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ANOTHER AUTISM CASE WINS IN VACCINE COURT **By Robert F. Kennedy, Jr.**

http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html

On February 12, the federal "Vaccine Court" in Washington issued a sweeping ruling in three highly touted "test cases" against families who claimed that their children's autism had been caused by vaccines. The Special Masters in those three cases found that Petitioners failed to establish causation between MMR vaccines, the mercury-laced vaccine preservative thimerosal, and autism (the court decision, which is under appeal, deferred any finding on a thimerosal-only theory of causation). The rulings could have a significant precedential impact on some 5,000 families who opted to bring their cases in the Omnibus Autism Proceedings (OAP) hoping that the vaccine court would officially hold that the MMR vaccine or thimerosal had caused autism in their children.

The *New York Times* joined the government Health Agency (HRSA) and its big pharma allies hailing the decisions as proof that the scientific doubts about vaccine safety had finally been "demolished." The US Department of Health and Human Services said the rulings should "help reassure parents that vaccines do not cause autism." The *Times*, which has made itself a blind mouthpiece for HRSA and a leading defender of vaccine safety, joined crowing government and vaccine industry flacks applauding the decisions like giddy cheerleaders, rooting for the same court that many of these same voices viscerally derided just one year ago, after Hannah Poling won compensation for her vaccine induced autism.

But last week, the parents of yet another child with autism spectrum disorder (ASD) were awarded a lump sum of more than \$810,000 (plus an estimated \$30-40,000 per year for autism services and care) in compensation by the Court, which [ruled that the measles-mumps-rubella \(MMR\) vaccine had caused acute brain damage](#) that led to his autism spectrum disorder.

The family of 10-year-old Bailey Banks won their case quietly and without fanfare in June of 2007, but the ruling has only now come to public attention. In the remarkably clear and eloquent decision, Special Master Richard Abell ruled that the Banks had successfully demonstrated that "the MMR vaccine at issue actually caused the conditions from which Bailey suffered and continues to suffer."

Bailey's diagnosis is Pervasive Developmental Disorder -- Not Otherwise Specified (PDD-NOS) which has been recognized as an autism spectrum disorder by CDC, HRSA and the other federal health agencies since at least the 1990s.

In his conclusion, Special Master Abell ruled that Petitioners had proven that the MMR had directly caused a brain inflammation illness called acute disseminated encephalomyelitis (ADEM) which, in turn, had caused the autism spectrum disorder PDD-NOS in the child:

The Court found that Bailey's ADEM was both caused-in-fact and proximately caused by his vaccination. It is well-understood that the vaccination at issue can cause ADEM, and the Court found, based upon a full reading and hearing of the pertinent facts in this case, that it did actually cause the ADEM. Furthermore, Bailey's ADEM was severe enough to cause lasting, residual damage, and retarded his developmental progress, which fits under the generalized heading of Pervasive Developmental Delay, or PDD . The Court found that Bailey would not have suffered this delay but for the administration of the MMR vaccine, and that this chain of causation was... a proximate sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay.

The Bailey decision is not an isolated ruling. We now know of at least two other successful ADEM cases argued in Vaccine Court. More significantly, an explosive investigation by CBS News has found that since 1988, the vaccine court has awarded money judgments, often in the millions of dollars, to thirteen hundred and twenty two families whose children suffered brain damage from vaccines. In many of these cases, the government paid out awards following a judicial finding that vaccine injury lead to the child's autism spectrum disorder. In each of these cases, the plaintiffs' attorneys made the same tactical decision made by Bailey Bank's lawyer, electing to opt out of the highly charged Omnibus Autism Proceedings and argue their autism cases in the regular vaccine court. In many other successful cases, attorneys elected to steer clear of the hot button autism issue altogether and seek recovery instead for the underlying brain damage that caused their client's autism.

Medical records associated with these proceedings clearly tell the tale. In perhaps hundreds of these cases, the children have all the classic symptoms of regressive autism; following vaccination a perfectly healthy child experiences high fever, seizures, and other illnesses, then gradually, over about three months, loses language, the ability to make eye contact, becomes "over-focused" and engages in stereotypical head banging and screaming and then suffers developmental delays characteristic of autism. Many of these children had received the autism diagnosis. Yet the radioactive word "autism" appears nowhere in the decision.

