motor movements, anything from finger
8	flicking to hand regard to hand flapping to twirling
9	or spinning of the hand to a whole group of
10	ritualistic actions that we do with our bodies
11	twirling yourself around, touching behaviors, things
12	of this nature.
13	Then fourthly, a persistent preoccupation
14	with parts of an object. In a way think of this as
15	missing the forest because of the trees. You're more
16	interested in the individual components of an object
17	than in the functional use of that object, so the
18	child may focus, for instance, not on the car and how
19	you play with the car, but on the wheel of the car or
20	the toy and how it spins.
21	I have parents who come in to me and tell me

how their children have taken apart toys just to get into the ball bearings that are at the bottom of the toy and just play with the ball bearings, ignoring the actual functional use of the toy. That's really what

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1616

1 we're talking about with this persistent 2 preoccupation. 3 You need at least one of these four at the 4 minimum in order to make diagnostic criteria. BY MR. JOHNSON: 5 6 All right. As we look next at Slide 16, can 0 7 you talk about, and you may have already some of this, 8 but some of the clinical presentations you see with 9 respect to this criterion? Well, a simple way of thinking of this is 10 А 11 and the way I categorize it when I do my teaching is 12 that there's several different types of restricted 13 interest repetitive behaviors. 14 For instance, there may be repetitive 15 actions that we can see in otherwise regular kids. 16 For instance, playing with a light switch, opening and 17 closing a door, opening and closing drawers and 18 cupboards. The issue here is the child does it to 19 excess. 20 While a typical toddler may play with a 21 light switch for a few minutes and then walk away, 22 these children may sit for 30 minutes, 60 minutes, and 23 do it until you actually stop the activity. The same 24 with other kinds of fixtures and structures. That's the same thing as I was talking about, spinning a 25

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1617

# WIZNITZER - DIRECT

1	plate or spinning a top and things like that.
2	I already talked about the motor
3	stereotypies, the hand regard, the finger flicking,
4	the flapping and such that we see.
5	The issue of compulsive behaviors, wanting
б	things to be a certain way, which is part of the
7	desire for sameness. Compulsive behaviors is
8	different than obsessive compulsive disorder in this
9	population, although treatment may be the same, but
10	there is a qualitative difference when it comes to
11	diagnostic criteria.
12	The desire for sameness, resistance to
13	change we already discussed, and we also already
14	discussed the issue of certain fascinations with
15	themes or topics that really pervade that individual's
16	life.
17	Q Doctor, on Slide 17, which is the next
18	slide, I believe you have a summary of some of these
19	points.
20	A Yes. According to the DSM-IV, what you need
21	to do from these three major categories is you need at
22	least I call it a Chinese menu. When ordering from
23	a Chinese menu, they always say a certain number of
24	orders from column A, column B and column C, so
25	therefore the same way the representation is here.
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1	You have to have two of the four criteria
2	from the socialization column, one of the four from
3	communication and one of the four from repetitive
4	behaviors, which means you need to have at least one
5	from each category, but you have to have at least six
6	of 12 where studies have shown that if you have at
7	least six of the 12 that really puts you into the
8	autistic disorders category.
9	Then obviously they identify that not only
10	do you have this dysfunction, but it's causing a
11	functional impairment. It's causing problems with
12	socialization. It's causing problems with the use of
13	language and social communication. It's causing
14	problems in play.
15	Onset prior to age three years, and you
16	can't account for it by another condition. Here they
17	list two conditions, but it can't be explained by
18	another medical or psychiatric disorder.
19	Q Doctor, in your practice when are children
20	with autism and ASD most symptomatic?
21	A They're symptomatic in the second and third
22	year of life.
23	Q And what is the typical progression of
24	autism?
25	A May I have the next slide?
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1619A

# WIZNITZER - DIRECT

1 This is Slide No. 18. 0 2 I made this slide basically to identify in a Α 3 typical child. This is not representative of all 4 children with autism. I think I really want to make sure that the 5 6 Court understands that. This is just a typical 7 timeline. There are other children who actually do 8 worse in their progression here. There are other 9 children who do better. This is something that's easily been 10 11 described. This is a pattern that children may follow 12 where in the second year of life the children really 13 don't have well developed imitation. They don't have 14 good language. There's a problem with socialization. 15 They don't play well. 16 By the time they get to about two years old 17 when they're significantly most involved, they 18 basically are social loners. They don't interact with 19 individuals around them. They don't respond to voice. 20 They don't turn when their names are called, but they 21 do turn when they hear their favorite television show, 22 which means their hearing is not impaired. 23 If they hear Sesame Street, Dora the 24 Explorer, Barney, the Thomas theme, two or three rooms away they come running. You call their name, they 25 Heritage Reporting Corporation (202) 628-4888

1620A

## WIZNITZER - DIRECT

1	don't turn around. Obviously if you want to think of
2	it this way, there's a selective hearing that's
3	present that we really still have to better understand
4	what drives it.
5	There's no real good play. By the second to
6	third year of life, we clearly will see fascinations
7	and stereotypies. The motor mannerisms show
8	themselves. There is data out there that if we don't
9	see those presenting by age three years we need to
10	look for other reasons why these children have their
11	problems. They also continue to have poor peer
12	interaction.
13	Then starting at about age three years,
14	around age three years before that if there's

15 vocalization from the children the vocalizations are in terms of jargon. They're nonspecific utterances 16 17 and babbling. Then about age three years we start 18 seeing the children being echolaliac, repeating either what people are saying around them or things that 19 20 they've heard previously, which means we always have 21 to be careful to some degree about what we say around 22 these children because it may be repeated later on in 23 situations that are not desired.

24 They also have an interest in puzzle play,
25 reflecting their relative strength in visual/spacial

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1	skills, but they still don't have good developed play.
2	I'm talking about symbolic or imaginative play that's
3	there, and socially they may be loners or they may
4	watch what other children are doing.
5	And then as we go on further through the
б	preschool years we find that they start doing some
7	response to adult interaction. They start showing
8	greater interest in watching what their peers do.
9	They start using some words or phrases to get requests
10	or to label things, to get their needs met.
11	They may start copying in a mechanical
12	fashion what other people around them are doing, but
13	again not standing on that copying to turn it into a
14	true symbolic play, and by the time they get to
15	school-age years there's limited peer interaction.
16	There may be none. There may be some, but it's still
17	impaired, what's there.
18	They will use language for simple
19	communication, but again it's impaired for social
20	communication. They really don't have good
21	imaginative play, and if there is what looks to be
22	imaginative play it usually revolves around a theme or
23	an interest.
24	As an example, I may have children taking
25	little characters, let's say little Disney characters,
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1	and using them to act out a Disney movie in an
2	appropriate fashion, but all they're doing is
3	repeating the script from the movie with the
4	characters.
5	If I asked them to take the characters and
6	act out some other scenario, they're at a loss in that
7	regard. There's a continuation of their areas of
8	fascination, which may change, but it's still there
9	over the repetitive motor activities.
10	So what we see is not a stagnant disorder,
11	but a disorder that over time shows a gradual
12	improvement in function, although you still have an
13	impairment in the core areas that define the entity.
14	We see gradual improvement, in some a minimal
15	improvement and in others a significant or obvious
16	improvement.
17	Q Doctor, what are your treatment goals with
18	your patients?
19	A My treatment goals with my patients are
20	several. Number one is parents should always be
21	informed consumers. They should understand what
22	they're dealing with. They should understand what's
23	available for intervention and understand how to
24	implement it.
25	Then in conjunction with the parents, our
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1	goal is to maximize that child's potential ability to
2	make the child as functional and as good a
3	contributing member to society as the child can
4	possibly be, which if you think about it is no
5	different than our goal with any other child that
6	either I take care of or who lives with us.
7	Q Doctor, Dr. Kinsbourne on Friday testified,
8	and I believe this is on page 1165 of the transcript
9	from Friday. Dr. Kinsbourne testified that a
10	physician can treat hundreds of thousands of children
11	with autism and have no understanding of the brain
12	mechanisms that might be contributing to its cause.
13	Just as a physician who treats hundreds of
14	children with autism, what is your reaction to that
15	statement?
16	A Well, let's be exact. As a physician who
17	has probably seen several thousand children in my
18	career, thousands of children with autism, I would
19	respectfully disagree with Dr. Kinsbourne.
20	To be an effective clinician and to have
21	expertise in autism in terms of interacting,
22	intervening, you need to understand what drives and
23	causes autism as best as we can understand it at the
24	present time.
25	Q Dr. Kinsbourne also testified, and this is
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1 at pages 1046 to 1047 of the transcript, that autistic 2 children usually have hobbies that, as he put it, have 3 no practical utility. 4 As a practicing physician who treats and cares for autistic patients, how do you deal with the 5 6 unusual fascinations that they have? 7 А One of the goals is to use those areas of 8 interest in order to further their functional 9 abilities, using those areas of interest in terms of 10 working with socialization. 11 I'll give you an educational example. If a 12 child has an interest in dinosaurs, use that interest 13 in order to do projects for school so that you 14 understand the learning strategy that you're supposed 15 to be taught in school. If I have to write a report 16 for school, the report will revolve around dinosaurs, 17 but at least I'm writing on that. 18 Getting individuals in interest groups that 19 again have the same area of interest. If I have a 20 fascination with trains, there's a lot of interest 21 groups, adults, who are train watchers out there. We 22 can use these skills for their benefit in terms of 23 learning. 24 I have patients in college who are basically using their areas of strength and interest, for 25 Heritage Reporting Corporation

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1625A

WIZNITZER - DIRECT 1 instance, in computer skills in order to get 2 Bachelor's and advanced degrees and successfully 3 transition into the workforce. 4 It would be inappropriate to say that there's no functional utility for these skills. 5 They 6 can be turned into a functioning utility in the hands of individuals who know how to do it. 7 8 In other words, your care of your patient 0 9 doesn't end with the diagnosis? А 10 No. 11 0 Doctor, have you reviewed the report and 12 testimony of Dr. Kinsbourne? 13 А Yes, I have. 14 Is it your understanding of Dr. Kinsbourne's 0 15 testimony that a persistent measles virus infection in 16 Michelle Cedillo's brain caused her to experience 17 regressive autism? 18 Α Yes. 19 As a pediatric neurologist, are you trained 0 20 to identify and treat infectious disease processes 21 that affect the brain? 22 А Yes, I am. 23 Q And have you actually treated kids with 24 infections in the brain? 25 Yes, I have. Α Heritage Reporting Corporation

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1 Are you familiar with any conditions or Q 2 diseases that are associated with the measles virus 3 infections in the brain? Yes, I am. 4 Α 5 0 And if you wouldn't mind please just 6 describing for the Court what those are? We're 7 looking at Slide 19. 8 There are three recognized central nervous Α 9 system complications associated with wild-type measles infections in children and adults. 10 11 Postinfectious encephalomyelitis is a 12 presumed immune-mediated disorder of the brain that 13 presents with a focal neurologic deficit, either 14 cranial nerve problems, motor or sensory problems, 15 impairment of consciousness and seizures. Onset is 16 usually within days to a few weeks after the onset of 17 the infection. It's a monophasic illness. 18 And what do you mean by monophasic? 0 19 Monophasic means you get it and one of two Α 20 things happens. You recover from it, or in rare 21 circumstances it can lead to death. 22 What is the clinical presentation of the 0 23 second condition that's on the slide? 24 Measles inclusion body encephalitis presents Α with a change in mental status, seizures and to some 25 Heritage Reporting Corporation (202) 628-4888

1627

1	degree focal neurologic deficits. Its onset is in the
2	months after the measles infection. People have
3	talked about as early as one month, as late as eight
4	to 10 months afterwards. It is a relentless,
5	progressive disorder with an outcome that is usually
б	described as death.
7	Q And for subacute sclerosing panencephalitis?
8	What is the clinical presentation for that condition?
9	A Subacute sclerosing panencephalitis is a
10	more insidious disorder with onset years after
11	exposure to the measles virus. People talk about
12	onsets three to 10 years afterwards. It occurs more
13	often in children who had wild-type measles infection
14	prior to age two years.
15	Its presentation is normally with some sort
16	of neurocognitive dysfunction, mental status changes,
17	behavioral changes. Ultimately you develop certain
18	kinds of jerks and jumps known as myoclonus. There's
19	again a progressive deterioration in function, and the
20	natural history of this disorder, ultimately it
21	results in death.
22	Q Doctor, are the diagnostic criteria and
23	clinical presentation of postinfectious
24	encephalomyelitis, SSPE or MIBE, are they similar to
25	ASD?
	New the new Demonstration of the section

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1 No, they're not. AA 2 How are they different? Q All of the known measles central nervous 3 Α system complications are associated with an impairment 4 in level of consciousness that persists and is 5 6 progressive. It's associated with the ultimate 7 appearance of focal neurologic deficit. 8 It is not associated with any of the 9 clinical criteria that I had mentioned beforehand to you about autism in terms of the impairment in 10 11 socialization, the impairment in the use of 12 communication, repetitive behaviors and restricted 13 interests. They're totally different, totally 14 different in terms of how they look and how they 15 present. 16 For instance, all these conditions at some 17 time or another -- postinfectious encephalomyelitis, 18 MIBE and SSPE -- will usually result in a hospital 19 admission because of the severity of the condition, 20 which is not something we typically have with autism. 21 Even more importantly, in autism, as I 22 explained in the natural history of autism, we have a 23 gradual improvement in function in these individuals. 24 It can be a mild improvement. It can be a significant improvement in how they function. 25

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1	In these three conditions, and I will say
2	especially in MIBE and SSPE, the natural history is
3	not that of improvement. The natural history is a
4	progressive deterioration and worsening until you die.
5	Q Doctor, are you aware of any other
б	conditions that are associated with a persistent
7	measles virus infection in the brain other than the
8	three that are on the slide?
9	A Well, let me qualify that postinfectious
10	encephalomyelitis is not due to a persistent measles
11	virus infection. It's due to an immune mediated
12	process associated with a measles virus infection.
13	Q Fair enough.
14	A But the other two, MIBE and SSPE, which are
15	persistent measles virus infections. These are the
16	only two that I know of that exist.
17	Q Doctor, have you had the opportunity to
18	review Michelle Cedillo's medical records?
19	A Yes, I have.
20	Q Have you seen anything in those records or
21	any of the other materials you've reviewed in
22	connection with your work on this case that would lead
23	you to diagnose Michelle with postinfectious
24	encephalomyelitis, SSPE or MIBE?
25	A There is nothing in the materials that would
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1630 WIZNITZER - DIRECT 1 lead to the diagnosis of any of these three 2 conditions. 3 0 Doctor, I'd like to turn now to the 4 hypothesis Dr. Kinsbourne has testified to in terms of 5 the mechanism that he believes is causing Michelle б Cedillo's autism. 7 Again, is it your understanding that his 8 opinion is based on a contention that there is a 9 persistent measles virus infection in Michelle's brain? 10 11 Α Yes. 12 0 Have you ever treated a child with measles 13 virus induced autism? 14 Α No. 15 0 And are you familiar with any literature 16 that proposes a scientifically proven model for 17 measles virus induced autism? 18 I am not familiar with any literature. Α 19 Did you hear Dr. Kinsbourne testify on 0 20 Friday? 21 Everything but the last hour. Α 22 And did you review the transcript from the 0 23 final hour? 24 Α Yes, I have. So you are familiar with the testimony he 25 0 Heritage Reporting Corporation (202) 628-4888

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WIZNITZER - DIRECT 1 gave last week? 2 Yes, I am. А 3 Q Can you briefly summarize your understanding of Dr. Kinsbourne's causal hypothesis? 4 5 SPECIAL MASTER HASTINGS: And now we're б looking at Slide 20, correct? 7 MR. JOHNSON: That's correct. 8 THE WITNESS: My understanding of Dr. 9 Kinsbourne's hypothesis is that the measles virus 10 enters the central nervous system, preferentially 11 infects glial cells, causes astrocytes, which is a 12 type of glial cell, to dysfunction. 13 The astrocyte dysfunction causes an 14 elevation in brain glutamate levels and that the 15 excessive glutamate that's present causes 16 overexcitation of neurons and provokes the autistic 17 phenotype or the autistic appearance that's present. 18 BY MR. JOHNSON: 19 Doctor, let's look first at the issue of 0 20 overexcitation that you referred to. The idea that 21 overexcitation in the brain causes autism, is that a 22 new idea? 23 Α No, it's not.

Q How about the part of the hypothesis that this overexcitation is caused by excessive glutamate Heritage Reporting Corporation (202) 628-4888

WIZNITZER - DIRECT 1 levels in the brain. Is that a new idea? 2 А That's a new idea. Have the scientific and medical communities 3 0 accepted this hypothesis? 4 5 Α No, they have not. May I? 6 0 Certainly. 7 Α It's only a hypothesis. There's no real 8 data to support it. Therefore, you can't accept a 9 hypothesis. 10 A hypothesis needs to be proven before 11 acceptance will occur or before people can consider 12 whether or not to accept it. 13 Doctor, on Friday Dr. Kinsbourne referred 0 14 the Court to an article by Rubenstein, and we're 15 looking now at Slide 21. Have you had an opportunity to review that article? 16 17 Α Yes, I have. 18 0 What does that article say? 19 Well, basically Rubenstein and Merzenich's Α 20 article talks about a model of autism that is thought 21 to be an overarousal or excessive excitation of the 22 brain. That's what they state. 23 Now, I know in the models that Dr. 24 Kinsbourne has proffered he basically says too much 25 excitation of the neurons due to excessive glutamate Heritage Reporting Corporation (202) 628-4888

1633A

# WIZNITZER - DIRECT

1	provokes autism features, but if we closely read
2	Rubenstein and Merzenich's article, and if I may have
3	the next slide, No. 22?
4	First of all, they start the article by
5	positing, as Dr. Kinsbourne did mention briefly in his
6	testimony on Friday, that we hypothesized that at
7	least some forms of autism are caused by a
8	disproportionate high level of excitation or
9	disproportionately weak inhibition in neurocircuits.
10	In other words, what they're saying is that
11	there's a natural balance in neurocircuits in the
12	brain. There's the excitatory neurons and there's the
13	inhibitory neurons, and they normally are in a
14	reasonable balance.
15	When that system becomes imbalanced, and it
16	can become imbalanced in one of two ways by
17	excessive excitation or by deficient inhibition it
18	leads to the Rubenstein and Merzenich model of what
19	they're talking about.
20	If I may move on to the next slide, No. 23?
21	Reading the article, and the wording that they use is
22	an imbalance of excitation and inhibition. Rubenstein
23	and Merzenich basically identify several different
24	mechanisms by which you may have increased excitation.
25	They say, for instance, the receptors of the
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1634A

# WIZNITZER - DIRECT

1	neurotransmitter in this case we'll talk about
2	glutamates, which is a primary excitatory
3	neurotransmitter in the brain, but the receptors for
4	glutamate, there may be a greater number of these
5	receptors than should be there, or these receptors may
6	not be in a greater number, but they are more
7	sensitive to the effect of glutamate. That's number
8	one.
9	Number two would be that there's many more
10	neurons that are putting out glutamate than we would
11	normally expect. There's an excessive number of
12	neurons that put glutamate into the synaptic cleft,
13	which is the space between two nerves.
14	Number three is there may be another
15	mechanism that after the signal is attached to the
16	receiving neuron there may be some other systems
17	either within the neuron or otherwise affecting that
18	neuron's function that amplify that signal so that you
19	had a weak signal at the beginning and it becomes
20	stronger as time goes on, or you may have too much
21	glutamate. That's number one.
22	On the other side of what Rubenstein and
23	Merzenich talk about is decreased inhibition, too
24	little inhibition, and they use GABA, gamma-
25	aminobutyric acid, GABA, which is a primary inhibitory
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1 neurotransmitter in the brain.

2 They basically posit several theoretical, 3 hypothetical reasons why you may have decreased 4 inhibition. You may not make enough GABA. There just 5 may be deficient GABA production. You may not have 6 good GABA signaling. The GABA that's there just 7 doesn't do the job it's supposed to do. It's just not 8 released well or whatever it would be that's going to 9 be happening. 10 You may have too few neurons that make GABA. 11 In other words, each neuron makes a sufficient amount 12 of GABA, but there's a decreased number of those 13 neurons, or there may not be enough neurons that will 14 receive the GABA in the receptors so that there's not 15 a good signal that's now being sent. 16 Part of the impaired GABA signaling can also 17 be that the neuron that's receiving the signal, 18 somehow that signal gets further dampened as it goes 19 downstream. It may be excessive static kicks in and 20 things like that. 21 Rubenstein and Merzenich in their paper posit or postulate or hypothesize that these are all 22 23 the different possible ways that something like this 24 can happen, and they don't necessarily focus just on 25 one.

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1636A

1	In fact, in their paper there is a focus on
2	the GABA production. Actually not yet, but the GABA
3	effect as it comes to certain areas of the brain, that
4	there may be decreased GABA in certain areas of the
5	brain. That's about as far as they go.
6	Q All right. Doctor, just to be clear, the
7	Rubenstein article actually discusses all eight of
8	these different possible mechanisms?
9	A It discusses all eight and does not
10	necessarily state that this is definitively the one.
11	Q All right. Did the authors draw any
12	conclusions or state any conclusions in the article?
13	A The authors were very careful. The authors
14	were very careful in their paper.
15	This is Slide 21, and now we're going to
16	something on page 263 of their article. The authors
17	basically make several statements. One is, "In
18	summary, increasing the ratio of excitation/inhibition
19	in key neurosystems, either genetically or
20	epigenetically, is postulated to be the common
21	pathway."
22	In other words, they're postulating it.
23	They don't have any definitive proof. They're
24	presenting a model that they think might need further
25	investigation. The wording they use then is, "This
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1 hypothesis can be useful."

