Government Concedes Vaccine-autism Case in Federal Court.

An 18-month-old child with an undiagnosed disease (mitochondrial disorder) developed symptoms of autism after receiving 9 vaccinations simultaneously, 2 of which contained mercury. The government has conceded that the vaccinations "significantly aggravated" the child's mitochondrial disorder, producing the autism-like symptoms.

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GOVERNMENT CONCEDES VACCINE-AUTISM CASE IN FEDERAL COURT

By David Kirby

After years of insisting there is no evidence to link vaccines with the onset of autism spectrum disorder (ASD), the US government has quietly conceded a vaccine-autism case in the Court of Federal Claims.

The unprecedented concession was filed on November 9, and sealed to protect the plaintiff's identify. It was obtained through individuals unrelated to the case.

The claim, one of 4,900 autism cases currently pending in Federal "Vaccine Court," was conceded by US Assistant Attorney General Peter Keisler and other Justice Department officials, on behalf of the Department of Health and Human Services, the "defendant" in all Vaccine Court cases.

The child's claim against the government -- that mercury-containing vaccines were the cause of her autism -- was supposed to be one of three "test cases" for the thimerosal-autism theory currently under consideration by a three-member panel of Special Masters, the presiding justices in Federal Claims Court.

Keisler wrote that medical personnel at the HHS Division of Vaccine Injury Compensation (DVIC) had reviewed the case and "concluded that compensation is appropriate."

The doctors conceded that the child was healthy and developing normally until her 18-month well-baby visit, when she received vaccinations against nine different diseases all at once (two contained thimerosal).

Days later, the girl began spiraling downward into a cascade of illnesses and setbacks that, within months, presented as symptoms of autism, including: No response to verbal direction; loss of language skills; no eye contact; loss of "relatedness;" insomnia; incessant screaming; arching; and "watching the florescent lights repeatedly during examination."

Seven months after vaccination, the patient was diagnosed by Dr. Andrew Zimmerman, a leading neurologist at the Kennedy Krieger

Children's Hospital Neurology Clinic, with "regressive encephalopathy (brain disease) with features consistent with autistic spectrum disorder, following normal development." The girl also met the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV) official criteria for autism.

In its written concession, the government said the child had a pre-existing mitochondrial disorder that was "aggravated" by her shots, and which ultimately resulted in an ASD diagnosis.

"The vaccinations received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder," the concession says, "which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of ASD."

This statement is good news for the girl and her family, who will now be compensated for the lifetime of care she will require. But its implications for the larger vaccine-autism debate, and for public health policy in general, are not as certain.

In fact, the government's concession seems to raise more questions than it answers.

1) Is there a connection between vaccines, mitochondrial disorders and a diagnosis of autism, at least in some cases?

Mitochondria, you may recall from biology class, are the little powerhouses within cells that convert food into electrical energy, partly through a complex process called "oxidative phosphorylation." If this process is impaired, mitochondrial disorder will ensue.

The child in this case had several markers for Mt disease, which was confirmed by muscle biopsy. Mt disease is often marked by lethargy, poor muscle tone, poor food digestion and bowel problems, something found in many children diagnosed with autism.

But mitochondrial disorders are rare in the general population, affecting some 2-per-10,000 people (or just 0.2%). So with 4,900 cases filed in Vaccine Court, this case should be the one and only, extremely rare instance of Mt disease in all the autism proceedings.

But it is not.

Mitochondrial disorders are now thought to be the most common disease associated with ASD. Some journal articles and other analyses have estimated that 10% to 20% of all autism cases may involve mitochondrial disorders, which would make them one thousand times more common among people with ASD than the general population.

Another article, published in the Journal of Child Neurology and co-authored by Dr. Zimmerman, showed that 38% of Kennedy Krieger Institute autism patients studied had one marker for impaired oxidative phosphorylation, and 47% had a second marker.

The authors -- who reported on a case-study of the same autism claim conceded in Vaccine Court -- noted that "children who have (mitochondrial-related) dysfunctional cellular energy metabolism might

be more prone to undergo autistic regression between 18 and 30 months of age if they also have infections or immunizations at the same time."