Instead the vaccine court Special Masters rest their judgments on their finding that the vaccines caused some generalized brain injury, mainly Encephalopathy/encephalitis (brain inflammation) or "seizure disorders" -- conditions known to cause autism-like symptoms. A large number of the children who have won these judgments have been separately diagnosed with autism. HRSA acknowledged this fact in a recent letter, but told us it does not keep data on how many of these children were autistic.

The Vaccine Court, in other words, seems quite willing to award millions of dollars in taxpayer funded compensation to vaccine-injured autistic children, so long as they don't have to call the injury by the loaded term "autism." That hazard is particularly acute for vaccine victims who appear before the Omnibus Autism Proceedings (OAP). Since that body's decisions are closely watched, published and accorded the weight of precedent, many lawyers consider the burden of proof for petitioners to be impossibly high before the OAP Panel. It was for this reason that Bailey's attorney, Mark McLaren, elected to opt out of the OAP and try his case separately, even

though Bailey has been receiving autism-related services in his home state and was eligible to file a case in the Court's Omnibus Autism Proceedings (OAP).

McLaren told us he wanted to avoid the added burden facing petitioners under the media glare and precedential weight attending OAP panel trials. "We considered because is on the autistic spectrum of disorders, but we thought we could try it separately and apart from the Omnibus, and not as a test case," explained McLaren. "We thought we'd have a better chance if we tried to on its own merit, away from the spotlights and the precedent setting pressures that attend these OAP test cases - and it worked."

Bob Krakow, a leading attorney for vaccine damaged children told that many lawyers are now convinced that filing a claim in the OAP is a losing proposition. "There's a growing conviction that if you have a autistic client who has also been diagnosed with encephalopathy/encephalitis or seizure disorder, you are better off not mentioning the word "autism" if you want to win the case." He recommended instead filing a non autism claim like "mental retardation with seizure disorder" for an autistic client.

Although the vaccine court is mandated to fairly serve the victims of vaccine injuries, their primary purpose and *raison d'etre* is to protect the vaccine program and vaccine makers. Damages are doled out from a 75-cent tax on every vaccine sold and not from the vaccine makers. "You can understand why special masters, burdened with their duty to protect vaccine programs, might be unwilling to make the direct causal link between autism and vaccines," Krakow observed. "If you ask the big question and answer it in the affirmative, there is a sense that it will damage the vaccine program irreparably."

Vaccine Court judges are equipped with a draconian armory of weapons deployable against plaintiffs intent on proving the causal connection between vaccines and autism. Jury trials are prohibited. Damages are capped; awards for pain and suffering are strictly limited and punitive damages banned altogether. Vaccine defenders have an army of Department of Justice attorneys with virtually unlimited resources for expert witnesses and other litigation costs. Plaintiffs, in contrast, must fund the up front costs for experts on their own. In a cultural choice that clearly favors defendants, vaccine court gives overwhelming weight to written medical records which are often inaccurate -- over all other forms of testimony and evidence. Observations by parents and other caretakers are given little weight.

Worst of all -- plaintiffs have no right to discovery either against the pharmaceutical industry or the government. Since autism is a behavioral affliction rather than a precisely defined biological injury -- epidemiological studies are critical to establishing its causation. But the greatest source of epidemiological data is the Vaccine Safety Datalink (VSD) -- the government maintained medical records of hundreds of thousands of vaccinated children -- which HHS has gone to great lengths to keep out of the hands of plaintiffs' attorneys and independent scientists. Unfortunately the vaccine court has judicially anointed this corrupt concealment by consistently denying every motion by petitioners to view the VSD. The raw data collected in the VSD would undoubtedly provide the epidemiological evidence needed to understand the relationship between vaccines and autism. The absence of such studies makes it easy for judges to say to plaintiffs they have not met their burden of ! proving causation.

Meanwhile, CDC has actively, openly and systematically suppressed and defunded epidemiological studies that might establish a causal link. CDC has ignored repeated pleadings that it fund peer reviewed studies of unvaccinated American cohorts like the Amish and home-schooled children. At the same time the agency has worked overtime ginning up a series of fatally-flawed European studies purporting to dispute the link. Even a cursory critical examination reveals that the oft-cited Danish, English, and Italian studies are rank tobacco science. Many of them were funded by CDC, a badly compromised agency, performed by vaccine industry scientists, and published in miserably conflicted journals.