2 They're very careful. They temper their 3 words. They're cautious in terms of saying you can't 4 use this right now to say that this is definitely the explanation. You can't use this right now to say that 5 6 this is more probably than not the explanation. They say in fact in their last line, "While 7 8 the models postulated in this review are 9 theoretical...", so the models are postulated. They're theoretical. They need to be further 10 11 investigated. They need to be further proven before 12 you can even use this information in a clinically 13 meaningful manner. 14 0 Doctor, are you aware of anyone who is 15 currently doing research in an attempt to prove Dr. 16 Kinsbourne's hypothetical mechanism? 17 The specific model that Dr. Kinsbourne Α 18 hypothesized, I'm not aware of anyone doing research. 19 MR. JOHNSON: Special Master, I'm about to 20 move into my questions dealing with Michelle Cedillo. 21 This would be the portion where we would 22 review some of the videotape, so I don't know if this 23 would be an appropriate time to take a break? 24 SPECIAL MASTER HASTINGS: All right. Before we do that, I want to clarify something in the copy of 25 Heritage Reporting Corporation

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1638A WIZNITZER - DIRECT 1 the slide presentation. What was the last slide you 2 had up there? 3 MR. JOHNSON: I believe it was No. 24. 4 SPECIAL MASTER HASTINGS: Can you put it 5 back up? б All right. Can you go back to Slide 4? And 7 go back to No. 3? I just want to make sure I didn't 8 get the numbering of the first few wrong. And No. 2? 9 And No. 1? Okay. Slide 1 was the title page. All right. 10 11 Also, are you aware where in the record is 12 the Rubenstein and Merzenich article? Is it in the 13 record? 14 MR. JOHNSON: Actually, Special Master, I'm 15 told it's 61-CCCC. 16 SPECIAL MASTER HASTINGS: Okay. Thank you. 17 Also, the other thing I wanted to do is that 18 we mark the exhibit containing the copies of Dr. 19 Wiznitzer's slides as Respondent's Exhibit 11. 20 Respondent's Trial Exhibit No. 11. 21 Will you be going back there? Now, in my 22 copy here there were some additional ones beyond 24. 23 Will you be going back to those? 24 MR. JOHNSON: Yes. There are some notations 25 related to the slides.

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## WIZNITZER - DIRECT

1	SPECIAL MASTER HASTINGS: Okay. All right.
2	Why don't we take our break at this point. Let's take
3	a 15 minute break. I have about 10:50, so we'll come
4	back at 11:05.
5	(Whereupon, a short recess was taken.)
6	SPECIAL MASTER HASTINGS: For those
7	listening at home, we are back from our morning break,
8	and we are going to be continuing with the testimony
9	of Dr. Wiznitzer, Mr. Johnson examining for the
10	Respondent. I want to note that, as we have on
11	several occasions during the trial, we are going to be
12	playing some videos from the families, videos of
13	Michelle as an infant.
14	What you are going to be hearing during that
15	time is you'll be hearing audio coming from the home
16	videos, voices, those voices will be coming from the
17	home videos and they will be playing videos here and
18	stopping and then you will be hearing the Respondent's
19	counsel and Dr. Wiznitzer comment on each of those
20	videos before they go to the next one. So we are
21	sorry you can't watch along with us, but at least you
22	maybe get a vague idea of what's going on.
23	So with that, Mr. Johnson, please go ahead.
24	MR. JOHNSON: Thank you, sir.
25	//

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1 BY MR. JOHNSON: 2 Dr. Wiznitzer, we are going to turn now to 0 3 the opinions that you have given in this case regarding the causation issues as they relate directly 4 to Michelle Cedillo, and I believe that you testified 5 earlier that in your opinion, Michelle Cedillo's 6 December 20, 1995, MMR vaccination did not cause her 7 8 to develop autism, is that correct? 9 Α That's correct. 10 0 What are you basing that opinion on? 11 I'm basing that opinion on my review of the Δ 12 medical records, on the videotapes that I was able to 13 watch, and on my clinical experience, expertise and 14 knowledge. 15 Q And we are going to show you your slide 16 number 25, and again, are these just the diagnostic 17 criteria that we discussed earlier? 18 Yes, they are, and if I may? Α 19 0 Certainly. 20 Α The purpose of this slide is basically to 21 point out areas of core deficits that we will see in 22 kids with autistic disorder. We have problems with 23 socialization, problems with communication, 24 specifically social communication, which is more use of language, problems with play as well as restricted 25 Heritage Reporting Corporation

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interest and repetitive behaviors, onset prior to age
 36 months.

3 An important qualifier here, as I had stated 4 before in the presentation I made, is that the features within each of these criteria are not 5 6 necessarily at the same level of severity at different 7 ages. And it's important to remember this, because 8 the early phenotype, or the early features, of an 9 autistic disorder, especially when you are looking at individuals in the first year of life, in the first 15 10 11 months of life, are not necessarily at the same level 12 of severity that you will see as the children 13 progress.

14 In other words, they are almost never at the 15 same level of severity as what we would see in 16 children who are two years old, two and a half years 17 old. And it's important to remember it's not 18 necessarily the severity, but whether this dysfunction 19 is present. And then basically, there is a natural 20 history of how things evolve, which I will address to 21 some degree later.

22 Q And looking at your next slide, number 26, 23 what are some of the most important features and 24 factors that you look for?

25 A The features that I look for are

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1 differences. Notice I didn't say 'deficits,' because 2 it's not true. It's not like you are missing the 3 behavior; it's that there is a difference in the behavior. It could be mild, it could be severe. The 4 5 differences in the behavior early on, in terms of 6 joint attention, that ability to do interaction with 7 other individuals, but the interaction is not just 8 responding to an individual, but more importantly, 9 initiating that kind of a contact with them revolving around a certain theme or an idea. 10 11 Number two is shared affect, which is really 12 more of an emotional give and take and an emotional 13 reciprocity that is present, again, not solely just 14 responding to what people are doing to you, which is 15 the easier thing to do, but being able to scale it up 16 and give it out in a consistent and repetitive manner. 17 Number three is the development of 18 communicative abilities. Obviously, in little 19 children, when we are looking at communicative 20 ability, we look at -- not only do we look at what 21 sounds they are making, whether they are making vowel 22 sounds when they are young in infancy, whether they 23 are babbling when they are in the later portion of 24 infancy, and whether they are using words when they are in the second year of life, but also what they are 25

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1 doing with it and how much they are doing with it. 2 So if I have a child who is saying words but 3 they are only imitative in nature, that's not 4 functional language. If I have a child who does vocalize, but the vocalization that is present is 5 6 minimal, it's not as much as I would expect, in other 7 words, the quantity is not as much as I would expect, 8 that's something that raises questions in my mind 9 about what's going on. If I have a child who does vocalize but 10 11 doesn't use the vocalization in a give-take fashion 12 the way I would normally expect, and an example I can 13 give the Court would be, if I take the average 10 to 14 12-month old who comes into my office, I can have a 15 complete conversation with that baby. If I babble to 16 the baby, the baby babbles back at me. We can keep 17 going for 5 minutes, 10 minutes, and then when I stop, 18 the baby looks at me and keeps going again, wants to 19 keep going because it's fun. So there, it's not only 20 what's being done, but it's also the quantity and how 21 it's being used. 22 And then lastly, the things that we look for 23 for early features of autism are, do we see some 24 evidence of some of the repetitive behaviors, some of the mannerisms, some of the restricted interests that 25 Heritage Reporting Corporation (202) 628-4888

1 might be present in these children? And one of the 2 ways that I will do this is, if I can't get a clear-3 cut history of what's going on, is I ask parents for 4 videotapes. 5 And I review videotapes on a regular basis 6 to look for some of these early features, realizing 7 that these early features may not be as flagrant as 8 the autistic features that we will see at age 2 or 3 years, but they will be different than what we would 9 normally expect for the behavior of an infant or a 10 11 young child in the second year of life. 12 You mentioned the review of videotapes. Is 0 13 that something that you commonly do in your practice? 14 А Yes, I do. If I may explain, when I do 15 videotapes, I do videotapes for a variety of reasons. 16 I love the technology. It's wonderful that it's been 17 done. Number one is, when there are questions about 18 time of onset, and parents basically will have 19 concerns whether things were or were not there, or 20 they may give you history on really close questioning 21 that suggests that there may have been features 22 present prior to the times that they thought the 23 features were there. 24 Number two is, when a child comes to my office and the parents relate a history and I can't 25 Heritage Reporting Corporation

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1 get enough behavior in my office or good enough 2 portions from the history, I'll ask for videos in the 3 contemporaneous world. In other words, get me a 4 videotape from the preschool, because it's easier for 5 you getting a tape than for my traveling, necessarily, 6 to the preschool, although I've done that on occasion 7 also. Number three is, when there's challenging 8 9 behaviors or there's something different that's going 10 on in the children, I many times will ask the parents 11 to tape it for me so that I can see exactly what they 12 are talking about and get a better understanding. 13 Have you had an opportunity to review the 0 14 videos provided by Petitioners of Michelle Cedillo

15 during her early childhood years?

16 A Yes, I have.

17 Q Did you review all of the videos provided by18 the Cedillos?

19 A The entire video collection that was given 20 to me, which starts at the baptism and ends, I can't 21 remember if it was her birthday or with her screaming 22 and yelling in the hallway.

Q And based on your review of the videos and other materials that you have reviewed in connection with this case, do you agree that Michelle suffers

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1 from ASD? 2 Yes, I do agree. Α 3 Q And within the spectrum, where, in your opinion, does Michelle fall? 4 Michelle Cedillo has autistic disorder. A 5 Α 6 combination of the historical information and the medical records, and the behaviors that she manifests 7 8 on the videotape here are consistent with that 9 diagnosis. Doctor, on a number of the videotapes, there 10 0 11 are family events and things of that nature and they 12 are obviously very personal moments. Based on your 13 review of those, what was your impression of 14 Michelle's parents and caregivers? 15 Α I think that her parents and caregivers have 16 done an excellent job. There is clearly a love and affection that is there, a desire for the best for 17 18 Michelle Cedillo. They have basically done what 19 parents are supposed to be doing, which is a credit to 20 them. 21 From reviewing these videos, do you have an 0 22 opinion as to when Michelle began exhibiting signs of 23 autism? 24 Yes, I do. Α And in your opinion, when did those signs 25 0 Heritage Reporting Corporation (202) 628-4888

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1 begin to become evident? 2 Α Those signs became evident in the first year of life. 3 Given that opinion, is it your opinion that 4 0 Michelle experienced autistic regression? 5 6 Α No, it is not my opinion that she 7 experienced autistic regression. 8 Q And why is that? 9 Α Autistic regression occurs in children who 10 basically had totally normal development prior to the 11 onset of the autistic features. In the videotapes, 12 and -- it's not really only the videotapes. It's from 13 the videotapes and in some of the historical information in the records, we have evidence of 14 15 preexisting impairment in the areas that I have 16 already defined for the Court. Therefore, by 17 definition, it's not considered to be a regression. 18 Probably, the better wording that we may use 19 is that there was a relative stagnation of 20 development. In the old days, people would say that 21 the kids either slowly developed, the kid either was 22 normal and then regressed, but now we know there's a 23 group of children who basically show development of 24 some impairments in development and then they seem to stagnate sometime in the second or third year of life 25

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and don't show as good development as a typical child 1 2 with autism. It appears that she may fall into that 3 third group. Doctor, for children who, again, are showing 4 0 5 signs of autistic behaviors even at an early age, are 6 these behaviors exhibited constantly? 7 А No. At an early age, what you see is a 8 combination of overtly what would look like adequate 9 child behaviors, although if you analyze them very 10 carefully, many times you find they are not, as well 11 as some overt features suggesting that it's clearly an 12 early feature of autism. 13 Let's take a look at the first video clip 0 14 that you are going to be discussing today, and looking 15 at slide number 27, which identifies the clip. This 16 is a video dated December 17, 1995. 17 Let me just lay the foundation here. Α 18 For the record, what are you looking at 0 19 right now? 20 Α These, I basically spent a long time 21 watching the videotape and I took notes on every 22 section of the videotape to basically define for 23 myself and to make sure that I kept a record of what 24 she was doing during those times, and what some of the features were that she was doing, and also just as a 25 Heritage Reporting Corporation (202) 628-4888

1	reminder of what was going on. And on the December
2	17, 1995, video, she's sitting in a ball bin with the
3	family outside this little ball bin container.
4	Q All right.
5	A And let me just point out, what we have to
б	watch in here is probably is several features. We
7	have to look for features of repetitive behavior.
8	Specifically here, we find evidence of a classic
9	behavior in this population which is known as hand
10	regard, where she looks at her hand in a fashion that
11	is not expected for a child of this age. So she
12	studies her hands for details, and that's what parents
13	will say to me it looks like. Whether that's actually
14	the reason they do it, I can't define why, but there's
15	hand regard that's present.
16	What you also find is that she responds to
17	prompts, not consistently, but responds to prompts,
18	but we don't see good initiation of prompts, and
19	there's a real impairment in the amount of verbal
20	communication that I would expect in a child of this
21	age, because at this point in time, we are talking
22	about a child who is 15, almost 16 months old.
23	(Whereupon, a video was played.)
24	THE WITNESS: May I comment while we are
25	playing it? Now, here we have her clearly responding,
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1650A WIZNITZER - DIRECT 1 then there's the hand regard, I mean, which is clearly 2 an abnormal behavior. 3 SPECIAL MASTER HASTINGS: Dr. Wiznitzer, why 4 don't we stop? 5 THE WITNESS: Okay, sorry, sir. 6 SPECIAL MASTER HASTINGS: I think to make it 7 easier for the reporter on here, why don't we play a 8 little bit and then have you comment on it? 9 THE WITNESS: Thank you. 10 SPECIAL MASTER HASTINGS: It will be easier, 11 I think, for us to hear. 12 (Whereupon, the video was continued.) 13 THE WITNESS: No, go back. That's not the 14 There we go. one. 15 (Whereupon, the video was continued.) 16 THE WITNESS: Let's freeze. Now, when you 17 watch the initial portion of this video, you see 18 several things. There is a response to interaction 19 from adults with some nonspecific vocalizations that 20 are being made. Just vocalizations, not necessarily 21 being said to people, but just nonspecific 22 vocalizations, but if you also watch her hands while 23 she is doing it, the first thing is we see the right 24 hand have a little movement, which is not something that we expect to see, but it is a mannerism that she 25 Heritage Reporting Corporation (202) 628-4888

1	actually shows later in the videos in the second and
2	third year of life where she actually shows a whole
3	rolling movement of the hands.
4	Then secondly, as we see right now on the
5	video, there is hand regard, which is clearly not a
6	behavior that we would normally expect from a child of
7	this age. Can we go on?
8	(Whereupon, the video was continued.)
9	THE WITNESS: Stop. And what we see in the
10	rest of this is, again, a response to stimuli in the
11	environment, but not necessarily any kind of an
12	initiation. There is a minimum amount of
13	vocalizations. We heard a little bit of vocalization
14	at the beginning, and when I played the videotape in
15	its entirety in the time period that was going on
16	before the MMR immunization was administered, what
17	struck me is the relative paucity of persistent
18	vocalizations, the amount of vocalization that I would
19	normally expect for a child as we are capturing the
20	child in these kinds of time periods.
21	It's not to say there's not sounds that are
22	made, but the quantity is clearly diminished from what
23	we would normally expect, and even how it's being
24	used. For instance, in this videotape, we didn't
25	really hear a good give and take of vocalization back
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1 and forth. We just heard a little bit of an utterance 2 and that was it. 3 Now can we go to the second? (Whereupon, the video was continued.) 4 THE WITNESS: Now can we just stop for a 5 б sec, and go back to my slide? This is a slide when 7 she was 9 months old, if I'm doing the math correctly. SPECIAL MASTER HASTINGS: Slide number 28. 8 9 THE WITNESS: And this is slide 28, and what we are looking for on this portion of the slide is two 10 11 things when it comes to social contact, which is 12 portions of joint attention and shared affect. One is 13 a limited response to social contact. It takes more 14 from the parent in order to elicit something from her 15 than we would normally expect of a child this age. In 16 other words, to elicit an interaction. 17 And we really don't see a good initiation of 18 social contact. Here is the parent talking to the 19 child, but do we see the child going after the parent 20 in order to continue these kinds of activities or 21 skills, or is there a relative deficit in this type of 22 behavior? 23 Now can we play the video? 24 SPECIAL MASTER HASTINGS: Now, before you 25 play this --Heritage Reporting Corporation

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THE WITNESS: Yes, sir. SPECIAL MASTER HASTINGS: -- I want to comment on the record, I think on the first one, you did mention the date, which is December 17. For the second one, you haven't mentioned the date. She was 9 months old. It was on June 4, 1995. (Whereupon, the video was continued.) THE WITNESS: What we see here is, again, she's responding to someone around her, but she doesn't sustain the contact with the person. She

11 looks and she looks away. And when we look at her, 12 she shows a relative difference in terms of the amount 13 of animation that we would normally expect with the 14 kind of social contact that's occurring in this 15 environment.

16 May I continue playing?

1

2

3

4

5

6

7

8

9

10

17 (Whereupon, the video was continued.) 18 THE WITNESS: Stop. And what we saw there 19 was more of a continuation. The adult is speaking to 20 her. She is looking at the mirror and herself rather 21 than necessarily the adult who is looking at her, 22 although she does focus on the mirror, but we don't 23 see a lot of, at this point, a lot of -- as much 24 facial expression as I would like, and I really didn't hear much in terms of vocalization, in terms of 25

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### WIZNITZER - DIRECT

1	responding to the adults around here.
2	This is a later portion of time with this
3	play toy, some people call it a jungle gym or a play
4	equipment set, and if we can continue?
5	(Whereupon, the video was continued.)
б	THE WITNESS: And we can stop. What we see
7	here is really very good efforts by the family to try
8	to engage her in some sort of a social contact, but
9	here she is more interested in some object than she is
10	in the social contact. Usually with kids, it's the
11	other way around. They may briefly focus on the
12	contact, but they you know, humans are social
13	animals, and we see there's no good eye contact to
14	either of the adults around her. There's no real
15	vocalizations that we can hear. There's a relative
16	deficit in the social affect and in this joint
17	attention that we are talking about.
18	Can we continue?
19	(Whereupon, the video was continued.)
20	THE WITNESS: And we'll stop. Basically,
21	that's the end there. Now, this is not to say that at
22	other times you may elicit more behavior from her, but
23	again, it's not always the quantity of behavior; it's
24	the quality of the interaction that's there. And when
25	you watch her when she shows more interaction
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# WIZNITZER - DIRECT

1	with some people, does she really sustain the
2	interaction the way we suspect children to do it?
3	Does she play with things around her in a
4	way we expect her to do it? Does she share, does she
5	initiate in the way we expect her to do it? And even
б	in the later portions of this part of the video, you
7	don't see that behavior, which is why we are saying
8	that in autism, it's a qualitative difference. In
9	other words, it's qualitative dysfunction. Not
10	quantitative, but qualitative. There's a difference
11	here by how she's acting compared to the average
12	infant.
13	And my next slide? And this is slide
14	BY MR. JOHNSON:
15	Q 29.
16	A 29, from May 29, 1995. On May 29, 1995,
17	she's basically in a stroller with her family outside.
18	What we want to look at is not, does she look at
19	people or not, but again, the amount and the quality.
20	Is there a sustained interaction or is there just a
21	brief glimpse and then a look away? What you will see
22	here is that basically there is an impairment in terms
23	of the social interaction responsiveness.
24	There is a limitation in the amount of eye
25	contact that occurs compared to what we want, and
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1	there's efforts to get her to call her name. She does
2	respond to some degree, but it takes much more to get
3	her to respond than we would normally expect for a
4	child of this age, and to some degree there is an
5	inconsistency in the response.
б	Can we play?
7	(Whereupon, the video was continued.)
8	THE WITNESS: Stop. If you look at the very
9	beginning of this, it starts with some of the and I
10	forgot to put this in my notes it starts with some
11	of the repetitive behaviors that she manifests with
12	her hands opening and closing, her mouth open at the
13	very beginning. And now we can watch some of the
14	social behavior.
15	(Whereupon, the video was continued.)
16	THE WITNESS: Can we stop? Here is an adult
17	trying to engage her. She briefly looks and then
18	basically looks away despite the fact that the adult
19	is continuing to try to engage her. In children, we
20	normally expect them to keep making reasonable eye
21	contact during that time, and there's not much
22	expression on her face while that engagement is
23	occurring. Next?
24	(Whereupon, the video was continued.)
25	THE WITNESS: And stop for a second. And I
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1657A

1	think, while it's subtle here, and you probably might
2	have to play it back to yourselves later on, when you
3	watch her right hand, she has a repetitive behavior
4	with a writhing movement of the right hand, which is
5	much more apparent when you look at the videos of
б	Michelle in the second and third year of life after
7	if the family said pre-MMR, after MMR that
8	basically that behavior was there before.
9	In other words, the mannerism and movement
10	was there before. We just saw a maturation of it as
11	it went into the later years. Next?
12	(Whereupon, the video was continued.)
13	THE WITNESS: And if I can stop? We have
14	several adults trying to socially engage her here, and
15	it takes quite an effort before we actually see her
16	responding, which means that the threshold for her is
17	elevated in comparison to what we would normally
18	expect, especially with what I assume to be familiar
19	individuals who are approaching her. Can we keep
20	going?
21	(Whereupon, the video was continued.)
22	THE WITNESS: Stop. And now what we have
23	here is, she briefly engages and then breaks it, while
24	we would expect for most children, if you are engaging
25	them, they would want to continue the engagement
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1	because, again, individuals are social animals. Next
2	slide? Here we have two videotapes from May 25, 1995,
3	and August 4, 1995, that basically are features
4	showing the presence of repetitive behaviors, what was
5	identified for us later on as her fascination or
б	fixation on Sesame Street, being apparent in the first
7	year of life, and also, a behavior showing a greater
8	response to television compared to people.
9	In other words, she was more fixated on her
10	area of interest or fascination than she was in
11	responding to these social overtures of adults in the
12	environment. And if I may?
13	(Whereupon, the video was continued.)
14	THE WITNESS: And if I may stop? I mean,
14 15	THE WITNESS: And if I may stop? I mean, this started with some excessive stiffening and
15	this started with some excessive stiffening and
15 16	this started with some excessive stiffening and movement of the legs, which, if you look at videos
15 16 17	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she
15 16 17 18	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she stiffens and extends her legs. And again, the parent
15 16 17 18 19	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she stiffens and extends her legs. And again, the parent is making a lot of effort to lead to some social
15 16 17 18 19 20	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she stiffens and extends her legs. And again, the parent is making a lot of effort to lead to some social engagement here.
15 16 17 18 19 20 21	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she stiffens and extends her legs. And again, the parent is making a lot of effort to lead to some social engagement here. She makes a brief look, she may smile, and
15 16 17 18 19 20 21 22	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she stiffens and extends her legs. And again, the parent is making a lot of effort to lead to some social engagement here. She makes a brief look, she may smile, and then she goes back to not really showing much
15 16 17 18 19 20 21 22 23	this started with some excessive stiffening and movement of the legs, which, if you look at videos afterwards, she shows similar behaviors where she stiffens and extends her legs. And again, the parent is making a lot of effort to lead to some social engagement here. She makes a brief look, she may smile, and then she goes back to not really showing much engagement, but if we watch here in the video, we are