An interesting aspect of Mt disease in autism is that, with ASD, the mitochondrial disease seems to be milder than in "classic" cases of Mt disorder. In fact, classic Mt disease is almost always inherited, either passed down by the mother through mitochondrial DNA, or by both parents through nuclear DNA.

In autism-related Mt disease, however, the disorder is not typically found in other family members, and instead appears to be largely of the sporadic variety, which may now account for 75% of all mitochondrial disorders.

Meanwhile, an informal survey of seven families of children with cases currently pending in Vaccine Court revealed that all seven showed markers for mitochondrial dysfunction, dating back to their earliest medical tests. The facts in all seven claims mirror the case just conceded by the government: Normal development followed by vaccination, immediate illness, and rapid decline culminating in an autism diagnosis.

2) With 4,900 cases pending, and more coming, will the government concede those with underlying Mt disease -- and if it not, will the Court award compensation?

The Court will soon begin processing the 4900 cases pending before it. What if 10% to 20% of them can demonstrate the same Mt disease and same set of facts as those in the conceded case? Would the government be obliged to concede 500, or even 1,000 cases? What impact would that have on public opinion? And is there enough money currently in the vaccine injury fund to cover so many settlements?

When asked for a comment last week about the court settlement, a spokesman for HHS furnished the following written statement:

"DVIC has reviewed the scientific information concerning the allegation that vaccines cause autism and has found no credible evidence to support the claim. Accordingly, in every case under the Vaccine Act, DVIC has maintained the position that vaccines do not cause autism, and has never concluded in any case that autism was caused by vaccination."

3) If the government is claiming that vaccines did not "cause" autism, but instead aggravated a condition to "manifest" as autism, isn't that a very fine distinction?

For most affected families, such linguistic gymnastics is not so important. And even if a vaccine injury "manifested" as autism in only one case, isn't that still a significant development worthy of informing the public?

On the other hand, perhaps what the government is claiming is that vaccination resulted in the symptoms of autism, but not in an actual, factually correct diagnosis of autism itself.

4) If the government is claiming that this child does NOT have autism, then how many other children might also have something else that merely "mimics" autism?

Is it possible that 10%-20% of the cases that we now label as "autism," are not autism at all, but rather some previously undefined "look-alike" syndrome that merely presents as "features" of autism?

This question gets to the heart of what autism actually is. The disorder is defined solely as a collection of features, nothing more. If you have the features (and the diagnosis), you have the disorder. The underlying biology is the great unknown.

But let's say the government does determine that these kids don't have actual "autism" (something I speculated on HuffPost a year ago). Then shouldn't the Feds go back and test all people with ASD for impaired oxidative phosphorylation, perhaps reclassifying many of them?

If so, will we then see "autism" cases drop by tens, if not hundreds of thousands of people? Will there be a corresponding ascension of a newly described disorder, perhaps something like "Vaccine Aggravated Mitochondrial Disease with Features of ASD?"

And if this child was technically "misdiagnosed" with DSM-IV autism by Dr Zimmerman, how does he feel about HHS doctors issuing a second opinion re-diagnosis of his patient, whom they presumably had neither met nor examined? (Zimmerman declined an interview).

And along those lines, aren't Bush administration officials somewhat wary of making long-distance, retroactive diagnoses from Washington, given that the Terry Schiavo incident has not yet faded from national memory?

5) Was this child's Mt disease caused by a genetic mutation, as the government implies, and wouldn't that have manifested as "ASD features" anyway?

In the concession, the government notes that the patient had a "single nucleotide change" in the mitochondrial DNA gene T2387C, implying that this was the underlying cause of her manifested "features" of autism.

While it's true that some inherited forms of Mt disease can manifest as developmental delays, (and even ASD in the form of Rhett Syndrome) these forms are linked to identified genetic mutations, of which T2387C is not involved. In fact little, if anything, is known about the function of this particular gene.

What's more, there is no evidence that this girl, prior to vaccination, suffered from any kind of "disorder" at all- genetic, mitochondrial or otherwise. Some forms of Mt disease are so mild that the person is unaware of being affected. This perfectly developing girl may have had Mt disorder at the time of vaccination, but nobody detected, or even suspected it.

And, there is no evidence to suggest that this girl would have regressed into symptoms consistent with a DSM-IV autism diagnosis

without her vaccinations. If there was such evidence, then why on earth would these extremely well-funded government attorneys compensate this alleged injury in Vaccine Court? Why wouldn't they move to dismiss, or at least fight the case at trial?