Needless to say, the existence of these phony studies, combined with the deliberate dearth of epidemiological evidence makes it easy for the special masters to dodge a politically explosive finding by holding that there is "insufficient evidence."

And, speaking of tobacco, it's worth recalling that for sixty years the tobacco industry successfully defended a product that was killing one out of every five of its customers against thousands of legal actions brought by its victims and their families. Tobacco lawyers protected the cigarette companies by arguing that there was no proven link between tobacco and lung cancer. Bob Krakow sees many parallels. Big tobacco uses the same tactic of manufacturing research that seems to dispute the connection to exploit the burdens on plaintiffs to prove causation. Big tobacco prevailed for six decades even without the help of supportive government agencies deliberately suppressing real science and research. In that sense vaccine victims must leap a much higher hurdle.

Despite the perilous odds stacked against them in vaccine court, the evidence of a vaccine/autism link is so strong that vaccine court judges and government agencies have now recognized at least two theories of how vaccines cause autism: the Vaccine-to-ADEM-to-ASD link in Bailey Banks' case, and vaccine-induced aggravation of an underlying mitochondrial dysfunction that caused full-blown autism in the Hannah Poling case. Both theories are different from those rejected in the three cases last week.

Perhaps, these new disclosures will prompt *The Times*, with all its influence, to actually make prudent journalistic inquiries into the phony science CDC uses to defend its claims of "vaccine safety." If it does, the paper will realize it has once again been ill used by government agencies in a tragic campaign of public deceit. The *Times* should make the reasonable demand that the government health agencies finally release the Vaccine Safety Datalink for independent scientific research and that CDC and HRSA lift their opposition to genuine epidemiological studies that might finally provide real scientific answers to this debate.

A NEW THEORY OF AUTISM CAUSATION?

By David Kirby

A ruling from Federal Vaccine Court -- that MMR vaccine caused an autism spectrum disorder in a young boy named Bailey Banks -- flies directly in the face of the triple-play decision against a vaccine-autism link issued by the Court on February 12.

The Special Masters in those three cases inferred that the vaccine-autism theory was the stuff of Alice in Wonderland fantasy, and virtually accused the childrens'

physicians of medical malpractice. (CNN's Dr. Sanjay Gupta called the Court's language "snide," and we agree).

Meanwhile, the US Department of Health and Human services said the rulings should "help reassure parents that vaccines do not cause autism." But why should parents feel reassured when two out of five autism cases (40%) - that we know of - have won taxpayer-funded compensation in Vaccine Court?

The Ruling

In his decision, Special Master Abell ruled that the MMR vaccine produced a side effect in Bailey called acute disseminated encephalomyelitis (ADEM). ADEM is a neurological disorder characterized by inflammation of the brain and spinal cord. The disorder results in damage to the myelin sheath, a fatty coating that insulates nerve fibers in the brain. ADEM can be caused by natural infections, especially from the measles virus. But it also is a recognized post-vaccination injury, especially from vaccines for rabies, pertussis, influenza, and MMR.

Evidence presented to support an MMR-ADEM link was compelling. It included a 1994 report from the Institute of Medicine that said it was biologically plausible for a vaccine to "induce... an autoimmune response... by nonspecific activation of the T cells directed against myelin proteins."

In fact, both parties in the Banks case agreed "that the IOM has cited demonstrative evidence of a biologically plausible relation between the measles vaccine and demyelinating diseases such as ADEM," the Court wrote.

Most cases of ADEM (80%) are in children. Symptoms usually appear within a few days to a couple of weeks. They include: headache, delirium, lethargy, seizures, stiff neck, fever, ataxia (incoordination), optic nerve damage, nausea, vomiting, weight loss, irritability and changes in mental status.

I know of thousands of parents who witnessed many of these same symptoms afflict their children shortly after vaccination, most typically the MMR. Did these children with autism also suffer initially from ADEM or some subclinical version of the disorder? We may never know (physical signs like myelin damage are transitory).