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1	get things done, and doing this behavior on a regular
2	basis which is what we would expect. Keep going.
3	(Whereupon, the video was continued.)
4	THE WITNESS: And then stop here for a
5	second. What we see in the rest of this is the
6	limitation in social engagement. It takes people to
7	get her to respond, and even when she does, she
8	basically looks at them, but if you look at the
9	expression on her face, it's not the expression that
10	you would expect from typical, active social
11	interaction for a child this age. The parent is
12	trying to engage her in making vocalizations, but we
13	don't hear any response from her.
14	I mean, this quietness that we notice in
15	terms of vocalization permeates the initial portions
16	of the videotape. We saw little snippets of this last
17	week, the portions where she did vocalize, but the
18	vast majority, we don't really hear these kinds of
19	we don't hear good vocalizations as people were trying
20	to elicit it. Many children no, I would say most
21	children, if you tried to engage them here, they would
22	make sounds back at you because that's what people do.
23	May I show the next?
24	SPECIAL MASTER HASTINGS: Now, before we do,
25	let me just note for the record that what you were
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1	showing the last couple minutes was, that video had
2	the date of May 25, 1995, and with Michelle in a
3	stroller. I assume now you are going to move next to
4	the August 4?
5	THE WITNESS: Yes, sir.
6	SPECIAL MASTER HASTINGS: Is that correct?
7	Okay.
8	THE WITNESS: Yes, sir.
9	SPECIAL MASTER HASTINGS: Go ahead.
10	(Whereupon, the video was continued.)
11	THE WITNESS: Can I stop for a second here,
12	please? Let's set the scene. I think by telling with
13	the theme music here, we can readily recognize that
14	this is Sesame Street music, and she's sitting and
15	watching. My interpretation of this scene is that
16	she's sitting and watching Sesame Street. What we'll
17	be seeing here is some repetitive mannerisms,
18	basically almost getting totally engaged in the
19	television show, despite vocal comments that are
20	coming from adults in her environment. May we play
21	it?
22	(Whereupon, the video was continued.)
23	THE WITNESS: So what we have here, you can
24	see on the videotape that there was an adult that came
25	forward, makes a brief look, but clearly is much more
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1	interested in the television than in the adult that's
2	there. There's no real response or acknowledgment of
3	the adults present in terms of a social smile or
4	anything else. Basically, she goes back to watching
5	her show. My next slide?
б	The next one we are going to look at is June
7	4, 1995. This is slide 31, and here she is sitting
8	and doing some interactions with some Sesame Street
9	dolls, if I'm not mistaken, just with some toys.
10	There's impaired communication and vocalization,
11	there's limited joint attention and social
12	interaction, similar to the stuff I've mentioned
13	before.
14	(Whereupon, the video was continued.)
15	THE WITNESS: I'm sorry, this is later.
16	Let's stop here. This is later in the scene. May I
17	stop? In the early part, she was playing with toys,
18	sitting at a table. This is when she is, again, at
19	her play station, and if you watch her, she basically
20	looks at the toys and not as much at the adults.
21	Brings a toy to her mouth, but you don't hear much in
22	terms of vocalizations, in terms of the social
23	reaction. Can we go on?
24	(Whereupon, the video was continued.)
25	THE WITNESS: And to me, this is
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1	representative of the majority of the tape when I
2	watched, because she really doesn't make noise
3	throughout the majority of the videotape. As I said,
4	we saw little small snippets when she did vocalize,
5	but those, again, it's a quantity and quality issue.
6	The quantity is diminished, and the quality of the
7	vocalizations and how they are used is not what we
8	would expect for a child of this age.
9	My next slide? This is her at her birthday,
10	which is August 30, 1995, and she is being given
11	presents. What we need to watch for, what I would
12	like people to look at is several factors. Number one
13	is her motor ability here, that she needs some support
14	to stand, and it seems to be that she is a bit low
15	toned in terms of how she stands.
16	But if you look at her and how she interacts
17	when people are really excited about giving her a
18	present and giving her things, there is not much of a
19	response to the people in the audience around her, and
20	unlike what I would normally expect for a child, what
21	I would normally expect for a child who is one year
22	old, who if you said to me, well, maybe they are not
23	that interested in the toy, I'd say fine.
24	We don't see her playing with the wrapping.
25	We don't see her playing with any kind of ribbons or
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### WIZNITZER - DIRECT

1	anything. She's not ripping things, which is a
2	behavior that I typically would expect to see in
3	children's behavior at their birthday party. They'll
4	play with something in that regard. And then I'll
5	comment about the last part later as we get closer to
б	it.
7	(Whereupon, the video was continued.)
8	THE WITNESS: May I stop here? Now, one of
9	the things we see is that she's not here, someone
10	has just given her a present. Not looking around the
11	room, look people, look what I've got here, share in
12	whatever I have, although she may not necessarily
13	understand what it is. She looks at the balloon
14	around her as a first choice, not necessarily at the
15	adults around her, and when you watch her putting her
16	hands on the present and lifting them up and putting
17	her hands on the present and lifting them up, it's
18	difficult to interpret whether that's just a regular
19	baby motion or whether there may be some tactile
20	hypersensitivity at this time.
21	SPECIAL MASTER HASTINGS: And before you
22	start again, I will just note for the record, this is

the same scene we saw played previously, and it's with 23 24 Michelle with a very large wrapped box in front of 25 her. Go ahead.

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1 (Whereupon, the video was continued.) 2 THE WITNESS: May I stop? Stop this tape 3 right here. And here we are at the scene where she 4 has this big box with a present. An adult has ripped the wrapping off, and a typical behavior in this 5 6 circumstance would be for the child to grab the 7 wrapping, pull at it, pull at the corners, do things 8 even though the child may not understand the concept 9 of unwrapping, but just to play with the paper, because this is what children do. They sit around and 10 11 they explore their environment in this manner. 12 Instead, we see her to be almost hesitant in 13 terms of putting her hands on the wrapping, and 14 turning away, and again showing, at least in this 15 portion -- we don't see this behavior occurring every 16 single time, but in this portion, there's a relative 17 decrease in the shared affect, in the interest in the 18 interaction with other people in the environment. 19 Keep on going. 20 (Whereupon, the video was continued.) 21 THE WITNESS: May I stop, please? What we 22 had just happen here is there's adults around her 23 singing happy birthday. In these circumstances, I can 24 expect the child to look at the adults around them, smile, perhaps get a little bit quiet and not do much, 25 Heritage Reporting Corporation

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1	but here it's more of the same behavior in that she
2	doesn't seem to acknowledge the other people around
3	her. She takes a brief look at the adults, at one of
4	the adults in the room and then goes back to looking
5	down at the box but not really doing much in terms of
6	interacting with individuals in the room.
7	(Whereupon, the video was continued.)
8	THE WITNESS: And now is there more?
9	Yes, you're going to show me the this is the other
10	segment from the birthday after the present has been
11	unwrapped.
12	(Whereupon, the video was continued.)
13	THE WITNESS: And let's just stop here.
14	Just to set the scene for everybody, Michelle Cedillo
15	has just been put on a riding horse that she has been
16	given for the first birthday. A behavior that we
17	would typically expect from a child is exactly what we
18	were hearing from an adult's saying in the room. We'd
19	see some giddyup behavior, some bouncing, some rocking
20	back and forth, some appropriate use of the toy.
21	And I think what we are going to see here is
22	really more of the pulling away in terms of shared
23	affect of the lack of relative acknowledgment of
24	what's happening in her environment, if we can play
25	this.

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1 (Whereupon, the video was continued.) 2 THE WITNESS: And if I may stop, while we 3 heard in the vocalization that she's riding her little pony, which you can say just by watching is true, I 4 think we would also notice that there is an adult who 5 6 is really quiding her and pulling her along in order 7 to encourage the motor movement that she is doing. 8 It's not a spontaneous action by the child. It's 9 really an adult-initiated and sustained action. So 10 it's not really the child's play. 11 (Whereupon, the video was continued.) 12 THE WITNESS: Let me stop. What we see here 13 is that Michelle Cedillo, having been on the riding 14 pony but not really doing any real play with it, has 15 been taken off the riding pony, has been put on the 16 floor, again, making -- it's not as if she's not 17 making eye contact. She makes brief eye contact. You 18 can see this. She takes brief looks at people around 19 her, but doesn't do it in a sustained fashion, in a 20 sharing fashion, 'look what I have,' which is the kind 21 of behavior I would normally expect from a child. 22 Now what's coming up is one of the 23 diagnostic criteria, what we talk about, more interest 24 in the parts than in the whole, where when you watch her, she's more interested in watching the wheels of 25 Heritage Reporting Corporation

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1 this toy, whether it's because of the sound they make, 2 because of the revolution they make, than necessarily playing with the toy in a more appropriate fashion. 3 4 If you can play it, please? 5 (Whereupon, the video was continued.) 6 THE WITNESS: May we stop? You can see her 7 eyes are focused on -- here it's on the back wheel. 8 Before it might have been briefly on the front wheel, 9 but clearly looking down and towards the wheel. You 10 can play it. 11 (Whereupon, the video was continued.) 12 BY MR. JOHNSON: 13 I believe that's the last of the video 0 14 clips. Dr. Wiznitzer, did you consult with or speak 15 with any of the other experts testifying in this case 16 before you reviewed the videos? 17 Α No, I did not. 18 In your practice --0 19 And may I also answer, I did not consult Α 20 with or speak with any of the experts before I 21 formulated my opinion as to what the video showed. 22 In your practice, is it common for parents 0 23 to not necessarily notice subtle signs of abnormal 24 behaviors that may appear early on? 25 Yes, it is. That's the importance of taking А Heritage Reporting Corporation (202) 628-4888

1	a good, detailed clinical history, which is what we
2	always try to do in the office regarding the children.
3	If I may? When we look at some of the details, in
4	other words, people always come in and say to me, my
5	child had five words and lost them. But what's
6	important to me is not, did my child have five words,
7	but what were the words, how were they being used?
8	Parents frequently will come to me and say,
9	everything was okay. They had five words and they
10	lost them. But when you take the detailed history,
11	you find out that the words were predominantly
12	imitative in nature, in other words, just repeating
13	what was being said to them, or it was almost like a
14	learned, taught behavior such as labeling. You open a
15	book, parent says 'ball,' the child says 'ball.' But
16	the words are not used in a good, functional manner to
17	get needs met, to do shared information with other
18	people around them, to display, point something out to
19	an adult, some information you want to share, get your
20	needs met.
21	That is not really language. That's just
22	more like miming or mimicking and nothing more than

24 themselves and don't persist because the child does 25 not understand what those words represent.

that, and those kinds of words don't sustain

23

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Words are supposed to represent to us, words stand for an internal representation in our body of something. And if we're talking about a child's word, it may be concrete items, that I have a word that when that item is not in the environment, I can use that word to represent that item and to get something about that item.

What happens when families give me histories 8 9 where they tell me the words are used in imitation, 10 that's not a representation. That's just basically 11 repeating what everyone's saying. The mental image 12 doesn't get fixed in memory, and therefore, in the 13 second year of life, the parents give me this history 14 that they lose these words. They lose these 15 utterances would be a better way of saying it because 16 the import of those utterances was never really 17 consolidated or established.

18 In the same way parents may come in and say 19 to me that my child was playing well, they're 20 socializing well when younger when the first year of 21 life, around the first birthday, whatever, but when you ask more detailed questions, you find out 22 23 information that's not there. Many times in my 24 clinical experience, it's been first time parents because you just don't have anyone else to compare 25

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1 them.

2 The parents come in of children that I've 3 taken care of, let's say they're first time parents, the child about whom I've consulted was the firstborn. 4 As I'm following the child clinically over time and a 5 6 sibling is born, frequently I will say to the parent 7 because the sibling is brought to the office with them 8 now that you've had a chance to compare the behavior 9 what do you think?

The parents say, you know, Dr. Wiznitzer, in 10 11 retrospect there were subtle features in the first 12 year of life that now that I can appreciate, but I 13 couldn't appreciate because I didn't have in front of 14 me a regular model to which to refer. Therefore, 15 that's why many times when people are arguing the 16 point of regression it's really a misnomer, the 17 wording is incorrect.

18 What it really is is the failure to 19 recognize these subtleties because parents are great 20 developmental specialists, but they're not necessarily 21 at the level. They're at a level for their children, 22 but not at the general level for knowing all the facts 23 that we know when we deal with autism on a regular 24 basis in the clinical fashion.

25 Q If parents don't notice early signs does Heritage Reporting Corporation (202) 628-4888

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1	that mean that they've done something wrong?
2	A No. No. In fact, I would tell you that
3	especially with firstborns, many times the parents
4	don't notice it and only later recognize. They've
5	done nothing wrong. They're just being the best
б	parent that they can be, which is all that we ever ask
7	from parents.
8	Q Dr. Wiznitzer, just to wrap up when did you
9	first become involved in this case?
10	A I got involved in this case in 2001.
11	Q Did you prepare a report at that time?
12	A Yes, I did.
13	Q What did you conclude in your initial
14	report?
15	A Well, I identified in the initial report
16	some of the features that we've talked about today.
17	For instance, I identified issues such as late
18	smiling, smiling at four to six months, she was
19	described as a good baby who cried little, that she
20	had words that were said mostly in imitation.
21	These are facts that I identified, and then
22	I concluded after reviewing all the historical
23	information that was available to me at that time that
24	there was no evidence in the medical records of the
25	presence of an acute encephalopathy as defined by the
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1	vaccine injury table, there was no evidence of
2	anaphylaxis as defined by the vaccine injury table and
3	that the argument that was made about causation in
4	fact, that somehow immunization caused the autism, in
5	this case the argument is the MMR immunization, was
б	not supported by the scientific literature.
7	Q And has your opinion changed since the time
8	you prepared your initial report?
9	A No, it has not.
10	MR. JOHNSON: Thank you. I have no further
11	questions.
12	SPECIAL MASTER HASTINGS: Thank you. It's
13	noon now. Should we begin the cross or do you want to
14	take a
15	MR. POWERS: Special Master, I'll be doing
16	the cross-examination today, and I think it will go
17	long enough that we ought to take lunch now, go
18	through the cross uninterrupted.
19	SPECIAL MASTER HASTINGS: All right. Why
20	don't we do that. It's now high noon, we'll start
21	again at 1:00 p.m.
22	(Whereupon, at 12:00 p.m., the hearing in
23	the above-entitled matter was recessed, to reconvene
24	this same day, June 19, 2007, at 1:00 p.m.)
25	//

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1673 1 AFTERNOON SESSION 2 (1:03 p.m.) SPECIAL MASTER HASTINGS: All right. We're 3 4 ready to go back on the record for the afternoon's activities. We will next proceed to the cross-5 examination of Dr. Wiznitzer, and Mr. Thomas Powers is 6 7 going to be cross-examining. 8 Go ahead, Mr. Powers. 9 MR. POWERS: Thank you, Special Master, and 10 good afternoon. CROSS-EXAMINATION 11 12 BY MR. POWERS: 13 Good afternoon, doctor. Q 14 Α Good afternoon, sir. Before I get into the nuts and bolts of my 15 0 16 questions I just want to make sure I understand the gist of your expert report. If I could boil it down 17 would it be fair to say that you disagree with Dr. 18 19 Kinsbourne's opinion in this case, and you have an alternative diagnosis to the one that the Petitioners 20 have offered about Michelle Cedillo's autism? Is that 21 22 a fair way to phrase your expert report? 23 Α No. 24 0 How would you phrase your expert report? Well, I don't understand what you mean by 25 Α Heritage Reporting Corporation (202) 628-4888

1674 WIZNITZER - CROSS 1 alternative diagnosis, sir. 2 Well, we'll explore that a little bit. Q Ιf 3 you disagree we'll explore that, and we'll move on to 4 other questions. Now, my understanding from your 5 direct testimony is you're not an immunologist, 6 correct? 7 Α Yes, sir. 8 Not a virologist? 0 9 А That's true. 10 0 Not a toxicologist? 11 Α True. 12 0 Not a gastroenterologist? 13 Α Correct. 14 Q Not a geneticist? 15 А Correct. 16 Q Not an epidemiologist? 17 Α Correct. 18 So your direct testimony and your expert 0 19 report is not offering any expert opinions or 20 conclusions in those areas of medical specialty, 21 correct? 22 It's not offering any opinions in those А 23 areas of medical specialty outside of the fact that 24 where these areas of specialty will impact on my 25 clinical neurology expertise.

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1	Q Understood. Now, you mentioned early on
2	that you've testified in Vaccine Court cases. You
3	remember that testimony?
4	A Yes, sir.
5	Q Have you also testified in civil litigations
6	involving issues like you see here today? We're
7	talking about outside the Vaccine Court program.
8	You've offered testimony in those cases, correct?
9	A I don't understand what you mean by issues
10	we see here today, sir.
11	Q Well, you did testify as an expert witness
12	in a case involving a child named Jordan Easter. It's
13	a case that was filed in Texas. Do you recall that?
14	A Would you please give me details, and I'd be
15	happy to answer, because that name does not ring a
16	bell right now, sir.
17	Q This was a case that was filed in U.S.
18	District Court in Texas. It involved a boy named
19	Jordan Easter. I guess you don't remember the child's
20	name, but it was a case that involved thimerosal
21	exposure through thimerosal containing vaccine and the
22	allegation was that thimerosal containing vaccines
23	contributed to the child's autism.
24	A Let me answer this for you, sir. I was
25	never involved in the case regarding the issue of
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1	thimerosal, issues of any kind with an individual
2	known as Jordan Easter. If you have documentation of
3	that to prove me wrong I'd be happy to look at it,
4	sir.
5	Q So you're saying that as you sit here today
б	you did not offer expert testimony in a U.S. District
7	Court case in the Eastern District of Texas in
8	Marshall, Texas, involving the Easter child?
9	A And this was a case involving thimerosal in?
10	Please fill me in.
11	Q I just did.
12	A In Rhogam? Is that what you said, sir?
13	Q No, I did not. No, I did not. We're going
14	to talk about Rhogam in a minute, but this is a case
15	involving thimerosal containing vaccines and a child's
16	autism.
17	A I don't remember that I was ever involved in
18	any kind of case of that type in Texas.
19	Q How many civil cases have you been involved
20	in as an expert witness involving vaccines?
21	A To my knowledge two.
22	Q Is one of them a Rhogam case that was heard
23	in North Carolina last year?
24	A Yes, sir.
25	Q And in that case you offered an expert
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1677 WIZNITZER - CROSS 1 report on behalf of the defendants in that case? 2 I wrote an expert report, sir. Yes. А 3 0 Your deposition was taken in that case. Is 4 that correct? 5 Α Yes, it was. 6 Q And you testified at a Daubert hearing in 7 front of the Judge, correct? 8 Yes, I did. А 9 Q What's the other case that you were involved 10 in? 11 This was another case in which I gave no Α 12 deposition, I wrote no report. 13 I didn't ask whether you wrote a report. To 0 14 make this easier I'm going to ask you a question, and 15 I'm going to ask you to answer it. I didn't ask what 16 you wrote or what you said. It's a simple question. 17 What was the case other than the Rhogam case? 18 А The other case was an allegation of seizure disorder after immunization. 19 20 0 And was that a case again outside the 21 vaccine program in the Courts? 22 А Yes. 23 0 And now I'll ask you what you wanted to 24 answer before. Did you prepare an expert report? 25 А No. Heritage Reporting Corporation

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1678 WIZNITZER - CROSS 1 Did you provide deposition testimony? 0 2 Α No. 3 Q Did you testify at a hearing? 4 Α No. 5 Q In the North Carolina Rhogam case you 6 testified at the Daubert hearing. Do you recall that? 7 А Yes, sir. 8 In that hearing you used a slide Q 9 presentation. Do you recall doing that? А 10 No. 11 Do you recall submitting a slide 0 12 presentation or Power Point presentation as an exhibit 13 to your deposition testimony or as an exhibit to your 14 Daubert hearing testimony? 15 Α I don't recall as we speak today whether I 16 did or didn't, sir. 17 0 So if somebody was to produce those slides 18 and point out that 18 of the slides in the exact order 19 that you used in that case were the same slides that 20 you used here, would that surprise you? 21 No, and may I explain? Α 22 Please do. 0 23 Α Thank you, sir. I basically choose those 24 slides from my clinical presentation slides, which 25 means the slides you saw today are the slides that I Heritage Reporting Corporation (202) 628-4888

1 use not for legal proceedings. I use them when I talk 2 to parent groups, when I speak to physicians, when I 3 speak to my trainees. These are my if you want to 4 call it part of my Autism 101 battery. 5 SPECIAL MASTER HASTINGS: Okay. Go ahead, 6 Mr. Powers. 7 BY MR. POWERS: 8 0 So, again, understanding that you've used 9 them in other settings, nonetheless, the 18 slides in the exact same order used in that Court were the ones 10 11 that you used here? 12 Α Yes. Well, sir, if you can show it to me I 13 would agree, but if you're representing to me that you 14 looked yourself and saw it I would never doubt that 15 you would misrepresent anything to me. 16 0 Right, and I was just asking if you 17 recollect, and if you don't know, you don't know. 18 Α I don't remember, sir. 19 That's a fair answer. Now, when did you 0 20 first begin to work on litigation, either in the Civil 21 Courts or here in the vaccine program involving 22 allegations that anything to do with vaccines is 23 associated with autism? 24 Sometime in the last seven to 10 years. Α Can you narrow it down any more precisely? 25 0 Heritage Reporting Corporation (202) 628-4888