6) What are the implications for research?

The concession raises at least two critical research questions: What are the causes of Mt dysfunction; and how could vaccines aggravate that dysfunction to the point of "autistic features?"

While some Mt disorders are clearly inherited, the "sporadic" form is thought to account for 75% of all cases, according to the United Mitochondrial Disease Foundation. So what causes sporadic Mt disease? "Medicines or other toxins," says the Cleveland Clinic, a leading authority on the subject.

Use of the AIDS drug AZT, for example, can cause Mt disorders by deleting large segments of mitochondrial DNA. If that is the case, might other exposures to drugs or toxins (i.e., thimerosal, mercury in fish, air pollution, pesticides, live viruses) also cause sporadic Mt disease in certain subsets of children, through similar genotoxic mechanisms?

Among the prime cellular targets of mercury are mitochondria, and thimerosal-induced cell death has been associated with the depolarization of mitochondrial membrane, according to the International Journal of Molecular Medicine among several others. (Coincidently, the first case of Mt disease was diagnosed in 1959, just 15 years after the first autism case was named, and two decades after thimerosal's introduction as a vaccine preservative.)

Regardless of its cause, shouldn't HHS sponsor research into Mt disease and the biological mechanisms by which vaccines could aggravate the disorder? We still do not know what it was, exactly, about this girl's vaccines that aggravated her condition. Was it the thimerosal? The three live viruses? The two attenuated viruses? Other ingredients like aluminium? A combination of the above?

And of course, if vaccine injuries can aggravate Mt disease to the point of manifesting as autism features, then what other underlying disorders or conditions (genetic, autoimmune, allergic, etc.) might also be aggravated to the same extent?

7) What are the implications for medicine and public health?

Should the government develop and approve new treatments for "aggravated mitochondrial disease with ASD features?" Interestingly, many of the treatments currently deployed in Mt disease (i.e., coenzyme Q10, vitamin B-12, lipoic acid, biotin, dietary changes, etc.) are part of the alternative treatment regimen that many parents use on their children with ASD.

And, if a significant minority of autism cases can be linked to Mt disease and vaccines, shouldn't these products one day carry an FDA Black Box warning label, and shouldn't children with Mt disorders be exempt from mandatory immunization?

8) What are the implications for the vaccine-autism debate?

It's too early to tell. But this concession could conceivably make it more difficult for some officials to continue insisting there is "absolutely no link" between vaccines and autism.

It also puts the Federal Government's Vaccine Court defense strategy somewhat into jeopardy. DOJ lawyers and witnesses have argued that autism is genetic, with no evidence to support an environmental component. And, they insist, it's simply impossible to construct a chain of events linking immunizations to the disorder.

Government officials may need to rethink their legal strategy, as well as their public relations campaigns, given their own slightly contradictory concession in this case.

9) What is the bottom line here?

The public, (including world leaders) will demand to know what is going on inside the US Federal health establishment. Yes, as of now, n=1, a solitary vaccine-autism concession. But what if n=10% or 20%? Who will pay to clean up that mess?

The significance of this concession will unfortunately be fought over in the usual, vitriolic way -- and I fully expect to be slammed for even raising these questions. Despite that, the language of this concession cannot be changed, or swept away.

Its key words are "aggravated" and "manifested." Without the aggravation of the vaccines, it is uncertain that the manifestation would have occurred at all.

When a kid with peanut allergy eats a peanut and dies, we don't say "his underlying metabolic condition was significantly aggravated to the extent of manifesting as an anaphylactic shock with features of death."

No, we say the peanut killed the poor boy. Remove the peanut from the equation, and he would still be with us today.

Many people look forward to hearing more from HHS officials about why they are settling this claim. But whatever their explanation, they cannot change the fundamental facts of this extraordinary case:

The United State government is compensating at least one child for vaccine injuries that resulted in a diagnosis of autism.

And that is big news, no matter how you want to say it.

NOTE: Full text of the government's statement is posted here.

David Kirby is the author of "Evidence of Harm -- Mercury in Vaccines and the Autism Epidemic, A Medical Controversy" (St. Martins Press 2005.