Bailey Banks was given an MRI when his parents brought him to the hospital 16 days after his MMR vaccine, and that helped confirm his diagnosis. The children I know who were brought in with similar symptoms were instead given Tylenol and told to go home.

(Interestingly, Tylenol can affect production of glutathione, an essential antioxidant and detoxifier. A preliminary study from UC San Diego showed that children who were given Tylenol after their MMR vaccine were several times more likely to develop autism than other children. "Tylenol and MMR was significantly associated with autistic disorder," the authors wrote. "More research needs to be completed to confirm the results of this preliminary study.")

Is vaccine-induced ADEM (and similar disorders) a neurological gateway for a subset of children to go on and develop an ASD? That question will now become subject to debate. Thousands of parents have reported similar reactions and symptoms following vaccination, yet they lack radiological proof of ADEM or related disorders in the form of an MRI. Meanwhile, most children with autism do not present with myelin damage, but many do test positive for antibodies to myelin basic protein (MBP).

Also worth noting is that ADEM causes an inflammatory response in the brain, primarily in the microglial cells. It is also associated with abnormal cytokine levels in the brain, and with autoimmunity. Autism, meanwhile, has been linked to brain inflammation, microglial cell activation, cytokine imbalances, and autoimmunity.

In most cases, symptoms of ADEM disappear within a few weeks or so, and the disorder may be treated with IV cortisone to help reduce inflammation. But none of the children with autism that I know were ever examined or treated for a possible case of ADEM or other acute cases of encephalitis/demyelinating disorder. By now, their myelin damage may have repaired itself, yet the damaging agents, (MBP antibodies), persist.

ADEM is said to be rare, but the disorder may be grossly under-diagnosed (or misdiagnosed). Even the government's chief witness against Bailey's case testified that he sees patients with ADEM "on a fairly regular basis." What's more, Bailey's was the third successful vaccine-ADEM case argued in Vaccine Court (that we know of) so far.

Can ADEM Cause PDD/ASD?

Special Master Abell had no trouble linking MMR to ADEM in Bailey Banks' case. But linking his ADEM to PDD/ASD was more difficult.

There is no medical literature to support an ADEM-PDD link. The government's expert witness, Dr. John MacDonald, testified that "all the medical literature is negative in that regard." Instead, he proposed an alternative hypothesis for Bailey's PDD (he suggested it was caused by glucose transporter 1 deficiency).

But Special Master Abell berated the government's witness in much the same way that Hastings et al. had criticized witnesses for the families in their three cases.

"This (glucose) hypothesis, which (MacDonald) declined to incorporate as a plausible, probable theory of explanation, was used by Respondent to blunt Petitioner's theory of ADEM," Abell wrote. "This hypothesis was not given to a reasonable degree of medical probability or certainty, and Respondent's expert admitted that it was merely 'a possible, not necessarily a probable diagnosis.'"

Abell also chided MacDonald for his assertion that "all the medical literature is negative" in regards to an ADEM-PDD link. "However, soon thereafter, he corrected this statement by clarifying, 'I can find no literature relating ADEM to autism or,'" Abell wrote. "It may be that Respondent's research reveals a dearth of evidence linking ADEM to PDD, but that is not the same as positive proof that the two are unrelated, something Respondent was unable to produce. Therefore, the statement that 'all the medical literature is negative' is incorrect."

The Court also took MacDonald to task for insisting that Bailey's initial symptoms were not 100% consistent with the signs of ADEM. "His distinction seems one of degree, not of type, and strikes as a trifle semantic," Abell sniffed. He also noted that MacDonald was having a hard time determining Bailey's current diagnosis. "He ultimately concluded that 'Bailey falls into the large group of children with autism/PDD in which by our current evidence-based medicine we rarely can make a specific diagnosis.'"

Special Master Abell seemed to lend more credence to witnesses for the Banks family.

Chief among them was Dr. Ivan Lopez, a neurologist and psychiatrist. Dr. Lopez testified that "the majority of patients with ADEM improve significantly," but added that "the exception to this rule is when patients have been exposed to measles, just like in the case of MMR vaccine," in which case subsequent brain damage "may occur in up to 50 percent of patients." He said such events include "mental syndromes such as PDD and others," and opined that "up to 50 percent of patients...who have had ADEM will show (PDD) as a consequence."