1 So it could be as long as 10, but as recently as 2 seven? 3 А To my recollection, sir, yes. Do you have any idea of how many hours of 4 0 work you have put into specifically litigation 5 6 activities in these cases involving vaccines and 7 autism? 8 А No. 9 The work that you've been doing, has that Q 10 been work that's been paid by at least in part the 11 Department of Justice for the Vaccine Court 12 proceedings? 13 Yes. The payment is not by the Department Α 14 of Justice, sir, but we'll just say that the payment 15 is actually through HHS to be exact. 16 0 The client agency. I assume the Department 17 of Justice lawyers contact you and retain you for a 18 particular case for which you're paid out of DHHS. Is 19 that correct? 20 Α No. HHS usually contacts me, and talks to 21 me and asks if I have some time to do this. 22 So the client agency contacts you directly? Q 23 Α Yes, sir. 24 What do you charge per hour for your 0 litigation work in Vaccine Court cases? 25 Heritage Reporting Corporation

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1 I charge what the government's reimbursement Α 2 rate has been established, which to my recollection at 3 the present time is \$250 an hour. And the \$250 an hour, is that a rate that 4 0 remains the same whether it's reviewing the medical 5 6 literature, testifying live, generating a report? Is that the same rate for all of those activities? 7 Yes, sir, it is. 8 Α 9 Q Again, any sense of how many total hours 10 that you've put in just in the Vaccine Court 11 litigation work for which you've been compensated? 12 Α No. 13 Let's switch gears and talk about cases in 0 14 the civil system outside the Vaccine Court. You've 15 been retained by pharmaceutical companies to testify 16 for the defense in those cases that you've been 17 involved in. Is that correct? 18 No. I've been asked to review cases by Α 19 lawyers, and they may be representing pharmaceutical 20 companies, but it's the lawyers who contact me not the 21 pharmaceutical company. 22 So sort of a different dynamic. When you're 0 23 in the program it's the client agency so to speak, but 24 outside the program it's the attorneys that may be representing the client pharmaceutical company for 25 Heritage Reporting Corporation (202) 628-4888

1682A WIZNITZER - CROSS 1 example. Is that fair? 2 Α Yes. 3 0 What's the hourly rate that you charge for 4 the civil cases? Four hundred dollars an hour. 5 Α And, again, is that the same for document б Q 7 review, writing a report, testifying? Do you have a 8 different rate for different activities? 9 Α No, sir. For trial testimony it's \$500 an hour. 10 11 Do you have a sense of how many total hours 0 12 that you've worked on vaccine litigations for the 13 pharmaceutical companies outside the program? 14 А Not much. That's what I can tell you. Not 15 many hours. 16 0 How much is not much? 17 I can't give you a number. I can just tell Α 18 you it's not a lot because I haven't done much in that 19 area. Therefore, the number can't be a lot. 20 0 The number of hours or dollars. Can you 21 describe how many dollars, if not, hours? 22 No, I can't do that, sir. Α 23 Q Either in the program or outside the program 24 you've never offered expert testimony in support of a plaintiff or a petitioner, have you? 25 Heritage Reporting Corporation

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1	A I have, sir. I don't understand why you
2	would say that otherwise.
3	Q Have you offered expert testimony in support
4	of plaintiffs or petitioners in autism cases?
5	A That's a different spin. No, I have not.
6	Q Now, your expert report here is dated
7	April 19, 2007. Is that right?
8	A Yes, sir.
9	Q And as of April 19, 2007, at that point from
10	reading the report I can't quite tell, have you
11	already seen the videotapes that you were discussing
12	today? I'll direct you to page 4. It's the final
13	page of your report, and it's the large paragraph
14	there sort of in the middle of the text.
15	At the very end of that paragraph you say in
16	the last sentence, review of these home videos in
17	total and with no editing would be useful to better
18	define the nature of her assuming Michelle of
19	Michelle's functioning in the first year of life.
20	From that sentence I just couldn't tell. Had you
21	already reviewed the home videos that you were
22	discussing today?
23	A Number one, I hadn't reviewed the home
24	videos, and number two, it's obvious from the sentence
25	here that the sentence tells that I would want to
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1684 WIZNITZER - CROSS 1 review the videos. That's what the sentence is 2 saying, sir. 3 Q Right. Well, I know what the sentence says. 4 That's why I was just asking had you reviewed --If I had already reviewed them I would not 5 А 6 have written that, sir. 7 0 Just let me finish my sentence. 8 Α Okay. 9 SPECIAL MASTER HASTINGS: Please, Doctor 10 Wiznitzer. 11 THE WITNESS: Okay, sir. 12 SPECIAL MASTER HASTINGS: We'll get through 13 this better if you just answer the question. You 14 don't need to elaborate, just answer it as concisely 15 as you can. 16 BY MR. POWERS: 17 Yes, because I just want to be very specific 0 18 because you add a parenthetical, in total and with no 19 editing. So my first question, because there are two 20 questions, the first is at the point that you wrote 21 this report is it fair to say you had not reviewed the 22 home videos in total and with no editing? Is that a 23 fair statement? 24 Α Yes, it is. Second question is had you reviewed these 25 0 Heritage Reporting Corporation (202) 628-4888

1 home videos in any edited form, that is in any form 2 that wasn't in total? 3 Δ When would that have been, sir? Well, all of my questions are just from the 4 0 date of this report, which is April 9. 5 6 Α The answer is I had not reviewed any home 7 videos of any type at that point in time. 8 Q Okay. We can pull that down. That was the 9 only question I had right now about your report. I want to talk a little bit about your medical practice 10 11 and your clinical practice. Can you describe for me 12 what sort of work up you do when a child who is 13 presenting with a possibility of an autism spectrum 14 disorder comes into your office? 15 What's the diagnostic procedure or the work 16 up procedure? I don't know what terminology you use, 17 but I'm using it as a layperson and I just want to 18 have you tell me what you do to examine these children 19 and make a diagnosis. 20 0 When a child comes into my office with a 21 question of an autistic spectrum disorder they come 22 into my office first of all usually with a 23 questionnaire that's already been completed by the 24 parents, which my office gives them, and also frequently they come with the appropriate medical 25 Heritage Reporting Corporation (202) 628-4888

1 records that are available.

2	We ask for the pediatric records if the
3	families can get them provided to us. We also ask for
4	any pertinent records in terms of therapy, evaluation,
5	early intervention programs and the such. So the
б	first step is basically to gather that information.
7	The second thing I do is I basically take a history.
8	I review the questionnaire that the parents
9	have provided, I sit down with the parents, I ask them
10	what their chief complaint is, I take a thorough
11	history asking questions about things all the time
12	from birth up to the point in time in terms of their
13	developmental milestones, I go through a review of
14	systems in terms of other areas that may be impacted
15	in the child's developmental issues, I identify any
16	pertinent points from past medical history, I ask
17	questions, our questionnaire automatically asks
18	questions about immunization just to let you know
19	that, I ask questions about family history, social
20	history, go through other details that might be
21	important that the family has brought up or that I
22	think should be addressed, we do a physical exam in
23	terms of a regular physical examination as well as a
24	neurologic examination.

25	Q	Let me ask just a quick question. If you
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1 could elaborate on neurological examination? What 2 typically would be included in a neurological 3 examination? Neurological examination includes, and not 4 Α 5 in any particular order, measuring head circumference, 6 we also usually get height, weight, blood pressure and 7 heart rate, which are measured beforehand, we check 8 cranial nerve function, we check motor function, which 9 includes tone and strength, we look at sensory 10 activity as best as can be assessed in a child of that 11 age, you look at coordination, balance, the presence 12 or absence of tremor, any extrapyramidal movements, 13 you look at reflexes. 14 What I do in that circumstance always is I 15 watch the child. I look at the child's level of 16 functioning. I basically may do some quick 17 investigatory testing to get a general idea of the 18 child's level of functioning. I look at how well the 19 child can engage with me, and if the child does not 20 engage with me why the child doesn't. 21 I listen to language, I get a sample of 22 play. 23 0 And let me interrupt you again on play. 24 When you say get a sample of play, are there particular methods that you use to evoke the samples 25 Heritage Reporting Corporation (202) 628-4888

1 of play that you think are useful to making an 2 accurate diagnosis? 3 Α There are no specific ways in which we do that. It all depends on the individual. For 4 instance, if I have a 20 year old in the office I'm 5 6 not going to do much in that regard -- you're asking, 7 that's why I'm answering -- but if I have a small 8 child, throw some blocks on the floor. It's not the 9 idea of the play, it's more of the engagement of the 10 individual as we sit and play. 11 We may sit, we may scribble, we may draw. 12 Basically, that's in a nutshell what we'll do in the 13 office. 14 0 Okay. Now Dr. Fombonne testified -- well, 15 actually, before I talk about that, anything else that 16 you do? I mean, you've described a long list of 17 things here. What else would you typically do in 18 order to offer a diagnosis? 19 This is a two part answer to your question. Α 20 If in the office setting the history and the features 21 in the office are quite clear that the child has 22 dysfunction within the autistic spectrum I can 23 basically voice an opinion at that point in time, and 24 as a clinician who is experienced in evaluating these children you basically can pick up or I can pick up 25

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1 the features that are not present in order to come to 2 that conclusion.

3 There are some children, maybe they're too young or they're a little bit older but there are some 4 vagaries in terms of the information that I have at 5 6 the end of my office visit, where I will ask for input 7 from other individuals, from teachers, from 8 therapists. As I stated before I may ask for a 9 videotape, and I may actually get a bit of a longer 10 sample of watching the child in action before I come 11 down with a conclusion.

12 Q And when you say a longer sample of watching 13 the child in action that's you personally observing 14 the child?

15 Α That would be me, and it also may be that I 16 don't make a determination at that office visit. I 17 may actually wait three or six months, follow the 18 child and see how the child is doing. Of course, 19 during that three to six month time period, especially 20 if the child has any developmental issues, we just 21 don't sit back and just wait and do nothing. I refer 22 them.

23 Usually when this comes up we're talking 24 about children who are very young. I refer them 25 either to an early intervention program in our county Heritage Reporting Corporation

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1 or I refer them if they're three and over to their 2 school system for further evaluation and integration 3 into an appropriate special education program. Right. And you mentioned a couple of times 4 0 5 age making a difference. Just now you said very 6 young, a moment ago you said sometimes they're too 7 young to offer a diagnosis. What age are you looking 8 at? Is it sort of preschool, is it before three, that 9 you're describing when you say sometimes they are too 10 young to enable you to offer a diagnosis at that point 11 from the initial visit? 12 Α I have kids who come in perhaps at age 18 13 months where there's a question about their 14 development, and about what they're doing and we're 15 not quite sure about exactly where they're going. 16 There are no clear cut features such as in this case 17 where we have clear cut features existing beforehand 18 in the first year of life that easily will give me the 19 information that I needed. 20 But when I don't have any kind of 21 information like that rather than applying a label, which is not necessarily in the family's best interest 22 23 that you say a specific label but you've identified 24 that the child has developmental issues, we will defer an exact label, put the child in an intervention 25

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1 program and track the child over time in order to get 2 an answer. 3 0 I'm assuming that as an experienced clinician what you're describing right here is the 4 standard of care that your office uses. Is that 5 6 correct? Standard of care that I use. 7 Α 8 0 It sounds pretty thorough going. I'm 9 assuming that some of it is for a reason you just 10 mentioned. The label can be very important to the 11 parents and to the child. Is that correct? 12 Α I don't understand your question. 13 Well, you used the word diagnostic label and 0 14 that you might be reluctant to offer a label too 15 young. I'm just asking is that because the diagnostic label has important ramifications for the child and 16 17 for the family? 18 А Yes and no. 19 In what ways yes? 0 20 Α In what ways yes is -- let me be clear about 21 this, in the state of Ohio, a label of an autistic 22 spectrum disorder actually qualifies you for access to 23 money that you can use to get yourself integrated or 24 put into various kinds of intervention programs. The state has an autism scholarship fund. 25

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I think they give you up to about \$16,000, \$20,000 that can be applied into any program that the parent chooses if they're not happy with what their school system will offer, so in that circumstance it's important.

6 However, no, because sometimes, and I've had 7 this happen to me with children who have come to me 8 for second or third opinions, that when labels are put 9 on children, for instance an autistic spectrum disorder is erroneously put on the child as a label, 10 11 it may stick and follow the child, and people may have 12 inappropriate views, and expectations and 13 interpretations of the child's functioning.

14 Therefore, I think we have to be cautious. 15 In those circumstances when I basically have a child 16 where there are developmental issues something as 17 simple as defining, basically detailing what the 18 developmental issues are, is much more important for 19 the child than saying this is problem A, B or C 20 because that's what they need in order to access the 21 early intervention services.

22 Q You mentioned taking a family and social 23 histories. One of the focuses of taking a family 24 history at least to look at possible heritability 25 issues in siblings and in family members. Basically,

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1 are you looking for anything in the history to suggest 2 a genetic component? 3 Α No. May I please explain my answer? 4 Because that's not a yes or no question in terms of what you're asking. I think you're misdefining 5 6 exactly why I take that history, and that's why -- may 7 I proceed? 8 0 You know, I hate being mystified, so if you 9 can educate me that would be great, but it was a 10 simple question just asking do you ask questions 11 designed to elicit information about the family's 12 genetic background relevant to autism? 13 If you phrase it in that way the answer is Α 14 yes. 15 What sort of questions? Q 16 I ask questions about other family members, Α 17 whether there's other family members who had the 18 diagnosis of autistic disorder or a dysfunction within 19 the autistic spectrum. If there's family members who 20 may have features of what's called the broader autism 21 phenotype, which means that you have maybe some individuals in the family who may have some language 22 23 issues, or some social issues, or some areas of 24 interest, or let's say an extreme hobbyist. 25 The example I always give is, you know, the Heritage Reporting Corporation (202) 628-4888

1	Uncle Ned that no one talks about. Those are the kind
2	of questions that I ask. I don't do this, though, to
3	answer your question to establish whether that child's
4	condition is clearly genetic or not. I do this just
5	to gather some information and get an idea of what's
б	going on in the family.
7	Q And then a follow-up to that. If those
8	questions and taking of history are not designed to
9	elicit genetic causation issues do you do any genetic
10	testing at all?
11	A Yes, but that wasn't during the office
12	visit, that's after the office visit.
13	Q Right. When might that be and under what
14	circumstances?
15	A The major circumstance, although in Ohio
16	it's not as much of an issue, is affordability.
17	There's a difference between diagnosing autism and
18	doing testing to try to determine the reason why the
19	autism is there. Autism is basically a clinical
20	diagnosis. It is. No genetic test alters that. It's
21	a clinical diagnosis.
22	The reason for testing that's being done,
23	basically it's to try to provide the family some
24	information as to the reason why the autism is there.
25	Traditionally what I'll end up doing is sending high
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1	resolution chromosomal analysis, DNA tests for Fragile
2	X, blood amino acids and lactate, urine organic acids
3	and then if I have an affected girl, especially a girl
4	who developmentally is not at an appropriate level,
5	I'll send the DNA testing for Rett syndrome.
6	With other things, if there's other features
7	that might be present there are certain other tests
8	that you can test for, but it depends on what you find
9	on the examination. But that I would say is my
10	minimum evaluation.
11	Q I'm sorry that is not?
12	A That is my minimum evaluation that I will
13	order.
14	Q Okay. And so, again, that evaluation as
15	your minimum would be part of the standard of care
16	that you use as a clinician?
17	A That is what I do as a clinician. Yes, sir.
18	Q And it's part of the diagnostic standard of
19	care that you would apply to get accurate and
20	comprehensive results on a child's diagnosis. Is that
21	correct?
22	A I don't understand what you mean by I would
23	apply.
24	Q You would apply the different testing
25	methodologies and modalities that you've described.
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1	You do that in order to get complete information to
2	provide an accurate diagnosis, correct?
3	A No, sir. As I stated before, autism is a
4	clinical diagnosis. The only reason I do that testing
5	is to get information to try to see if I can establish
б	an identifiable reason why the autism is there. Those
7	are two different points, sir.
8	Q Right. No, I understand. I understand. In
9	your experience have you ever diagnosed a child as
10	being autistic and then that child was later diagnosed
11	by you or by somebody else to be not autistic?
12	A Probably.
13	Q Let me break it down a little bit. Since
14	it's in the realm of probability that this might have
15	happened have you ever diagnosed a child as autistic
16	and then the child, based on your continued work with
17	the child, eventually lost the diagnosis so to speak?
18	A Yes.
19	Q How often does that happen?
20	A I can count on one hand in my clinical
21	experience probably the total number. I can't tell
22	you how many. Literally just a few.
23	Q Of the children that you have diagnosed with
24	autism have you ever in your follow-up work come to
25	the conclusion that your initial diagnosis of autism
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1 was incorrect? Not that the child grew out of it, but 2 that you were incorrect in your diagnosis. 3 Α No, and again, that's not a yes or no question. If I may elaborate? 4 5 0 Seemed like a yes or no question, but go 6 ahead. 7 Α But it's not that simple because you're 8 asking me -- there's two points. When you first see 9 the child at the age at which the child is being 10 evaluated you may have enough features of enough 11 information that's in front of you that it clearly 12 states the child fits somewhere within the autistic 13 spectrum, therefore, you basically have features that 14 are there. 15 Extremely rarely what you'll find is that as 16 the child gets older one of two things happens, and 17 there are children who do this. There are children 18 who do outgrow the autism diagnosis, albeit, it's a 19 rare condition, but it does happen. Therefore, I have 20 patients like that in my practice. It's not that my 21 diagnosis was incorrect, it's that they seem to have 22 outgrown it for reasons that were not quite clear. 23 Even though they still may have certain 24 actions or behaviors they no longer fit within the spectrum as we define it. There's literature that 25 Heritage Reporting Corporation

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# WIZNITZER - CROSS

1	supports this conclusion. Secondly, there may be
2	someone that on the basis of historical information
3	that is provided to me I come to a conclusion that the
4	child fits within the autistic spectrum.
5	Further investigation finds that historical
б	information was not what it seemed and was not
7	necessarily accurate when we do further checks or as I
8	follow the child it may happen that way at which point
9	I then would take the diagnosis and say with now the
10	newer information that's available to me it doesn't
11	fit.
12	Q So either the child changes in some way that
13	the child loses the diagnosis or more history comes to
14	light that allows you to change the diagnosis,
15	correct?
16	A Yes. There may be another historian or
17	someone else who gives me information. I can recall a
18	circumstance where that clearly happened.
19	Q So then would it be fair to say from your
20	perspective that you personally have never
21	misdiagnosed a case of autism, that is your error rate
22	in diagnosis is zero?
23	A No. My error rate is not zero.
24	Q What is your error rate?
25	A I can't tell you. I know it's low. If
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1	anything I would argue that in my situation I tend to
2	err on the side of safety, and I will under call, and
3	follow children over time and then see whether they
4	truly have autistic features or not.
5	In other words, I may say at the beginning
6	they don't have the diagnosis because I don't find
7	sufficient data yet as I follow them over time I find
8	that with more information and with more developmental
9	history that's available to me that I do find it.
10	That tends to be more of the area where it
11	happens to me.
12	Q When did you first start using home videos
13	as part of your assessment of children for autism
14	diagnoses?
15	A How long have we had VCRs?
16	Q I don't know. I'm not asking you how long
17	we've had VCRs.
18	A But I'm just answering. Seriously.
19	Basically, let me think back. Probably at least 15 to
20	20 years since I've had access to VCR tapes.
21	Q Now, you would never use just a video to
22	make a diagnosis. Is that correct?
23	A No.
24	Q You would sometimes use only a video to make
25	a diagnosis?
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1	A No, I would not use just a video. Again,
2	that's not a yes or no question, but let's just say
3	that in my clinical practice I did not use a video
4	solely to make a diagnosis. Let me explain that
5	someone can send me a video of a child where the
6	behavior is obvious and you can see just on the
7	videotape the child meets all diagnostic criteria.
8	This is what we do with some of the
9	assessment tools that are being used that you can
10	accurately rank them as such, but clinically I don't.
11	If a child makes an appointment to see me I see the
12	child, I just don't see a videotape.
13	Q Right. And in this case with Michelle
14	Cedillo, the Cedillo family never received a
15	questionnaire from your office? They never filled out
16	a questionnaire that your patients presenting with
17	would have filled out, correct?
18	A No, they did not.
19	Q You've never had a conversation with the
20	parents or interviewed them in any way, have you?
21	A No.
22	Q You haven't interviewed any of their
23	relatives, have you?
24	A No.
25	Q You haven't viewed any other pictures or any
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1	other photographic record that might exist aside from
2	the videos that you've described here?
3	A What do you mean by photographic records?
4	Q I'm asking you.
5	A But, sir, you're the one who used the term,
б	that's why I'm asking you to better define it for me.
7	Q Photographs. Anything.
8	A Just still pictures. Is that what you mean?
9	Q Anything.
10	A Still pictures?
11	Q Anything that's a visual capture, whether
12	it's pictures, DVD, videotape. Anything at all. Any
13	photographic record.
14	A But, sir, what I did request and hopefully
15	you folks provided to me, was that when I made my
16	initial request for them I asked for as I said total
17	and unedited videotape from the first 15 months of
18	life, so I do have a photographic record that was
19	supplied to me using your definition and terminology.
20	I do not have any still pictures, but
21	unfortunately still pictures really don't help me in
22	this circumstance, it's the videotape that does.
23	Q You haven't interviewed any care providers
24	or therapists that Michelle Cedillo has seen over the
25	years, have you?
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1702 WIZNITZER - CROSS 1 Α No. 2 You haven't been the one to sit down and 0 3 take a history from the parents or any other relatives 4 of Michelle Cedillo. Is that right? 5 Α Correct. 6 0 You haven't been the one to sit down and do 7 a review of symptoms, correct? 8 А Correct. 9 You haven't done a physical exam of Michelle Q Cedillo? 10 11 Α Correct. 12 0 You have not conducted a neurological exam of Michelle Cedillo? 13 14 Α Correct. 15 You haven't tested her sensory activity. Q 16 You haven't tested her nerve function. Is that right? 17 Α Correct. 18 You haven't tested her motor function, 0 19 correct? 20 Α Correct. 21 You haven't done any watching of the child Q 22 as she developed in person, correct? 23 Α Correct. 24 You haven't supervised any play with 0 25 Michelle Cedillo, correct? Heritage Reporting Corporation (202) 628-4888