Dr. Lopez, a member of the US Military, gave his testimony by phone from Mobile, AL where, the next day, he was to ship out for a tour of duty in Iraq.

In his conclusion, Special Master Abell wrote:

The Court found that Bailey's ADEM was both caused-in-fact and proximately caused by his vaccination. It is well-understood that the vaccination at issue can cause ADEM, and the Court found, based upon a full reading and hearing of the pertinent facts in this case, that it did actually cause the ADEM. Furthermore, Bailey's ADEM was severe enough to cause lasting, residual damage, and retarded his developmental progress, which fits under the generalized heading of Pervasive Developmental Delay, or PDD. The Court found that Bailey would not have suffered this delay but for the administration of the MMR vaccine, and that this chain of causation was not too remote, but was rather a proximate sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay.

And he added this:

Petitioner's theory of PDD caused by vaccine-related ADEM causally connects the vaccination and the ultimate injury, and does so by explaining a logical sequence of cause and effect showing that the vaccination was the ultimate reason for the injury.

Does Bailey Banks Have Autism?

Bailey Banks does not have "classic" or full-blown autism. But he has been diagnosed with PDD-NOS, which is squarely on the autism spectrum of disorders. There was quite a bit of back-and-forth on Bailey's diagnosis in the ruling, whose heading included the term "Non-autistic developmental delay." At several points in the proceedings, witnesses took great pains to say that Bailey does not have "autism" which, technical speaking, is true.

On the other hand, Special Master Abell included notations declaring that "Pervasive Developmental Delay describes a class of conditions, and it is apparent from the record that the parties and the medical records are referring to Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)."

Even so, some will argue that Bailey does not have an ASD. They are simply wrong. The diagnosis of PDD-NOS was added to the list of autism spectrum disorders in the 1980s. It was precisely from the inclusion of these "milder" cases into the total number, that the CDC came up with the estimate of 1-in-150 US children with some form of "autism/ASD."

So, if Bailey does not have ASD, then the number of "autism" cases is well below the 1-in-150 mark and needs to be revised downward (the CDC once estimated that 40% of ASD cases were "non-autistic" in the classic sense).

What's more, Bailey does not have a "mild" form of ASD -- he struggles every day with endless challenges. He receives autism services in his home state and attends a

special school for children with autism. Bailey was also completely eligible to file a case in the Court's Omnibus Autism Proceedings (OAP), along with 5,000 other claims.

And besides, if the government chooses after-the-fact to argue that Banks simply has another form of brain damage but not, specifically "autism," is that really any comfort?

This particular theory of causation -- Vaccine-to-ADEM-to-ASD -- is different from the three cases that lost, and different than the theory in the Hannah Poling case (vaccine-induced aggravation of an underlying mitochondrial dysfunction caused full-blown autism).

So we now have two novel theories of how vaccines might contribute to ASD -- both ADEM and mitochondrial dysfunction are recognized by the Court as contributing factors.

And yet the government insists it has never made an award for vaccine induced ASD, just vaccine related ASD.

"The government has never compensated, nor has it ever been ordered to compensate, any case based on a determination that autism was actually caused by vaccines," said David Bowman, a spokesman for HHS's Health Resources and Services Administration. "We have compensated cases in which children exhibited an encephalopathy, or general brain disease. Encephalopathy may be accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures."

"Some children who have been compensated for vaccine injuries may have shown signs of autism before the decision to compensate," he added, "or may ultimately end up with autism or autistic symptoms, but we do not track cases on this basis.

Unfortunately, the track record on vaccines is cloudy in this particular Court: Three out of four ADEM cases have been successful; and (at least) two out of five ASD cases have also won.

People will argue that ADEM is rare; that vaccines "only" caused PDD in Bailey; and that this was a legal and not scientific decision. The problem is we don't know how prevalent ADEM is because we never looked; while "PDD" is interchangeable with "ASD" in the language of public health. And, the three cases that lost were also "legal" decisions.

Robert Kennedy, Jr. and I would love nothing more than to reassure parents that the nation's current vaccine program is 100% safe for all kids, and that zero credible evidence has been presented to link vaccines with autism. But that simply isn't true - - as at least two court cases have found.

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