1703

1 Α Correct. 2 You haven't seen how Michelle Cedillo at any 0 point interacted with her peers in person, correct? 3 4 Α Correct. You haven't seen how she interacts with 5 0 6 adults in person, correct? 7 Α Correct. 8 0 You haven't seen any sample play that she 9 has done in person, correct? 10 А Correct. 11 You haven't seen her and followed her over 0 12 the course of many, many months as you do with other 13 patients in your clinic, right? 14 А Correct. Now, you're talking about in 15 person followed her? 16 0 That's what I'm asking. 17 А No. I was able to follow her on the 18 videotape over time clearly. I mean, I had videotape 19 evidence for quite a long period of time, for a period 20 of months. 21 Yes, but not for years, correct? Fifteen 0 22 months is what you described. 23 А No, we had years because the videotape that 24 was provided to me went at least through her fourth 25 birthday, and let me just finish. It was represented Heritage Reporting Corporation (202) 628-4888

1704A WIZNITZER - CROSS 1 to me that that videotape was basically all the 2 videotapes of Michelle Cedillo that were available 3 from the time that the videotapes started until the time that the videotapes stopped unless you're going 4 to tell me that's an incorrect assumption. 5 6 0 I would not tell you that that's incorrect. 7 Α Okay, sir. 8 0 Now what you described that you didn't do 9 with Michelle Cedillo is what you would do in your clinical practice, correct? 10 11 А Correct. 12 0 And you've described that your clinical 13 practice is the standard of care for an experienced 14 clinician such as yourself. That's what you testified 15 to a little while ago. 16 I stated that's what I do in my office. Α No. 17 I know you use the words standard of care, but that's 18 what I do. 19 And you responded to that question. 0 20 Α I agree with you. I said that's what I do 21 in my office. So I agree with you. 22 Right. So that is your standard of care? 0 23 Α That is my standard of care. 24 And you did not in offering this alternative 0 diagnosis for the purposes of litigation meet that 25 Heritage Reporting Corporation (202) 628-4888

1 standard of care that you would use in your own 2 clinical practice. 3 Α Again, sir, what alternative diagnosis? I 4 don't understand what you mean by that. The diagnosis that you offered earlier today 5 0 that Michelle Cedillo did not have regressive autism, 6 and that she in fact was autistic much earlier than 7 8 the Petitioners have claimed she was. That's the 9 testimony that you've offered here, and that testimony is not based on the exercise of the standard of care 10 11 that you use in your clinical practice, correct? 12 Α That is not based on what I do in my 13 clinical practice. I agree with you, sir. 14 0 Let's talk about the MMR and injuries that 15 might be associated with the MMR. In your report 16 obviously you're focusing on the specific injuries at 17 issue in this case. Is that correct? 18 Α Yes. 19 Do you have any information about other 0 20 injuries that might be related to the MMR aside from 21 I know you have talked about potential weight? 22 measles infection injuries. We'll speak about those 23 later. 24 I don't understand your question. Α Are there any injuries that you would 25 0 Heritage Reporting Corporation (202) 628-4888

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1 associate in your practice with the administration of 2 the MMR? 3 А Are you talking about as a child 4 neurologist? I'm talking about as a child neurologist are 5 0 6 you aware of any injuries associated with the MMR 7 vaccine? 8 А Maybe I'm missing what you mean. I don't 9 understand what you mean by injury. No, seriously, sir. 10 11 I'm saying injury. What injuries do you 0 12 recognize as associated if any with administration of 13 MMR? 14 Α I don't understand what you mean by injury. 15 Can you explain? 16 As a doctor what's your understanding of the 0 17 word injury? 18 No, but, sir, you're asking the question, Α 19 and seriously, if it's your question I want to make 20 sure that you give me the definition about --21 SPECIAL MASTER HASTINGS: Let me try to help 22 you. He's asking do you know of any conditions, 23 illnesses or injuries, make it as broad as you can, 24 any ill effects brought on by the MMR vaccine? Did 25 that do it?

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1707

WIZNITZER - CROSS

1 MR. POWERS: That does it for me. 2 SPECIAL MASTER HASTINGS: All right. 3 THE WITNESS: That would be better. To me 4 when you say injury it means something physically happened to a person, like I hit somebody and they 5 6 have an injury versus some sort of a complication, 7 which is I assume what you're saying, Special Master. 8 Is that correct? 9 SPECIAL MASTER HASTINGS: Right. 10 THE WITNESS: Okay. 11 MR. POWERS: Complications, conditions. 12 THE WITNESS: Off the top of my head in my 13 clinical practice I don't think I've ever seen a 14 complication from MMR from a neurology standpoint if 15 that's what you're asking me. I've never seen that 16 amongst all the children in Cleveland. 17 MR. POWERS: Yes. That's how I was asking 18 it. 19 THE WITNESS: Yeah. I have not seen that, 20 sir. 21 BY MR. POWERS: 22 Now, I'm curious that you make the 0 23 distinction that in your role as a neurologist you 24 haven't seen any. In any other role in which you've served are you aware of injuries as we've broadly 25 Heritage Reporting Corporation (202) 628-4888

1708 WIZNITZER - CROSS 1 defined them that are related to administration of the 2 MMR? 3 Α You're talking about involving the nervous 4 system or anything else? 5 0 Broader. Anything. 6 Α Well, I really have no opinion about the 7 other areas because that's not my area of focus, so I 8 can't comment on that. 9 0 Now, I'm not asking for an opinion, I'm just asking it as a matter of fact, are you aware of any? 10 11 That's all I'm asking. 12 Α No, I'm not. 13 Okay. Now, you know in the vaccine injury 0 14 program there's a table of injuries. Are you familiar with that? 15 16 Α Yes. 17 0 And that under certain time constraints one 18 has a presumption that the MMR caused encephalopathy. 19 Is that correct? 20 Α That is my recollection. It causes 21 encephalopathy. I'm sorry. Now that you've reminded 22 me anaphylaxis clearly is I guess one would call it a 23 complication or reaction that can occur from almost 24 any immunization so that anaphylaxis would be one 25 about which I'm aware. Heritage Reporting Corporation

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Are you aware that MMR is a presumed cause, 1 0 2 again, recognizing the language of the vaccine table, 3 of encephalitis? 4 I thought it was encephalopathy. Α 5 0 Both. And if you don't know, you don't 6 know. 7 Α Again, sir, to my knowledge I thought it was 8 encephalopathy as defined by the table, and then the 9 table defines what encephalopathy is. Right. Okay. Are you aware that under the 10 0 11 table MMR can cause arthritis? In fact, it can be 12 presumed to cause arthritis? 13 I can't comment on that. I don't know. Α 14 But you do know that arthritis is a disease 0 15 that affects the immune system, correct? 16 Α It's one of the reasons. No. Arthritis can 17 be due to immune problems? Is that what you mean? 18 0 Yes. 19 Arthritis doesn't affect the immune system. Α 20 0 Does it involve the immune system? 21 Is it associated with the immune system? It Α 22 can be. 23 0 Okay. Can the MMR vaccine cause measles in 24 an immune suppressed person? 25 Cause clinical measles? Α Heritage Reporting Corporation

1 0 Yes. 2 Don't know the answer to that, and let me Α 3 explain why. I know that when you have a regular 4 vaccination you can get a mild reaction that occurs in the time course of a traditional measles infection 5 6 that includes, you know, fever, coryza, rash, things 7 of that nature. 8 So my assumption is that if you have a 9 measles picture that can occur as a consequence of the 10 vaccination I assume it can happen to anyone because 11 we know that's a mild-like picture, but I'm not 12 talking about wild type measles. Were you talking 13 about vaccine measles? That's all I'll really say 14 about that. 15 Right. Now, do you believe that the MMR can 0 16 cause Guillain-Barr, syndrome? 17 Α No. I don't have any data to tell me that 18 it can. 19 So does that mean that you do not have an 0 20 opinion one way or the other or that you have an 21 opinion and it is an opinion that rejects that causal 22 association? My answer to your question would be to my 23 Α 24 knowledge there's no association. 25 How about acute disseminating 0 Heritage Reporting Corporation (202) 628-4888

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1 encephalomyelitis? 2 Acute disseminated encephalomyelitis? Α 3 Q Yes. If you're asking on a theoretical basis 4 Α 5 whether it may, yes, on a theoretical basis it might. 6 0 And how about paraplegia? Do you have an 7 opinion as to whether the MMR vaccine can cause 8 paraplegia? 9 Α Yes. To my knowledge it doesn't. 10 0 To your knowledge can the MMR cause 11 transverse myelitis? 12 Α I don't have an opinion. 13 Do you have an opinion as to whether the MMR 0 14 can cause a seizure disorder? 15 Α I think you need to give me more information 16 in that question because seizure disorder, that means 17 a chronic seizure disorder. You're talking about 18 epilepsy? 19 0 Just a seizure disorder. 20 Α Well, no. Seizure disorder or a seizure? 21 Seizure disorder. 0 22 MMR can be associated with a seizure. A Α 23 seizure can occur and temporally related to MMR. Ι 24 agree on that. Seizure disorder is a different To my knowledge there's no data telling us 25 creature. Heritage Reporting Corporation (202) 628-4888

1	that MMR itself causes a chronic seizure disorder.
2	Q Would you be surprised to know that of all
3	the adverse outcomes I just listed related to the MMR $$
4	those have been adverse outcomes in which petitioners
5	have prevailed in the vaccine program on causation?
б	A I would not be surprised, sir.
7	Q Do you have an opinion as to whether the MMR
8	can cause attention deficit disorder?
9	A Yes.
10	Q What's your opinion?
11	A No.
12	Q Do you have an opinion as to whether it can
13	cause learning disabilities?
14	A Yes.
15	Q What's your opinion?
16	A No.
17	Q How about behavioral problems. Do you have
18	an opinion as to whether the MMR can cause behavioral
19	problems?
20	A Just a behavioral problem by itself with
21	nothing else? The child gets an MMR then years later
22	has a behavioral problem and nothing more than that?
23	In other words, there's nothing else that's going on
24	in between? The answer is no.
25	Q Would you be surprised to know that the
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1 Department of Health and Human Services stipulated to 2 compensation in a case involving all of those 3 conditions? 4 MR. MATANOSKI: Excuse me, Your Honor. I'm 5 going to object to this line of questioning because of б the relevance. 7 SPECIAL MASTER HASTINGS: I understand your 8 relevance objection. I think we'll take it for what 9 it's worth. Go ahead. 10 11 THE WITNESS: Let me answer very simply by 12 saying that assuming that the facts that you put in 13 place were the only facts involved with the MMR and 14 that it was a child who got an MMR, nothing else 15 happened and then later on had a learning disability, 16 attention disorder, and what was the third thing you 17 said, and behavior problems, I'd have to read the 18 complete record before answering your question and 19 seeing if you represented all the information 20 accurately. 21 BY MR. POWERS: 22 But as you sit here today I was just asking 0 23 for your opinions in general not related to a 24 particular --But your questions are too vague with not 25 Α Heritage Reporting Corporation

1714 WIZNITZER - CROSS 1 enough information within them in order to provide a 2 good opinion. 3 0 Although you were happy to provide the 4 answers until the objection came. 5 А No. 6 0 So we'll move on to the next round of 7 questions. 8 Α Sir? 9 SPECIAL MASTER HASTINGS: Go ahead. Let's 10 just ask any further questions that you have. 11 MR. MATANOSKI: I'd ask that he spare the 12 argument. 13 SPECIAL MASTER HASTINGS: Pardon me? 14 MR. MATANOSKI: I'd ask that he spare the 15 argument in asking a question. 16 SPECIAL MASTER HASTINGS: Go ahead and ask 17 your questions. 18 BY MR. POWERS: 19 Now, the video analysis that you did today 0 20 and that Dr. Fombonne did yesterday, this is sort of a 21 retrospect or a hindsight diagnosis, correct? 22 It's retrospective, yes, and the reason it's Α 23 retrospective is because we're looking at a videotape 24 on a child about whom we actually do know the outcome, I agree with you, and on a child where the child is 25 Heritage Reporting Corporation

1 much older than when she was on the videotape, so by 2 definition that is retrospective. 3 Q Right. No. I was going to state, and the 4 Α 5 definition of retrospective is not hindsight, sir, 6 just to let you know that. 7 0 Okay. Thanks. Now, what do you think 8 hindsight is? Is it different from retrospective? 9 Α A retrospective study is when you have for instance medical records or medical information that's 10 11 here that has not been acquired in a prospective 12 fashion and you go back and analyze that information. 13 That's what retrospective means. It means going 14 backwards. Hindsight basically means that you're 15 looking back with foreknowledge already of what the 16 conclusion was, but that's not what retrospective 17 means. 18 But in this case looking back with knowledge 0 19 of the outcome, to that extent those two definitions 20 overlap because you said it was retrospective in that 21 we know the outcome and you just said in defining 22 hindsight that part of the definition of hindsight is 23 that you know the outcome. 24 So we can agree that although they're slightly different definitions, and we can have all 25

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1	the rhetorical angels we want dancing on the semantic
2	head of the pin, the bottom line is that you know the
3	outcome, and you're looking back and you're
4	identifying events that support the outcome, correct?
5	A Wrong.
б	Q That sure seems like what we saw.
7	A No.
8	SPECIAL MASTER HASTINGS: Mr. Powers and
9	doctor, I don't think it makes a lot of difference for
10	the outcome in this case what your corresponding
11	definitions of retrospective and hindsight. It's very
12	obvious Dr. Wiznitzer knew the outcome of Michelle's
13	case as he viewed that videotape. So let's go on.
14	BY MR. POWERS:
15	Q Now, as we've discussed your analysis of
16	these tapes did not include a whole set of things you
17	would already do in your clinic if you were treating a
18	patient and diagnosing. We've already addressed that
19	issue. Have you ever done an analysis of your
20	reliance on videos in your practice to see if using
21	those videos creates an over diagnosis, or an under
22	diagnosis, or an accurate diagnosis ultimately of the
23	children for whom you reviewed the tapes?
24	A No.
25	Q So you've never designed a study to examine
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1 that question? 2 А No. 3 Q So you wouldn't know sitting here today 4 based on your clinical practice where you use the tape 5 how often the tape accurately would have predicted a б diagnosis that was later made, correct? 7 А Say that again. I didn't catch everything 8 you said. 9 0 What I was asking is that you've never done 10 a study or an investigation to see how accurately the 11 use of the tapes ultimately proved to be in your 12 diagnosis of a child with autism? 13 А No. 14 0 So you don't know what any sort of error 15 rate there would be if any? 16 Α In my clinical practice, no. 17 Now, yesterday when Dr. Fombonne was 0 18 testifying -- and I'm going to ask Mr. Shoemaker to 19 help me out here -- there was a slide that was 20 presented, it was Slide No. 15, and we'll see if Cliff 21 can help us get that up. I want to ask you a couple 22 of things about that. I hate it when you see 23 application error. 24 SPECIAL MASTER HASTINGS: Well, we all have 25 a copy.

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1718 WIZNITZER - CROSS 1 MR. POWERS: I was just going to say. 2 SPECIAL MASTER HASTINGS: Maybe we can just 3 do it the old-fashioned way and look at our paper 4 copy. 5 MR. POWERS: Legal pad and paper, and I'm 6 happy with that. 7 Doctor, do you all have a copy that you 8 could pass on? 9 MR. MATANOSKI: We don't. We didn't expect that Dr. Wiznitzer would be --10 11 BY MR. POWERS: 12 Here we go. All right. Now, Dr. Wiznitzer, 0 13 on your monitor there can you see the slide? It's called the developmental trajectories in ASD. 14 15 А Yes, sir. 16 Have you ever seen this slide before? 0 17 Α Yes, I have. 18 In what context have you seen this slide? Q 19 А In a review of some slides from Dr. Fombonne 20 last week. 21 Okay. Now, when did this review of slides 0 22 with Dr. Fombonne --23 Α I didn't review with him. I looked at the 24 slides. 25 You looked at his slides? 0 Heritage Reporting Corporation (202) 628-4888

1719

1 I just looked at the slides. Α 2 So were you looking at his slides in Q 3 preparation for your testimony today? 4 Α No. 5 0 For what purpose were you looking at his slides? б 7 А To make sure there was no overlap in what we 8 were saying. 9 0 Did you review the slides or any other materials that any other witness was going to be using 10 11 in their testimony? 12 Α No. 13 Do you know whether your presentation was 0 14 shared with any other witnesses before they testified? 15 А I have no idea. 16 Okay. Now, in looking at the slide we have 0 17 a very straight line. I'm sort of color blind. Is 18 that like a turquoise? The straight line that's the 19 highest line of all them? 20 Α Yes, sir. 21 Now, that line as I understand is the 0 22 trajectory of normal development that you would expect 23 in the child. Is that correct? 24 Α Yes, sir. 25 And the vertical axis represents 0 Heritage Reporting Corporation (202) 628-4888

1	developmental milestones, and the horizontal axis is
2	time, so that as you go up that slope you are
3	developing over the course of time in a normal way.
4	Is that accurate?
5	A Yes.
6	Q Now, as it's drawn here this is a very,
7	very, very thin line. Is it fair to say that the
8	range of what constitutes normal development is
9	broader than a single point to point line? Is that
10	accurate?
11	A Yes, sir, it is.
12	Q So can you tell by looking at this graph how
13	broad that line ought to be to capture normal
14	development over time?
15	A No. I have no information about exactly
16	what is represented on the Y axis, what part of the
17	development, are we talking total development or are
18	we talking about specific developmental issues?
19	Therefore, to make the line thin or thick would be
20	irrelevant in this circumstance.
21	Q So based on this slide one cannot have an
22	informed idea of what the range of normal development
23	in a child would be, correct?
24	A To my knowledge that's not the purpose of
25	this slide. What this slide is to show developmental
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1	trajectory. I mean, it says it on top. It doesn't
2	say range of developmental trajectory. So what we do
3	is we take a child and this is the child's
4	developmental trajectory, the normal child's
5	developmental trajectory.
6	You can change what the Y axis represents
7	dependent on which child it is and have it do it
8	within the normal range. That is how I interpret what
9	the what color did you say that line is?
10	Q You know, you could tell me.
11	SPECIAL MASTER HASTINGS: Just say yellow.
12	MR. POWERS: Yellow. Yes. I honestly can't
13	tell.
14	THE WITNESS: Okay. That's how I interpret
15	the yellow line, sir.
16	MR. POWERS: Okay. Go ahead. We can pull
17	that down.
18	BY MR. POWERS:
19	Q Now, the use of the video that you employed
20	here, and again this is not to get into an argument
21	about semantics, and I'm happy to use your term. This
22	is a retrospective use of video in order to arrive at
23	a diagnosis. Is that correct?
24	A The answer is yes and no; in that it is
25	retrospective. But in the circumstance here, we know
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1722A

# WIZNITZER - CROSS

1	the diagnosis. The use of the video is not to arrive
2	at a diagnosis. The use of the video is to try to
3	establish the onset of the condition. Do you
4	understand the difference between the two points?
5	Q Well, my question is, were you using this
6	video, using retrospective analysis, to establish a
7	diagnosis? If so, my understanding is that your
8	answer is no.
9	A Well, no, sir, I didn't say that. Again, as
10	I stated to you before, because in this circumstance
11	we know the diagnosis. The diagnosis is autistic
12	disorder. All I used the video to define is the onset
13	of the features of autistic disorder, knowing the
14	child's diagnosis. It's just a defined onset. If I
15	may use an analogy
16	SPECIAL MASTER HASTINGS: Well, I think
17	you've answered the question.
18	THE WITNESS: Okay, yes, sir.
19	SPECIAL MASTER HASTINGS: To the extent you
20	two fine gentleman can avoid sparring over semantics,
21	that sparring is not helping us learn about the case.
22	So do the best to try to accommodate each other and
23	see if we can get through this.
24	BY MR. POWERS:
25	Q Now you're not aware of any error rate that
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1722B

WIZNITZER - CROSS

1 would be applicable to using this retrospective

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1 analysis. Is that right? 2 А No, I'm not. 3 Q Are you aware of any studies that have examined the potential error rate for using 4 5 retrospective video analysis to confirm diagnoses of 6 autism? 7 А No. In your experience, has your reliance on 8 0 9 using retrospective video analysis has that ever produced a result that was not later confirmed by a 10 11 full on-clinical diagnosis? 12 Α Again, I'm confused. I mean, I know the 13 clinical diagnosis. The issue is, in other words, if 14 I looked at a videotape of a child and saw features 15 similar to Michelle Cedillo; and then later on asked 16 myself, was this child developmentally normal or not, 17 the answer would be no, I've never had that occur. 18 You've never gone back and looked at video 0 19 and said, yes, this is just at odds with the diagnosis 20 that we know we have in hand? 21 Not in this circumstance; not in the Δ 22 circumstance of a child with autism, no. 23 0 So as far as you know, again, the error rate 24 would then be zero. In my clinical practice, for looking at 25 Α Heritage Reporting Corporation (202) 628-4888

1	videos to define the onset of the condition, and when
2	there have been features consistent with similar
3	things that were cited to Michelle Cedillo, that is
4	correct. It's been consistent with the later
5	diagnosis.
6	Q Are you familiar with any studies that have
7	reached the conclusion that using retrospective video
8	analysis can lead to an over-diagnosis of autism?
9	A I'm familiar with studies that have been
10	done that analysis of the video at a very young age,
11	under 12 months of age, can over-call features where
12	not all the children end up having ASD, but may have
13	other developmental issues.
14	Q I just missed the term; over-call?
15	A May over-call ASD, but the children may have
16	other developmental issues. That, I'm aware of. I'm
17	not aware of looking at videos at older ages.
18	Q When you say very young ages, again, you
19	just mentioned one year?
20	A Under one year.
21	Q Under one year.
22	A Yes.
23	Q And that's a significant amount of the video
24	here, when Michelle was one year or less in age.
25	A Let me answer your question, if I may. It
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1724A

1725A WIZNITZER - CROSS 1 is probably a small majority of the entire video that 2 I watched. 3 Q A small? Majority -- yes, I would just say maybe a 4 Α 5 small majority. б 0 So by that, you mean slightly more than 7 half? 8 I'm only counting by the number of pages. А 9 The real way to really do this, sir, and I don't have time to do it now, is to sit down and count minutes. 10 11 Q Okay. 12 Α Obviously, I don't have the availability of 13 counting minutes. 14 SPECIAL MASTER HASTINGS: Let's don't try to 15 do that. Go ahead. 16 MR. POWERS: And I would not suggest it. 17 THE WITNESS: But if you take that as an 18 answer, there's still a significant amount of time for 19 which we have video at and after one year of age, even 20 if we use that information for analysis. Furthermore, 21 if we have video at and after one year of age, but 22 before the MMR immunization that shows features 23 consistent with ASD, it confirms the findings that you 24 had under one year of age, and tells us that they were not an over-call. 25

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1726 WIZNITZER - CROSS 1 BY MR. POWERS: 2 Now your work, I think you've testified is Q 3 primarily as a clinician, correct? I mean, you do 4 some research, and you do some publishing, in addition to your clinical work? 5 б А Yes, sir. 7 0 And in reviewing the CV that you submitted, 8 I saw three papers that seem to be related to autism. 9 Does that sound correct? 10 А No, there's more. 11 0 Because I saw one on autism and tuberous 12 sclerosis. 13 Α Yes, sir. 14 0 And there's one with an open clinical trial 15 of Risperidone? 16 А Yes. 17 Another was a high dose Magnesium test. You 0 18 were looking for the efficacy of that. 19 Yes, I mean, I think you must have missed Α 20 some of the other papers. 21 I'll go back and review. Those are the 0 22 three that I saw. 23 Α I'm happy to tell you where the other papers 24 are. Yes, what are they? 25 0 Heritage Reporting Corporation (202) 628-4888

1727A

## WIZNITZER - CROSS

1	A Soon after the Risperidone paper, there was
2	another paper that dealt with side effects of
3	Risperidone, which included a sizeable number of my
4	patients from my autism population. If you read the
5	paper, you'd know that that's where they were
6	recruited. Therefore, it had to do with the
7	theoretical concept of possible drug side effects in
8	this population, as well as in kids who don't have
9	ASD.
10	There was a paper that was written by David
11	Mendelbaum, that dealt with sensory motor issues from
12	our longitudinal study of children with ASD, mental
13	retardation, and normal development, that was
14	published either late last year or earlier this year
15	in developmental medicine in child neurology; and
16	there was a review article that I wrote with I'm
17	blanking on Susan's last name Sarah's last name,
18	Sarah Spense, if I'm not mistaken, that had to do with
19	diagnosis and assessment of autism.
20	Q Was that a diagnosis assessment in case
21	management?
22	A No, that was an article from seminars and
23	pediatric neurology, if I'm not mistaken. That's in
24	addition to the book chapters.
25	Q Right, and I saw the book chapters. I
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1	wasn't inquiring about those. The scientific journal
2	articles that you've written, those articles don't
3	deal with issues of causation in autism, do they?
4	A The article with Sarah does, insofar as we
5	talk about the write-up. I mean, if you're talking
6	about the work-up that we do to try to determine the
7	reason why autism is, there's an algorithm in there
8	that discusses the work-up.
9	Q And work-up is the diagnostic work-up?
10	A Yes, well, remember, again sir, as I stated,
11	it's not the diagnosis of, autism is a clinical
12	diagnosis. What it is, is further medical evaluation
13	to see if we can identify the reason why the autism
14	is.
15	Q Would you say the reason to see why the
16	autism is, it would be the autism in that particular
17	patient?
18	A Yes, for instance, tuberous sclerosis,
19	Fragile X Syndrome, marcochromosome 15, conditions of
20	that type.
21	Q I want to shift gears and talk a little bit
22	about your comments on Dr. Kinsbourne's expert report
23	and your comments on his testimony. You spent some
24	time talking about the Rubenstein and Merzenich I
25	don't know the fellow, but I'll just call it the
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1728A

1729

1 Merzenich paper -- the 2003 paper. Do you recall that 2 discussion? 3 Α Yes. You recall talking about the hypotheses that 4 0 5 were being advanced in that paper. Do you recall that б part of your testimony? 7 Α The hypothesis that was in that paper, yes. If we could have Slide 22, I don't think 8 0 9 we've had a chance to load this into our computer. But if you all would be so kind to put Slide 22 up, 10 11 that would be helpful. 12 SPECIAL MASTER HASTINGS: Slide 22 of what? 13 MR. POWERS: I don't know what exhibit this 14 was for the Respondent. 15 SPECIAL MASTER HASTINGS: Of his slides? MR. POWERS: Of Dr. Wiznitzer's slide 16 17 presentation, yes. 18 SPECIAL MASTER HASTINGS: Okay. 19 BY MR. POWERS: 20 0 That slide is a quote from the paper. So 21 this isn't your testimony. This is a quote that you pulled from the paper, correct? 22 23 Α Yes, sir. 24 And it states what their hypothesis is, and 0 that's the hypothesis that you were discussing in your 25

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1 direct testimony, correct?

2 A Yes, sir.

3 0 Now in describing their hypothesis, as I was taking notes, I heard three different terms that you 4 5 used. I want to explore them again, not as a matter 6 of playing semantics, but when we start talking about 7 scientific definitions and lay definitions, I think 8 it's going to be important, because it's going to 9 relate to evidentiary issues that we're going to need to explore. 10

11 So I say that as a preface. That's not a 12 sparring match, and I don't intend it to be that. I 13 hope it doesn't turn into that. But I simply want to 14 get clarification so I understand what your testimony 15 meant.

16 Now I've heard three different terms that 17 were used, it sounded like, interchangeably to me --18 theoretical, hypothetical, and that is a postulate. 19 Did you mean to use those three terms interchangeably? 20 That is, do you think that they all mean the same 21 thing? These are the terms that the authors used, 22 Α 23 and basically, I was quoting from the authors. 24 Well, I see the hypothesis, but you used the 0 terms theoretical and postulate. But those are also 25

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1731A WIZNITZER - CROSS 1 what they use? 2 Can we move two slides forward? These are Α 3 the author's words. 4 Yes, so it's a postulate and it's 0 theoretical. 5 6 Α And hypothesis, plus all these words, were 7 used within the same page. 8 Q Yes, almost in the same paragraph, if I 9 recall. The first two were used in the same 10 А 11 paragraph. The other was in the following paragraphs. 12 0 They were very close together in that paper. 13 Yes, sir. Α 14 What's your understanding as a scientists of 0 15 what the word "hypothesis" means? 16 Hypothesis is an idea that is proffered. Α 17 And if a hypothesis is proffered in a peer 0 18 reviewed scientific journal, you would agree with me 19 that it's a hypothesis that is at least consistent 20 with the evidence that is described in that peer 21 review journal article. Is that a fair statement? 22 Sometimes -- I'm not trying to be Α 23 argumentative. But it really depends on the journal, 24 and it depends on its rules for how they accept articles. I read the small print from the editorial 25 Heritage Reporting Corporation (202) 628-4888

1 section for how sometimes they'll take hypothetical 2 models from a substantiation. 3 I, personally, don't know in this journal 4 what their criteria are. But we just say that the evidence that they used to try to support the 5 6 hypothesis, in terms of framing why this hypothesis 7 should be studied, is something that usually has a 8 basis. Do you understand what I'm telling you? 9 0 Yes, and in this case in particular, aside 10 from what the journal's standards were, you would 11 agree that in this particular article, the hypothesis 12 that is put out here is consistent with the evidence 13 that's contained within the body of the article. 14 Would you agree with that? 15 I think the words you used are perfect, sir; Α 16 that it's the evidence within the body of the article, 17 which means that there very well may be evidence 18 outside the article that does not support it, which is 19 true in this case. But it's not within the article. 20 0 So the hypothesis is based on evidence, 21 correct? 22 No, I want to make sure that we understand Α 23 that there's evidence that they have, and then they 24 formulate a hypothesis to say this is how we want to explain the evidence. The evidence doesn't support 25 Heritage Reporting Corporation (202) 628-4888

1 it. The hypothesis is an explanation. Do you see the 2 difference? It's semantic, but it's critically 3 important. 4 Q Right. 5 Α Because if you have evidence to support a 6 hypothesis, this article does not contain evidence to 7 support a hypothesis. This article contains evidence, 8 and then the authors are trying to tie it together in 9 a hypothesis. Right, and I was actually going to ask if 10 0 11 that is one of the definitions of a hypothesis; that 12 it is something that is postulated in order to explain 13 evidence, in an effort to explain evidence. Is that 14 right? 15 А I guess you can say it. But as long as we 16 qualify here, that the evidence does not support or 17 confirm the hypothesis. Do you understand what I'm 18 trying to say there? 19 But the evidence, at least, does not 0 20 contradict the hypothesis. Is that fair? 21 Right, there very well may be some evidence Α 22 within there that would contradict it. But the idea 23 that overall, they're saying, we have an idea. Here's 24 the reason why we have the idea. Now we need to go prove the idea. 25

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1	The idea there is the hypothesis, and that's
2	what this article contains entirely. There are some
3	ideas and here's the formulation of how I tie these
4	ideas together, and now I need to prove them. They
5	provide nothing within the article about proof.
б	Q So you say there's nothing in the article
7	that would prove whether the hypothesis is true or
8	not?
9	A Because they say it. That's what they
10	state; that the article states that it's a hypothesis.
11	I really don't want to play semantic games. But I'm
12	afraid that you may not be reflecting accurately what
13	hypothesis does and how you build a hypothesis.
14	If I have some information that's available
15	to me, I can see how I can tie it all together. For
16	instance, an example would be, the grass is green.
17	This sounds absurd, but I'm just going to say it. A
18	hypothesis is, someone goes out there every night and
19	paints it. Then you need to do research to see
20	whether that hypothesis is supported or not.
21	Here, we have a lot of statements of, the
22	grass is green, the grass is green, the grass is
23	green, with the hypothesis put together with
24	information. Then they say, we need to go out and see
25	whether we can prove that this idea is correct or
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1 incorrect. That's what this article is saying. 2 As you understand it, they're using the 0 3 words postulate, hypothesis, and theoretical. Is it 4 your understanding they're using those words 5 interchangeably? 6 Α I think here they are. In fact, I think 7 that, yes; that basically they're interchangeable. 8 They all basically mean we have an idea. It's 9 speculative right now in nature, and it either needs to be confirmed or refuted. The only way to do it is 10 11 to do further research. 12 Now you mentioned that you're not aware of 0 13 any research in this area, after the 2003 publication 14 of this paper? 15 Α No, I'm just not aware; no, sir. 16 You're just not aware of it. So if there's 0 17 research going on out there, it's something that's 18 unknown to you, in terms of whether it's going on and 19 what the content might be. 20 Δ I have not seen anything that's been 21 proffered to support it, sir. There's nothing that 22 I've seen that was published that was directly related 23 to this idea. 24 Well, let's talk about the idea a little 0 bit. I mean, the basic hypothesis here, as I 25 Heritage Reporting Corporation

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1	understand it again, in my lay person understanding
2	is that there is a balance or an equilibrium of
3	excitatory and inhibitory activity in the brain. Is
4	that correct?
5	A Yes.
б	Q And that there are brain function problems
7	that are caused by disequilibrium between the
8	inhibitory and the excitatory, correct?
9	A That's the hypothesis, yes.
10	Q And it could be a result of one or perhaps
11	both an increased excitation on its own, assuming
12	inhibition stays the same. That is excitation goes
13	up. It could also be that excitation stays the same,
14	but inhibition goes down; or it could be that
15	inhibition goes down and excitation goes up. Is that
16	correct?
17	A Yes.
18	Q Now all of those potential outcomes, those
19	are all consistent, isn't it true, with what we know
20	about brain biochemistry.
21	A I really don't understand the question, sir.
22	It's too vague of a question; biochemistry of what?
23	Q Is there anything that we know about brain
24	biochemistry that is inconsistent with the excitation
25	inhibition functions as two different functions in the
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1737A WIZNITZER - CROSS 1 brain? 2 Oh, no, we have excitation and inhabitation А 3 functions in the brain; yes, sir. So that's well known. That's accepted. 4 Q That's accepted, right. 5 Α 6 Q Now we also know that excitation and 7 inhibition are related to things like cytokines, 8 correct? 9 Α The way I'll answer you is, yes, I know that cytokines have an influence. They have a 10 11 neuromodularatory influence. I can't give you 12 specifics about excitation inhibition. 13 Now you would also agree that astrocytes 0 14 help with synaptic function in the brain, correct? 15 А Oh, yes. 16 And astrocytes help with regulating 0 17 mitochondria metabolism in the brain, or the function 18 of mitochondria in the brain, excuse me. I don't understand that statement. 19 Α That 20 doesn't make sense to me. 21 Do astrocytes help control the flow of 0 22 glutamine in the brain? 23 Α Gluta what? 24 Glutamine; am I pronouncing that right? 0 25 А Glutamine. Heritage Reporting Corporation (202) 628-4888

1738A WIZNITZER - CROSS 1 Glutamine and glutamate are different 0 2 things. 3 А Glutamine? 4 0 A-M-I-N-E. Yes, they deal with glutamine in the brain. 5 А б Q And astrocytes activate neurons? 7 Α They modulate. They modulate neuronal 8 function. That's a different word than activate. 9 0 Okay. A better word is modulate. 10 А 11 0 And this is involved with the neurotransmitter activity. Is that correct? 12 13 Α Yes, sir. 14 0 Now there are pre-synaptic neurons. Is that 15 right? 16 А Yes. 17 Pre-synaptic neurons, do they release Q 18 glutamine? 19 Α No. 20 Q What do they do with glutamine? 21 They take it up. They don't release it. Α 22 So post-synaptic neurons are not the neurons 0 23 that pick up glutamine? 24 No, glutamate is the neurotransmitter, not Α 25 glutamine. Heritage Reporting Corporation (202) 628-4888

1 And astrocytes play a role in modulating the Q 2 activity of glutamine as a neurotransmitter. 3 А Glutamates. I'm sorry. I'm sorry. I was getting ahead 4 0 5 of myself. So the astrocyte do modulate and are 6 involved in glutamate in the brain. 7 Α Well, no, your original statement was 8 correct. They are also involved with glutamine. But 9 you were talking about the neurotransmitter, 10 glutamate. 11 Exactly; now pro-inflammatory cytokines --0 12 if pro-inflammatory cytokines exist at a high level in 13 the brain, isn't it true that the pro-inflammatory 14 cytokines can produce sort of a globalized or non-15 local excitation of brain activity? 16 А I can't answer that question. It's too 17 vague. 18 Well, you particularly took issue in your 0 19 report -- and let's go ahead and maybe get your report 20 up on the screen -- with something that Dr. Kinsbourne 21 said. What we're referring to, this is Respondent's Exhibit DD, I believe, the Doctor's Export Report. 22 SPECIAL MASTER HASTINGS: What page are we 23 24 going to look at? 25 MR. POWERS: I've got to find my glasses. I Heritage Reporting Corporation (202) 628-4888

1740A WIZNITZER - CROSS believe it's page one -- page three. 1 2 SPECIAL MASTER VOWELL: Mr. Powers, it's 3 numbered in the upper right hand corner. 4 MR. POWERS: Yes, and on this screen, it's so hard to read the small print. I was straining. 5 6 But in the third paragraph, the second half of that --7 SPECIAL MASTER HASTINGS: Again, what page 8 are we on? 9 MR. POWERS: We're on page three. 10 SPECIAL MASTER HASTINGS: Page three, thank 11 you. 12 MR. POWERS: Page three, paragraph three. 13 SPECIAL MASTER HASTINGS: Okav. 14 BY MR. POWERS: 15 Now at the very bottom, you take issue with 0 Dr. Kinsbourne statement. Dr. Kinsbourne said this in 16 17 his report. "Chronic inflammation has been found in 18 the cerebrum and the cerebellum of children with ASD, that is consistent with the effect of chronic virus 19 20 infection." Then that quote closes, and you say that 21 it's not supported by this medical literature; 22 referring to a Bauman and Kemper report. Am I 23 interpreting that correctly? 24 No, it's based on the neuropathology Α reports, the daily report, as well as the Bauman and 25 Heritage Reporting Corporation (202) 628-4888

1741A

#### WIZNITZER - CROSS

Kemper, and the Kemper and Bauman reports. 1 2 0 Okay, now since those papers came out back 3 in 1998, there was another paper published; and this 4 is from Respondent's expert report. It was an 5 attachment to Dr. Zimmerman's expert report. It's 6 something that he cited in his paper, and I just have the tab on that as Tab 51. But I don't know if that 7 8 matches the record we have -- I mean, if that matches 9 the Court's exhibit. If we could zero in on the top half, this is 10 11 page one. The name of the article is Neuro-Glial 12 Activation and Neuro Inflammation in the Brains of Patients with Autism, and this is a paper by Diana 13 14 Vargas, and Dr. Zimmerman is one of the co-authors or 15 co-investigators on this paper. Do you see that on 16 the screen, Doctor? 17 А Yes. 18 Now halfway down in the very top of the 0 19 page, there's a sentence that begins, "We 20 demonstrate." Do you see that? If there's any way we 21 could zero in on "We." "We demonstrate an active 22 neuroinflammatory process." 23 Now Dr. Kinsbourne described an active 24 neuroinflammatory process. Is that correct? No, he speculated on the presence. 25 Α Heritage Reporting Corporation (202) 628-4888

1742A

# WIZNITZER - CROSS

1	Q But he's describing something, and then we
2	see a study that describes the same thing, an active
3	neuroinflammatory process.
4	A No, that's not what Dr. Kinsbourne stated.
5	Dr. Kinsbourne speculated that something like that
6	might be present. That's what he stated.
7	Q And we know that at least in the subjects in
8	this paper, that the very thing Dr. Kinsbourne was
9	describing, as a hypothesis, is in these folks
10	actively confirmed an active neuroinflammatory
11	process.
12	A Before I answer your question, because it
13	would not otherwise be fair without me being fully
14	informed what is going on, I want to look at the
15	paper.
16	SPECIAL MASTER HASTINGS: I'm sorry, you
17	want to know what?
18	THE WITNESS: I would like to look at the
19	paper in toto, and not just take one sentence out of
20	context.
21	SPECIAL MASTER HASTINGS: Do you have a copy
22	of that paper?
23	SPECIAL MASTER VOWELL: It's Exhibit 61, Tab
24	MMM.
25	SPECIAL MASTER HASTINGS: We'll get you a
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1743A WIZNITZER - CROSS 1 copy of the paper. 2 BY MR. POWERS: So as we get a copy, let me just ask, have 3 Q you seen this paper before it was referred to just a 4 5 moment ago by me? 6 Α I've seen this in the past, yes. 7 0 When do you recall last seeing it? Well, when it came out. 8 Α 9 Q And you realized Dr. Zimmerman was one of 10 the experts that filed an expert report on 11 Respondent's side in this case, correct? 12 А I know he was one of the experts. I don't 13 know if he did or didn't file a report. 14 SPECIAL MASTER HASTINGS: Did you get a 15 copy? 16 SPECIAL MASTER VOWELL: I think you need to 17 hand it to the witness, if you would, Ms. Chin-Caplan. 18 SPECIAL MASTER HASTINGS: The idea is to 19 give it to the witness. 20 BY MR. POWERS: 21 So go ahead and take the time you need, and Q 22 then if you could look up when you're done. 23 Α Now go back to your question, sir. 24 Have you had a chance to review the document 0 that was handed to you? This is the Vargas/Zimmerman 25 Heritage Reporting Corporation (202) 628-4888

1744A WIZNITZER - CROSS 1 article. 2 А Yes, sir. 3 0 And in that article, would you agree that 4 the investigators in this study did find active neuroinflammatory Proc. 8, an active neuroinflammatory 5 6 process in the cerebral cortex. Do you agree with 7 that? 8 That's what they write here. Yes, that's Α 9 what they wrote. And they also found the activation of 10 0 11 microglia and astroglia, correct? 12 Α That's what they wrote; yes, sir. 13 They also found this neuroinflammatory 0 14 process, not just in the cerebral cortex, but in the 15 white matter and in the cerebellum of autistic 16 patients, correct? 17 Yes, that's what they wrote, sir. Α 18 Dr. Kinsbourne, in part, in his hypothesis, 0 19 relied on a finding that there is an active 20 neuroinflammatory process in the cerebral cortex, 21 didn't he? 22 А Yes, he did. 23 Q And he relied on the presence of an active 24 neuroinflammatory process in the white matter and in the cerebellum, correct? 25 Heritage Reporting Corporation (202) 628-4888

1744B

WIZNITZER - CROSS

1 A I don't remember that he did. I just

1 remember he stated a neuroinflammatory process in the 2 brain. I think that's what he stated. 3 0 And he specifically did say that the 4 inflammatory process involved an activation of microglia and astroglia, correct? 5 6 Α I know he stated there was an activation of 7 microglia. I don't remember that he said astroglia. 8 If you can show me it, then I'd be happy to be 9 reminded. But you're not sure, sitting there right 10 0 11 now, whether he said that or not? 12 Α I don't remember if he said that or not. 13 You also recall that he testified that the 0 14 pro-inflammatory cytokines, among the various 15 cytokines in the brain -- that the pro-inflammatory 16 cytokines in his hypothesis were the most prevalent in 17 the brain, correct? 18 А That's what he stated, yes. 19 And that is a finding that they found in the 0 20 subjects in this study; that the most prevalent 21 cytokines were pro-inflammatory cytokines, correct? 22 А I don't see that written in the abstract, 23 sir. 24 It says that MCP-1 and 2 or growth factor 0 Beta 1, derived from neuroglia were the most prevalent 25 Heritage Reporting Corporation (202) 628-4888

1 cytokines? 2 Α That's what they wrote, sir. 3 Q Okay, they also indicate or they say that 4 their findings indicate that innate neuroimmune reactions play a pathogenic role in an undefined 5 б proportion of autistic patients, and I'm just reading 7 their abstract. 8 Α You're reading it into the record, and 9 that's what they wrote. And Dr. Kinsbourne talked about innate 10 0 11 neuroimmune reactions that might play a role in an 12 undefined population of autistic patients, correct? 13 I don't remember him using those words. Α 14 You're not saying he did. You just don't 0 15 remember? 16 I don't remember him using those words. Α 17 That's all I can say. 18 Do you know Dr. Zimmerman professionally? Q 19 Professionally, I know him. Α 20 Q I'm sorry? 21 I know him professionally, yes. Α 22 And do you know Dr. Vargas? Q 23 Α No. 24 Do you know any of the other authors or 0 investigators that are on this article? 25 Heritage Reporting Corporation (202) 628-4888

1747A WIZNITZER - CROSS 1 Α No. 2 As far as you know, by professional Q reputation, Dr. Zimmerman is a good researcher and a 3 4 good doctor? 5 Α I have no comment. That part, I don't know. 6 I just don't know him well enough. I've met him 7 professionally at a few meetings. 8 Q So you don't know him well enough to form a 9 professional opinion? Exactly, sir; I would be lying if I gave 10 Α 11 something, one way or the other. 12 0 Now you testified, as I think we referenced 13 before, that you're not aware of any other research 14 going on, after the 2003 article by Rubenstein and 15 Merzenich. Is that correct? 16 Α Merzenich? 17 0 Merzenich. 18 Α Yes. 19 All right, are you aware of any National 0 20 Institute of Health Study that's ongoing, that is 21 looking at potential treatment modalities arising from 22 the theory that neuroinflammation may play a role in 23 some autistic patients? 24 Is that a spin-off on the Merzenich question Α or is that a different question? 25 Heritage Reporting Corporation

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### WIZNITZER - CROSS

1 It's a different question. 0 2 I just want to make sure in my mind. I am Α 3 not aware, one way or the other. 4 Are you aware of whether Doctors Vargas and 0 Zimmerman are continuing to do additional research 5 6 with an eye towards publishing papers further 7 developing the neuroinflammatory theory implicated in 8 some autistic patients? 9 Α I am not aware, one way or the other. 10 0 One way or the other -- you mentioned at 11 another point in your testimony that you were involved 12 in ongoing research in pharmacokinetics. Am I 13 recalling that correctly? 14 Α Pharmacokinetics, yes. 15 Q Pharmacokinetics -- who funds that work? 16 Α I don't know. 17 Do you raise the money for that work? 0 18 No, I don't raise the money, no. Α 19 Who does raise the money for that work? 0 20 Α Probably our Pharmacology Research Unit. 21 What's your role in that ongoing research? Q just literally, functionally, what do you do? 22 I mean, 23 Α Functionally, I recruit the patients. 24 And these would be patients from your 0 25 clinic?

# WIZNITZER - CROSS

1	A Yes, my clinical practice.
2	Q You also mentioned somewhere early on in
3	your testimony that out of all the children that you
4	see because you don't just see autistic children
5	you see a range of patients that include non-autistic
б	children, also?
7	A Yes.
8	Q If I recall, you said something along the
9	lines and you could probably clarify, because I
10	just scribbled something down that about one
11	quarter of the children that you see end up being
12	diagnosed at your clinic as autistic. Did I state
13	that correctly?
14	A No.
15	Q You remember talking about one quarter?
16	A I was asked about what percentage of my
17	patient population has a diagnosis of an autistic
18	spectrum disorder.
19	Q Does that include patients who came to the
20	clinic with a diagnosis already?
21	A Yes.
22	Q And it includes patients who arrive without
23	a diagnosis, but who are then diagnosed?
24	A Yes.
25	Q So that's the total. So 25 percent of your
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# WIZNITZER - CROSS

1	patient caseload, so to speak, is made up of children
2	who have an autism diagnosis?
3	A Yes, and I just want to tell you that it's a
4	number I came up with as a round-about figure, just
5	looking at how my clinics are set up, how often I see
6	patients and stuff like that. Since about a quarter
7	of my clinics are autism clinics, I see only kids with
8	autism or the question of autism there.
9	Then within my non-autism clinics, I
10	actually have a percentage of kids within those
11	clinics who also have a diagnosis of autism. Twenty-
12	five percent may be accurate and may be an under-call.
13	Q Yes, and it sounded like an estimate. But I
14	was just trying to get an idea of what universe that
15	25 percent represented. So it does involve people who
16	come in without the diagnosis, and people who come in
17	with the diagnosis, and that's your total. Has that
18	twenty-five percent changed over time?
19	A Yes.
20	Q In what way?
21	A It was lower when I first started. The
22	other thing I really need to correct for you, to make
23	sure that you have an accurate understanding, is that
24	there is an influx and e-flux of patients.
25	In other words, I may see children and make
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1751

1	a diagnosis of autism, but that's basically why they
2	came to me. They just wanted to have a diagnosis,
3	because they may live far away, or they may have other
4	providers, or they're from out of the insurance
5	network and, therefore, basically want my input.
6	I never see those kids again. The number I
7	gave you, in terms of the twenty-five percent, for the
8	most part, if you want to think of it as my steady
9	patient calculation.
10	Q I'm sorry?
11	A That's my steady patient population.
12	Q Okay.
13	A Realizing there's going to be some influx
14	and e-flux.
15	Q Right, but again, understanding if we use
16	that as sort of the population we're looking at, has
17	that twenty-five percent changed over time?
18	A It has grown, and we've put limits on it, in
19	order to make sure that my medical practice is not
20	solely autism. It could be 100 percent. I mean, if I
21	basically just changed my schedule tomorrow, it would
22	be 100 percent. But we deliberately chose within the
23	practice that I would limit the number of kids that I
24	see, so that I would have a more rounded child
25	neurology practice.

1752A

### WIZNITZER - CROSS

1	Q And the twenty-five, you say, that has gone
2	up over time, do you believe that that represents the
3	fact that there are more children at a higher
4	prevalence of autism in the pediatric population over
5	time?
б	A Oh, there is a higher prevalence of
7	identified individuals; but my practice has not grown
8	because of that. My practice has grown because people
9	came to see me for a diagnosis, because of my
10	expertise in the area.
11	Q But again, what was the term that you used,
12	people who have an apparent what was the word you
13	just used? What I was asking is whether you think the
14	increase in the proportion of children that you see as
15	being autistic children have the number of actual
16	autistic children in the population increased?
17	A Not from my population the question you
18	asked me was, in my population, was the increase due
19	to the increased prevalence, and the answer was no.
20	The increase is due because of my expertise. There's
21	enough kids with the diagnosis of an autistic spectrum
22	disorder out in the community, no matter what
23	prevalence numbers you would want to use, for me to
24	see.
25	Q Right, so it's almost like a selection bias
	Hawitago Donostiss Comparation

1 that people are coming to you. 2 No, it's not a selection bias. I have a А 3 long waiting list for new patients in that regard, and 4 I've had a long waiting list of up to six months for 5 years. б Do you think that the actual rates of autism 0 7 have increased over time in the U.S. pediatric 8 population? 9 Α I agree that the prevalence rates have gone 10 up, yes. 11 And I'm not asking about prevalence rates, 0 12 because that's based on a diagnosis, correct? When 13 you say prevalence rate, that's the rate at which 14 people are diagnosed with autism in the population? 15 What do you mean by prevalence? It's the total number of individuals with a 16 А 17 label of an autistic spectrum disorder in the 18 population. 19 And you do believe that that number has gone 0 20 up over time? 21 The prevalence number clearly has gone up, Α 22 yes. 23 0 Do you believe that the incidence of autism 24 has increased in the U.S. pediatric population? 25 I think there is no data to support that Α Heritage Reporting Corporation (202) 628-4888

1753A

1754A

### WIZNITZER - CROSS

1 claim in any meaningful matter; and may I? Let me 2 explain why. 3 0 But I was unclear about the answer. Are you saying you don't have an opinion, one way or the 4 other; or that you do have an opinion? I just wasn't 5 6 sure what the answer was. 7 А If you'd let me explain; may I, if it's all 8 right? 9 When I first started in child neurology and seeing children with autism, we had much more 10 11 restrictive diagnostic criteria for autism and for 12 autism spectrum disorder. There were very relatively 13 rigid criteria. 14 Soon afterwards, the criteria became much 15 looser. I can tell you that I used to see a lot more 16 older individuals for first-time diagnosis in my early 17 years than I see now; which means there was decreased 18 recognition. 19 As we would normally expect with any kind of 20 a diagnosis, when people are first going into things; 21 to some degree, there is an element of over-labeling 22 where people have expanded the criteria beyond what 23 the DSM really has defined. 24 In those circumstances, it's very difficult to state that the incidence truly has written, because 25 Heritage Reporting Corporation (202) 628-4888

1755A

#### WIZNITZER - CROSS

1 we've got reasons why the numbers have actually gone 2 up. If we loosen the diagnostic criteria, there are 3 going to be more individuals. 4 If we lead to earlier recognition and earlier knowledge of it, we're getting individuals 5 6 coming in at a younger age, who would not have come in 7 before. If we have individuals who are using the 8 9 label in a somewhat inappropriate fashion, we're going to get over-calls. Therefore, to get an idea of 10 11 incidence, it's very difficult to answer your 12 question, because of all those factors. 13 Do you believe that you, in your clinic, 0 14 have loosened your diagnostic criteria? 15 А Yes, we're following more on the trend that 16 kids who, in the past, would not have fallen within 17 the autistic spectrum have now been included within 18 it, yes. 19 You mentioned over-calling. Do you believe 0 20 that you, in your clinic, have over-called diagnoses? 21 No, and I think I answered that question for Α you before; with the caveat of the answer that I gave 22 23 you earlier today about that. But as a general 24 wholesale over-call, because of a decreased knowledge of what the diagnostic criteria actually represents, 25

1 the answer is no. 2 So you, in your clinic, would you believe 0 that you have over-diagnosed? That was another phrase 3 you used, just a moment ago. 4 5 Α No, that's not been happening. 6 Now in the video testimony, or the Q 7 commentary on the video, that portion of your 8 testimony, about how much time did you spend preparing 9 to offer that testimony today? Do you have any idea? First, I reviewed the entire video, and I 10 А 11 think we have three to four hours worth of video 12 there. I then replayed portions of that video. I 13 think went back and re-checked some of the portions, 14 because I wanted to be absolutely clear in my mind. I 15 would probably say, in terms of playing the video 16 itself to myself, and to define what's going on and 17 everything else, at least six to eight hours. 18 How long does it take to do a clinical work-0 19 up with a patient in your practice, in order to reach 20 a diagnosis? 21 Under an hour, for the most part. Α And that obviously under an hour would 22 0 23 exclude those instances where you have to follow those 24 people over a significant amount of time in order to reach a diagnosis? 25

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1757A

Α I assumed you meant the average patient that comes to see me. Q Well, what's the range. Well, no, the average patient is clearly Α under an hour, and then there are some children who show up, that you know within the first minutes -- in fact, parents will ask me that question, because that's what they suspected themselves. So the range can be 15 minutes, to within the hour; sometimes I spent an hour and-a-half, even though it's supposed to be an hour, and then I run late. But I do things like that. There's only a very small number where I need to follow them out over time. That's probably five percent or less of the children. А Do you know what percentage of children that you diagnosed where you review videos; do you track that? No, I don't really track it. I just 0 remember these mounds of videos in my office, because we recently moved. And I remember a box, two boxes of videos for children that I haven't reviewed. If you can figure a big shipping box and count the number in there.

25 So it's a sizeable minority; we'll just say Heritage Reporting Corporation (202) 628-4888

1 it that way. It's not a majority because in the 2 majority, there's no need. The information is quite 3 clear. It's quite clear-cut, and the diagnosis can be 4 made. I only will ask for a video review when 5 6 there's issues regarding diagnosis, or issues 7 regarding timing on onset. 8 In doing the video, when you do a video 9 review, about how much time do you spend reviewing video on a typical case, where you feel that's called 10 11 for. 12 As much time as it's clinically indicated; 13 it depends on how much video the families give me. 14 But if the families give me three hours of video, I 15 will review all three hours of the video and then re-16 review things. If they give me what they consider to 17 be half an hour or an hour, which is important, I will 18 do that. In other words, it's as much time as is 19 needed to clinically come to a conclusion that the 20 features that are there, are there, and that I'm 21 comfortable with these conclusions. 22 Are you aware of any other practitioners or 0 23 clinics in your field that rely exclusively on video 24 reviews -- particularly retrospective video reviews -to either make a diagnosis of autism or confirm a 25 Heritage Reporting Corporation (202) 628-4888

WIZNITZER - CROSS 1 diagnosis of autism? 2 Well, maybe I misunderstand your question. Α 3 What do you mean by "other"? Am I aware of 4 individuals out there who only do it solely by video, 5 and nowhere else? б Q Right. 7 I am not aware of anyone who does it solely Α 8 by video, and that's the only thing they ever do. 9 0 Are you aware of any studies that might be 10 ongoing, that are looking to gauge the accuracy of 11 this retrospective video review? 12 Α I'm sure there are probably studies that are 13 ongoing. I'm sure there are. I just can't give you 14 the names of them right now. 15 0 Are you participating in any of those studies? 16 17 Α No. 18 Do you have any plans to participate in 0 19 those studies? 20 Α No. 21 Has anybody contacted you about Q 22 participating in such a study? 23 Α No. 24 What sort of treatments do you typically --0 or I shouldn't say typically, because I don't want to 25 Heritage Reporting Corporation (202) 628-4888

1 be too vaque. What sort of treatments do you use at 2 your clinic when you diagnose a child with autism? 3 Δ For a child with autism, first of all, it depends why they come to see me. If a child with 4 5 autism comes to see me because we have a diagnosis, 6 but there's challenging behaviors that are going on, 7 or just issues that require that -- for instance, my 8 patient may have sleep disturbances or things of that 9 nature. 10 Basically, I work on trying to identify 11 factors that are causing that behavior, which is due 12 to a functional analysis of behavior; and then 13 instituting interventions whether they're behavioral 14 or medication-based, in terms of working with that. 15 If there's a child who's been newly 16 diagnosed with autism, my first recommendation always 17 is to get him into an intervention program. I provide 18 parents with a list of resources that are in the 19 community. I tell them to contact them, find out what 20 resources that they're comfortable with. 21 I tell parents to do some reading regarding autism, so they're comfortable about the diagnosis. I 22 23 ask them to also do some reading about what type of 24 interventions are available, so that they understand what's to be done in that regard. So in other words, 25

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1761A

#### WIZNITZER - CROSS

1 it really depends why they're there and what the issue 2 is. 3 Q And when you say "interventions", what are you speaking about? 4 Educational interventions -- we may have 5 Α 6 children who get put into a discrete trial training 7 program. We may have children who get put into a 8 floor-time type program. We may have children who get 9 put into a more eclectic, which means a mixed usage, intervention program, depending on what the child's 10 11 individual needs are, in terms of what's being 12 identified. 13 These are the kinds of interventions, if the 14 patient has challenging behaviors that we believe 15 would be responsive to behavioral strategies; get him 16 hooked up with someone to work on those behaviors. 17 As I stated before, if the child is not 18 sleeping at night, which is a very common occurrence 19 in this population, we help them in that regard, in 20 terms of getting them to sleep. 21 I've heard of something called ABA applied 0 22 behavior. 23 Α That's discrete trial training. 24 I'm sorry? 0 That's also discrete trial training. ABA is 25 А Heritage Reporting Corporation (202) 628-4888

1762A

1 the generic term. But the specific strategy that Ivar 2 Lomas talked about was a discrete trial training, ABA 3 program. 4 And so are those synonymous terms? Q No, discrete trial training is a form of 5 Α 6 ABA. But the kind that people normally use is this 7 discrete trial training technique. 8 Do you do anything that might be termed a 0 9 biomedical intervention? 10 А Could you be more specific, what you mean by 11 biomedical? 12 0 Well, I'm just using the term very broadly. 13 If you have an understanding, you could answer the 14 question, based on what your understanding of it is. 15 Because you've talked about educational interventions 16 and behavioral. I'm just wondering if there's any --17 I'm really serious, sir. I really don't Α 18 know what you mean by the term. I mean, you're the 19 one who used the term. So that's why I'm trying to 20 figure out, what does "biomedical" mean. 21 So when you hear the term "biomedical Q 22 treatment" as it applies to autism, that term is 23 meaningless to you? 24 I want to know what you mean. I have to be А very careful. 25

### WIZNITZER - CROSS

1 SPECIAL MASTER HASTINGS: Well, he's asking 2 you the question. 3 THE WITNESS: It's not meaningless to me. 4 If you're saying that we do medical intervention, my 5 medical intervention may not be pharmacologic in 6 nature. My medical intervention will be counseling 7 the families and working with them, getting hooked up 8 with the behaviorist to work on some things. 9 For instance, if a child's not sleeping at 10 night because the child has poor sleep hygiene, I 11 don't give him drugs. I basically work on parenting 12 strategies to help the child develop good sleep 13 hygiene. 14 Do I use medications in the management; yes. 15 Do I use some naturalistic interventions? The answer 16 is yes. I use all those as we see fit for the child. 17 If that's what you mean by biomedical, then that would 18 be the answer. 19 BY MR. POWERS: 20 0 Yes, that is helpful; and particularly since 21 you mentioned two specific things. One, was that 22 naturalistic? 23 Α Yes, sir. 24 0 And the other was medication. Yes, sir. 25 А Heritage Reporting Corporation (202) 628-4888

1764A

#### WIZNITZER - CROSS

1 Could you describe what you describe as 0 2 naturalistic? What are some of those treatments or 3 interventions? The main one that I use is Melatonin for 4 Α 5 sleep. It's very helpful in this population. Now in 6 that situation, also, I may have families who contact 7 me and say, we want to do some vitamin therapy. What 8 do we do? How do we dose it? Then my nurse will 9 provide them with the information about how to do it. 10 I may have families who contact me and say, 11 we want to do some other supplement therapy. What do 12 we do? How do we dose it? We give them information 13 about how to do it appropriately and where to access 14 the preparations. 15 I may have families who come to me and say, 16 we want to do special diets. We discuss it. I tell 17 them who to talk to, where to get hooked up, what 18 reading they have to do in order to implement the diet 19 and answer feedback about what happens. 20 0 And when you mention diet, I mean, I've 21 heard of the GFCF gluten-free, casein-free. 22 That's the one that parents always ask me Α 23 about. 24 Right, and so when you were just saying you 0 help parents who raise that issue do it appropriately, 25 Heritage Reporting Corporation (202) 628-4888

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1 that you're talking about the gluten-free, casein-free 2 diet? 3 Α Yes, sir. Okay, are there any other naturalistic, as 4 0 5 you frame the therapies that you do? 6 Α Those are the main ones that come to mind. How about medications? 7 0 I use medications as clinically indicated 8 Α 9 for the children. For children, primarily, I use medications for sleep, when it's indicated. I use 10 11 medications for anxiety. I use medication for 12 obsessive compulsive disorder, for ADHD, mood 13 disturbances, aggression, and violent behaviors, when 14 we can't define an obvious trigger or a physical 15 reason why that may be occurring. 16 I use medication for the management of 17 epilepsy when it occurs in this population. I'm sure 18 there's a few other reasons, but those are the main 19 ones. 20 0 Do you have a sense what proportion of your 21 autism patient population is being prescribed the 22 medications that you were just talking about? 23 Α The difficulty with your question, if I may 24 answer it in this way please, is that there's an inherent bias. Usually, the children with autism, who 25 Heritage Reporting Corporation (202) 628-4888

1	don't need any kind of medication, I discharge them by
2	the time they get to the early school-age years, and
3	tell the parents, call me if you need me.
4	The ones who do need to continue to be
5	treated, especially with medication, will stay in my
б	practice. Therefore, I would say the majority. But
7	again, it's a select group, and it's not really an
8	accurate reflection of the patient population that I
9	initially see.
10	Q So it's a majority of a subset of your
11	patient population.
12	A Yes, sir.
13	Q Well, I'm curious then. Do you have an idea
14	of what portion of your patient population you
15	continue to treat on an ongoing basis, as opposed to
16	discharge? I guess that's the word.
17	A I don't think I've ever done the numbers.
18	It's a good question. I've never done the numbers.
19	Q Then this is sort of the same question on
20	the naturalistic treatments that you do. Do you have
21	an idea of what percentage of your autistic population
22	you are working with on naturalistic treatments?
23	A Let me split it into two parts for your
24	answer. I can tell you that the majority of my
25	families will try naturalistic treatments. It's only
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1	a percentage of those that will actually call and
2	discuss it with us; and in the others, they inform me
3	after the fact. Here's what we're doing; here's what
4	is going on. Therefore, I can't give you an exact
5	number. But I know it's the majority who actually try
6	something.
7	Q Do you believe that autism can be cured?
8	A Not in the traditional sense, no.
9	Q Do you believe in any sense that autism can
10	be cured?
11	A When I say not in the traditional sense,
12	it's that I think you can outgrow it or get to the
13	point where functionally, it does not interfere with
14	your day-to-day functions. I would consider that to
15	be a cure, in the sense that when that happens, the
16	individual is able to function adequately within
17	society.
18	Q Do you have a sense of what percentage of
19	your patients, given that definition, you would say
20	have been cured?
21	A Under 10 percent, that's all that I can tell
22	you.
23	Q Do have a sense of what that percentage
24	might be within the larger population of children? Do
25	you have any idea?
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1768 WIZNITZER - CROSS 1 Α No. 2 Q Is it an area that you've looked at, have 3 you? 4 I've looked at it in the past, but I can't Α 5 quote numbers to you right now. 6 Do you believe that there is a phenotype of 0 autism that would be described as regressive autism? 7 8 А Yes. 9 Q What percentage of the autistic population do you believe has regressive autism? 10 11 The traditional numbers that people provide Δ 12 is let's say 15 maybe 20 percent. I think some of 13 those numbers are clouded by historical issues in 14 terms of families giving an inaccurate history. 15 It's not the family's fault. They're 16 basically giving a history where enough information is 17 not gleaned, probably in the 15-to-20 percent range. 18 That 15-to-20 percent range, as far as you 0 19 know, has that percentage remained constant over time, 20 or has it changed? 21 I think more recently we've been trying to Α 22 get good, accurate numbers. The numbers we've had in 23 the past were not that accurate, so there's no good 24 answer to your question. So it would be fair to say that you just 25 0 Heritage Reporting Corporation

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1769 WIZNITZER - CROSS 1 don't know? 2 Α There is no answer; therefore, we can't know 3 if there is no good answer. You mentioned a term, in describing the 4 0 5 process of Michelle Cedillo, as stagnated. Do you 6 recall using that term in direct testimony? 7 А Yes. Stagnation, is that a clinical term? 8 0 9 А No, that's just my term. Is there a distinct phenotype of autism that 10 0 11 stagnation applies to? 12 Α There is a phenotype that people will 13 describe, that they would say is more like the word 14 plateau. Some people have written about that. 15 Now, Michelle Cedillo, because she has several factors that we need to consider within her 16 17 situation. One factor is that she clearly showed 18 features early on before her first birthday. 19 Therefore, there was a developmental progress that was 20 there. 21 The second one is that, even at her first 22 birthday, when you watch her behavior and watch her 23 actions, and also read the records as far as we have, 24 she clearly was not developmentally at an ageappropriate level. 25

## WIZNITZER - CROSS

1	Therefore, she may not really fit the true	
2	phenotype of what people talk about in terms of	
3	plateau in autism because she has more of an early	
4	onset with associated cognitive impairment.	
5	Q So this plateau, and I'm just trying to get	
б	the term straight again, diagnostic terms. My	
7	understanding a moment ago was that stagnated and	
8	plateau, you were sort of using as roughly equivalent	
9	terms?	
10	A No.	
11	Q Okay, that's fine.	
12	A When I used the word, I wasn't using it as a	
13	diagnostic word. But what we had was that we saw that	
14	her development was slow during that time period. But	
15	we also noted that her development was slower before	
16	that time period.	
17	Q When you say we, using the plural, who were	
18	you referring to?	
19	A The medical records tell me. She was late	
20	in smiling, according to the medical records. She had	
21	some issues that I think was identified in terms of	
22	perhaps the sitting.	
23	I'm concerned about the history	
24	//	
25	//	
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# WIZNITZER - CROSS

1	that was given to us about walking at age sixteen		
2	months. Because, again, the only representation I have		
3	of walking at sixteen months is walking with support		
4	and not walking independently.		
5	The video tape that we have, showing		
б	Michelle Cedillo at the playground in February of		
7	1996, which puts her at about seventeen-and-a-half		
8	months, if I'm not mistaken, still shows that she		
9	needs to have someone hold her hand in order to do		
10	supportive walking. It suggests that she may have		
11	some delays in terms of her motor development.		
12	Q I don't want to interrupt you, but that's		
13	not my question.		
14	A But that's what I'm saying. So the thing		
15	is: basically the information I get from the medical		
16	records, that's what I meant by we.		
17	Q So you and the records are the collective		
18	plural?		
19	A Yes.		
20	Q So when you say we or us, you're talking		
21	about you and the medical records.		
22	A In this case, I'm talking about the records,		
23	yes.		
24	Q Because there's nobody else that you worked		
25	with in order to reach the conclusions that you		
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WIZNITZER - CROSS

1772A

1 reached in this particular case? 2 There is no one else. These were totally А 3 reached in an independent fashion. 4 Completely independent? 0 5 А Totally. 6 MR. POWERS: I think we're done. 7 SPECIAL MASTER HASTINGS: All right. Any 8 questions for this witness? 9 Let me ask the Doctor, there's been the 10 discussion about whether Michelle's autism is properly 11 within the regressive category or not? Does that make 12 a difference to your view of the case on the causation 13 issue? 14 THE WITNESS: No, may I explain? 15 SPECIAL MASTER HASTINGS: Go ahead. 16 THE WITNESS: We have two issues here. One 17 issue, as you pointed out, was: Was there truly an 18 autistic regression? 19 Yet, I don't think we have any firm 20 documentation in the medical records that there was 21 really a language regression, as I had stated earlier 22 today in my testimony. The reason we don't have this 23 is because, the history that we obtained, is that the 24 words that were present were words primarily used in 25 imitation.

# WIZNITZER - CROSS

1	On the video tapes, which are really only a	
2	recorded record of Michelle Cedillo's functioning	
3	during that time period on which the questions are	
4	derived, we really don't see any word use being done.	
5	And there were plenty of opportunities on those video	
6	tapes for us to see words, or hear words.	
7	I mean when we tape children, we always tape	
8	them saying words. Therefore, the final regression is	
9	a loss of a skill. In this case, it would be the loss	
10	of language. There is no loss of language because it	
11	was not real language that we're talking about.	
12	That's No. 1. No. 2, as I stated before, in	
13	my interpretation of the video tapes, there is clear-	
14	cut evidence of features within the early autism	
15	phenotype being present on the video tapes, supporting	
16	the fact that regression isn't there.	
17	But, now, to answer your question: Let's	
18	assume that regression did occur, sir. Because I	
19	think that that is also what you're asking. For	
20	regression to occur, we still have the statement made,	
21	and please tell me if I'm wrong, but my understanding	
22	of the case, that the regression occurred as a	
23	consequence of exposure to an MMR vaccine and entry of	
24	a measles virus into the brain that caused the	
25	autistic regression. That's my understanding, in a	
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### WIZNITZER - CROSS

1 nutshell, of what their case is.

2 The difficulty in that situation and why I 3 answered no is that it does not follow any biologic model of a measles infection of the brain, that's No. 4 1. And we do have biologic models that have been 5 6 present for generations of measles infection of the brain: Post-infectious encephalomyelitis, measles 7 8 inclusion body encephalitis, and SSPE. We have those. 9 So now we have nothing that follows along that's a time-proven infection model that affects the brain. 10 11 In addition to that, the only basis upon 12 which we're reaching this conclusion is Dr. 13 Kinsbourne's testimony. There is no physical evidence 14 that there is measles in the brain. Neuro- imaging 15 looks normal. There's no evidence there. 16 We have no spinal fluid to look at to see if 17 there's an inflammatory process. It was never done. 18 In other words, the workup that you would normally do 19 to say: Is there measles virus in the brain? is not 20 there. The virologist probably can give you some more sophisticated testing that might be appropriate, but 21 it's not been investigated, so people are saying: 22 23 Therefore, it must be there. 24 We don't have a biologic -- we're not following with the known biologic model. There's an 25 Heritage Reporting Corporation (202) 628-4888

WIZNITZER - FURTHER CROSS

1	invocation of a novel, never-heretofore-defined model			
2	that not even the minimal evaluation being done that			
3	would be done in a standard assessment of children			
4	with an infectious process of the brain.			
5	I don't function on hypotheticals; I don't			
6	function on speculation. I function on information			
7	and that's not here. Therefore, that's why my opinion			
8	is that whether or not there is a that whether or			
9	not there is truly a regressive autism, it doesn't			
10	matter.			
11	SPECIAL MASTER HASTINGS: All right. Any			
12	question?			
13	SPECIAL MASTER CAMPBELL- SMITH: I'd like to			
14	follow up with what Dr. Wiznitzer said.			
15	FURTHER CROSS-EXAMINATION			
16	BY MS. CHIN-CAPLAN:			
17	Q If you were to find a measles virus in			
18	spinal fluid how would affect your opinion?			
19	A Well, the question, define first of			
20	all			
21	Q If tests revealed that?			
22	A Well, if yoU do a test, we would actually			
23	culture a measles virus out of there, you'd find RNA,			
24	which is just a wholesale fingerprint.			
25	Q What would you need?			
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1775A

WIZNITZER - FURTHER CROSS

1776A

1	A What would I need? It's not enough to find		
2	a virus that's in there. You'd also have to find		
3	you'd also have to have the clinical picture that's		
4	consistent with the viral infection.		
5	Right now, we don't have a clinical picture.		
б	Again, there's a speculation that's present. In a		
7	way, you may find a virus in there, but it has nothing		
8	to do with the autism. It may be something that's		
9	there, you know, concurrently, just to give you		
10	there's several possibilities.		
11	One is: It's a lab error. Two is: It's real		
12	but it's not related to what's going on. Three is: It		
13	may be related to what's going on. If it's related to		
14	what's going on, we ought to be able to follow the		
15	biologic models that previously exist.		
16	I mean children have had exposure to measles		
17	virus for generations and generations and generations.		
18	We should see that there's a biologic model that fits		
19	that. Again, as I stated, if we posit a newer novel,		
20	biologic model, then we you need to get evidence		
21	that what you find there is directly related to what's		
22	going on in the brain that we see; there's evidence of		
23	inflammation in the brain, which is what we would see		
24	with the models that we have at the present time.		
25	We just we don't have that kind of		
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## WIZNITZER - FURTHER CROSS

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1 information.

2	Q So if I can rephrase what you've said to	
3	make sure that I understand: Even if you had that	
4	finding, the finding of measles, some presence,	
5	something having been tested in the cerebral spinal	
б	fluid	
7	A Yes.	
8	Q and there would an indication perhaps of	
9	measle virus there. That alone, in the absence of, as	
10	you described it, clinical findings, or a pattern that	
11	does not mimic what we know to be established	
12	biological models for measles virus in the brain, your	
13	opinion does not change?	
14	A My opinion can't it would not change.	
15	What I would need is more than just the virus. If you	
16	came to me and said: I have virus the other	
17	example, the other reason I'm giving you this is that	
18	we know the natural history of measles virus	
19	involvement in the brain.	
20	When you're looking at measles virus,	
21	irrespective of you know the ones that are	
22	persistent, and there are two that are persistent:	
23	MIBE and SSPE. The natural history, without	
24	intervention, is basically: neurologic deterioration	
25	and death.	

WIZNITZER - FURTHER CROSS 1 Therefore, if, in this case, you said: I've 2 found some virus, where is the rest of that pattern of 3 the neurologic impairment and neurologic 4 deterioration, the changes on imaging, things of that nature that we would expect normally to see when you 5 6 have a persistent virus that basically is causing, as 7 was stated, is continuing to injure the brain, 8 suggesting that it is a progressive process. It's 9 ongoing. I need a clinical history. If you give me 10 11 the clinical history, you give me the virus, and then 12 I would pay serious attention to these kinds of 13 claims. 14 SPECIAL MASTER HASTINGS: Any redirect for 15 this witness? 16 MR. MATANOSKI: We will, but we thought we'd 17 like to take a break. 18 SPECIAL MASTER HASTINGS: Let's take a 15-19 minute break at this point. We'll meet back at 3:30 20 p.m. 21 (Whereupon, a short recess was taken.) 22 THE CLERK: Please rise. 23 SPECIAL MASTER HASTINGS: All right. We're 24 back from our afternoon break. We're going to have the redirect exam of Dr. Wiznitzer. We have attorney 25 Heritage Reporting Corporation (202) 628-4888

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1 Johnson on for the Respondents, so please go ahead, 2 sir. 3 MR. JOHNSON: Thank you, sir. REDIRECT EXAMINATION 4 5 BY MR. JOHNSON: 6 Dr. Wiznitzer, on cross-examination, you 0 7 were asked a number of questions about your diagnostic 8 methods in your clinical practice, and then your use 9 of videos in this case. And I'd like to ask you some questions about that. First of all, when you reviewed 10 11 the videos, you already had a diagnosis for Michelle 12 Cedillo, is that right? 13 Α Yes, I did. 14 0 What was that diagnosis? 15 Α That she had an autistic disorder. 16 Did you have materials that were already 0 17 available to you from your review of the case files, 18 that supported that diagnosis? 19 Yes, I did. Α 20 0 What was the purpose of reviewing the 21 videos? 22 The purpose of reviewing the video tapes was Α 23 to time the onset of the autistic features, just 24 solely that. Are you familiar with studies that support 25 0 Heritage Reporting Corporation (202) 628-4888

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1 that the review of videos for that purpose can be 2 helpful?

3 A Yes, I am.

Q What kinds of things in the videos that you
reviewed were you looking at to help you establish the
time of onset of Michelle Cedillo's autism?

7 А I was looking for several things. No. 1, 8 and not necessarily in any specific order, I was 9 looking for the quality of communication behavior that she manifested. I was looking for the amount of 10 11 utterances, the amounts of vocalizations that she had, 12 the type of noises, or sounds that she made. Did I 13 hear any words at all during the entire time that, if 14 you took the tape out and listened to it without her 15 there, that it would be understood to be a word. I 16 didn't find that there were any words that I could 17 hear. I found that there was a decrease in the amount 18 of total utterances, which really means how much 19 talking -- or how many sounds she made. That's not 20 talking. How many sounds she made, the quality of the 21 sound that she made were actually delayed for age. 22 When they were, she was babbling at too late of an age 23 when she -- I'm sorry, she was making vowel sounds, 24 the A, O, E cooing-type noises, when she should have already been making babbling, consonant-vowel 25

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## WIZNITZER - REDIRECT

1 babbling, that was not there.

1	No. 2, I was looking for how she interacted		
2	with individuals in her environment. Did she provoke		
3	the interaction, did she promote the interaction,or		
4	was it that she was reacting to other people around		
5	her?		
6	I basically could find no consistent		
7	evidence that she was actually seeking out and		
8	promoting and provoking, and encouraging and		
9	initiating interaction with others in her environment.		
10	In addition to that, it took longer than you		
11	would normally expect for a child of her age, at the		
12	various ages that we saw in the video, to respond to		
13	basically social overtures, which includes		
14	verbalizations from family members. And there were		
15	some times when she there were many times, in fact		
16	the majority of the times when we didn't see a		
17	response in the timing that we should expect.		
18	That also includes the issue of joint		
19	attention, the ability to sustain and continue an		
20	interaction with others in her environment, which we		
21	clearly found that there was poor evidence of on the		
22	video. So there was nothing that was clearly		
23	consistent, and we would expect for a child in		
24	infancy, in the early second year of life.		
25	Lastly, and as telling as the other points,		
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#### WIZNITZER - REDIRECT

1	it was the presence of any repetitive behaviors. We
2	clearly saw on the video that she had a hand reguard
3	when it shouldn't be there. On the videos, part of
4	what I saw, part of other things that I reviewed, she
5	had hand mannerisms, including flapping and twisting
б	of the hand that we saw later on in the video tape
7	after she was clearly identified as having autism, and
8	with these behaviors being identified as being
9	autistic behaviors.

10 Basically, things falling into those four 11 categories: the presence of inappropriate repetitive 12 behaviors; the relative decrease in the amount of 13 joint attention that's expected for age; the 14 difference and the diminution of the quality and 15 quantity of vocalizations; and the decrease and 16 somewhat -- I want to use the word impairment in 17 shared affect, basically those four points which are 18 important in terms of trying to define whether you 19 have the early features of autism present during 20 infancy were there on the videotape, manifested both 21 on the review plus many other portions that we did not 22 review.

23 Q So, if I understand you correctly, you were 24 reviewing the video tapes to identify early signs of 25 abnormal behavior and developmental delays to

## WIZNITZER - REDIRECT

1	establish the time of onset, and not to establish the		
2	diagnosis of autistic disorders, that's correct?		
3	MR. POWERS: Special Master, I am loathe to		
4	interrupt with an objection, but this is a repeat of		
5	the direct testimony. This is really a redirect, this		
6	is a restatement of the direct testimony that we heard		
7	earlier.		
8	SPECIAL MASTER HASTINGS: Sometimes that has		
9	happened on redirect once or twice in my legal career		
10	and we let it go in.		
11	MR. JOHNSON: Thank you, sir. I'll move on.		
12	BY MR. JOHNSON:		
13	Q Dr. Wiznitzer, you were also asked a series		
14	of questions about an article by the lead author		
15	Vargas, a 2005 article; and you reviewed the article		
16	while you were testifying, I believe.		
17	Now does the Vargas article say anything		
18	about a chronic virus infection in any of the study's		
19	subjects?		
20	A No.		
21	Q Does the Vargas article mention the measles		
22	virus?		
23	A No.		
24	Q Does the Vargas article mention MMR?		
25	//		
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1784A WIZNITZER - REDIRECT 1 Α No. 2 Q Does the Vargas article mention glutamate? 3 Α No. Does the Vargas article adopt, in any way, 4 0 the hypothesis that Dr. Kinsbourne has put forward 5 6 about glutamate levels in the brain? 7 А No. 8 At the conclusion of that article, did the 0 9 authors draw any conclusions about whether neural inflammation, that they may have found, was the cause 10 11 of autism or the effect of autism? Did they make a 12 conclusion one way or the other? 13 No, they did not. Α 14 0 Doctor, I would finally like to ask you a 15 few questions about the Rubenstein article that you 16 testified about on direct, and then were asked 17 questions about on cross. 18 As Mr. Powers pointed out, there were three 19 terms used. There was: theoretical, hypothetical and 20 postulate. You're a peer reviewer, correct? 21 Yes. Α 22 When you read over that article, did 0 23 measles virus ever get mentioned in that article? 24 Α No. Did MMR ever get mentioned as playing any 25 0 Heritage Reporting Corporation (202) 628-4888

1785 WIZNITZER - REDIRECT 1 role in the hypothesis described in that article? 2 А No. 3 MR. JOHNSON: I believe that's all I have, 4 sir. 5 SPECIAL MASTER HASTINGS: All right. Any б recross, Mr. Powers? 7 MR. POWERS: No, no recross, Special Master. 8 SPECIAL MASTER HASTINGS: All right. I 9 assume that we're done with the evidence for today, 10 then. 11 MR. MATANOSKI: Yes, sir, but there is one 12 brief matter that I could take up perhaps before we 13 leave, for the record. 14 SPECIAL MASTER HASTINGS: Okay, go ahead. 15 MR. MATANOSKI: If we could approach the 16 bench. SPECIAL MASTER HASTINGS: Well, I have one I 17 18 want to do, maybe it's the same one. I have one that 19 I want to do on the record, which is the motion that 20 was filed yesterday by the Petitioners. It was filed 21 electronically in response to exclude the expert 22 report and testimony of Dr. Bustin. 23 Now, that wasn't called to my attention 24 until today, though it was electronically filed yesterday. I assume, by the reference to the expert 25 Heritage Reporting Corporation (202) 628-4888

1	report, Dr. Bustin filed the report as Respondent's		
2	Exhibit UU on May 31st. It is a very short motion.		
3	The motion notes that this report was filed		
4	on the eve of trial. It also says that it's		
5	duplicative that the government has filed other expert		
б	reports that address the same issue, which is the		
7	reliability of the O'Leary laboratory.		
8	I am going to deny the motion to exclude the		
9	expert report, and the testimony for the following		
10	reasons: As set forth in my evidentiary ruling, on a		
11	different matter that was filed last Friday, June 8th,		
12	into the record of this case. A number of documents		
13	in this case were filed late.		
	As a counselor, I'm sure you're painfully		
14	As a counselor, I'm sure you're painfully		
14 15	As a counselor, I'm sure you're painfully aware we took on a very ambitious timetable on the		
15	aware we took on a very ambitious timetable on the		
15 16	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked		
15 16 17	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for		
15 16 17 18	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for this hearing on relatively short notice, given the		
15 16 17 18 19	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for this hearing on relatively short notice, given the amount of issues, and the importance of the issues		
15 16 17 18 19 20	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for this hearing on relatively short notice, given the amount of issues, and the importance of the issues involved.		
15 16 17 18 19 20 21	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for this hearing on relatively short notice, given the amount of issues, and the importance of the issues involved. At one point, I set a date for the filing of		
15 16 17 18 19 20 21 22	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for this hearing on relatively short notice, given the amount of issues, and the importance of the issues involved. At one point, I set a date for the filing of evidence, a deadline of May 25th. A number of things		
15 16 17 18 19 20 21 22 23	aware we took on a very ambitious timetable on the Petitioners' suggestions; and everybody has worked enormously hard the last few months to get ready for this hearing on relatively short notice, given the amount of issues, and the importance of the issues involved. At one point, I set a date for the filing of evidence, a deadline of May 25th. A number of things were filed after that, including quite a few by the		

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## WIZNITZER - REDIRECT

1 to the other side filing a few things past that 2 deadline. 3 Other than the other two, there were two reports that came from the UK litigation file. Those 4 were a separate matter, and there was a separate 5 6 fairness issue. I ruled on that and the written 7 ruling was filed on June 8th. But, in terms of just 8 the lateness of the filling, neither side has objected 9 to the other's late filing with the exception of this. 10 I think there is also a special 11 circumstance, with respect to this report of Dr. 12 Bustin. That this report of Dr. Bustin, as I read it, 13 was an answer to an expert report of Dr. Hepner, filed 14 by the Petitioners on May 22. 15 Now the Petitioners, it's important that the 16 Petitioners' expert reports were due February 20th, 17 and four such expert reports were filed on February 18 20th; and Respondent's reports were then filed on 19 April 24th. 20 So when the Petitioners filed a fifth expert 21 report on May 22nd, and then a sixth one later than 22 that. At some time, even after the May 25th deadline, 23 the Respondent did file Dr. Bustin's expert report on 24 May 31st as a response to that. 25 So, in the context of those facts, the fact Heritage Reporting Corporation (202) 628-4888

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that quite a few documents from both sides had been filed after May 25th; and the fact that this report was a response to an expert report filed three months late itself, I feel that it's reasonable to allow it to be filed. It is also true that there are other expert

7 reports in the file here that address this issue, the 8 issue of the reliability of the O'Leary laboratory, 9 but our posture, throughout the eighteen year history 10 of the program that let each side file those expert 11 reports and present those experts that it wants to. 12 There may be more than one report on an issue, but we 13 will let the parties put in what they want, and we'll 14 consider it.

I do know that one of the experts that also addressed the issue. Dr. Gershon, the Respondent is not putting on any oral testimony from Dr. Gershon. So it may turn out to be somewhat duplicative. We really won't know until we hear the expert testimony, but I am going to deny the motion.

21 Tomorrow, we have the testimony of Dr.
22 Bustin and one other expert. Mr. Matanoski, who is
23 the other one for tomorrow, Dr. Ward?

24 MR. MATANOSKI: It's Dr. Ward, sir.

25 SPECIAL MASTER HASTINGS: Okay. So that

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1789A WIZNITZER - REDIRECT 1 ends my housekeeping matter. Did you want to --2 MR. MATANOSKI: That's it, sir. 3 SPECIAL MASTER HASTINGS: Was that the 4 matter you wanted to address? 5 MR. MATANOSKI: Actually, there is another 6 matter, but it's unrelated to housekeeping. Perhaps 7 we can do it off the record. 8 SPECIAL MASTER HASTINGS: All right. Is 9 there anything else we ought to do on the record today? 10 11 MR. MATANOSKI: No, sir. 12 SPECIAL MASTER HASTINGS: Okay. Well, then, 13 we are adjourned for the day. We will start again at 14 9:00 a.m. tomorrow morning with the testimony of Dr. 15 Ward and Dr. Bustin. 16 (Whereupon, at 3:53 p.m., the hearing in the 17 above-entitled matter was adjourned, to reconvene 18 Wednesday, June 20, 2007, at 9:00 a.m.) 19 11 20 11 21 11 22 11 23 11 24 11 11 25

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## REPORTER'S CERTIFICATE

DOCKET NO.:	98-916V
CASE TITLE:	Theresa Cedillo v. HHS
HEARING DATE:	June 19, 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 Office of Special Masters.

Date: June 19, 2007

Christina Chesley Official Reporter Heritage Reporting Corporation Suite 600 1220 L Street, N.W. Washington, D.C. 20005-4018