

## **THE EVIDENCE SHOWS THAT VACCINES CAUSE “MENTAL RETARDATION”\***

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Michele Bachmann was ferociously criticized last week for making presumably unfounded statements about injuries caused by the human papillomavirus (“HPV”) vaccine. Were her statements crazy? While her claims may have missed the mark and utilized imprecise terms, perhaps the claim that vaccines can cause “mental retardation” is not so irresponsible, after careful examination. While there is no evidence that the HPV vaccine causes “mental retardation” there is evidence that it causes neurological problems, brain injury and associated cognitive problems.<sup>1</sup> And there is evidence, as we document below, that vaccines can and do cause “mental retardation.”

On September 12, 2011, Republican Presidential candidate Michele Bachmann publicly stated in connection with a campaign controversy over mandated vaccines for human papillomavirus (“HPV”),

The problem is, it comes with some very significant consequences. There’s a woman who came up crying to me tonight after the debate. She said her daughter was given that vaccine. She told me her daughter suffered mental retardation as a result of that vaccine. There are very dangerous consequences. It’s not good enough to take, quote, “a mulligan” where you want a do-over, not when you have little children’s lives at risk.<sup>2</sup>

The firestorm of rebuke against Rep. Bachmann has been startling, but is itself plagued with a faulty premise. CNN’s anchor Anderson Cooper, and various political

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<sup>1</sup> From 2006-2009 there were many reports of adverse events associated with Gardasil reported to the governments Vaccine Adverse Event Reporting System (VAERS). There were a total of 13,115 adverse event reports, 269 of which involved life-threatening injuries, 1444 hospitalizations and 456 involving some type of disability. Souayah, Nizar et al. 2011. “Guillain-Barré syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009.” *Vaccine* 29(5): 886–889.

<sup>2</sup> <http://factcheck.org/2011/09/an-antidote-for-bachmanns-anecdote/> (accessed September 17, 2011).

analysts and advisers filled a chorus of criticism, with Cooper, for example, suggesting that Rep. Bachmann's statement was "incredibly irresponsible". Cooper, calling Bachmann's statement an "all out falsehood, a dangerous falsehood", reported that the CDC has said that the HPV vaccine has "no link, whatsoever, to the onset of "mental disabilities." Political pundits such as Harvard Kennedy School of Government's David Gergen saw Bachmann's statement as "anti-science".<sup>3</sup> The crescendo of challenge reached its zenith when Arthur Caplan, Professor of Bioethics at Pennsylvania University, in a most novel method of advancing presumed medical ethical precepts, offered a \$10,000 contribution to a charity of Rep. Bachmann's choice if she could produce proof of the claim that an HPV vaccine has caused mental retardation.<sup>4</sup>

An important point about vaccine safety has been lost, however, in the misplaced public debate over Rep. Bachmann's statement. The pundits and professorial bioethicists have rallied with zeal to the defense of HPV vaccines, along with Gov. Rick Perry who signed a law mandating the vaccine for teenage girls, without acknowledging the serious questions about the vaccine's safety. There have been thousands of adverse event reports regarding Gardasil over the four years since the Advisory Committee on Immunization Practice of the CDC recommended<sup>5</sup> the vaccine for girls age 9 and up.<sup>6</sup> Pundits have failed to note that there was concern at the outset regarding the CDC's recommendation favoring

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<sup>3</sup> AC – 360 "Has Michele Bachmann told her last lie", [http://www.youtube.com/watch?v=lgQuZLlrMmc&feature=player\\_embedded](http://www.youtube.com/watch?v=lgQuZLlrMmc&feature=player_embedded) (accessed September 18, 2011).

<sup>4</sup> "Ethicist to Bachmann: Show me the Proof : \$10,000 wager to produce HPV vaccine victim", <http://ac360.blogs.cnn.com/2011/09/15/caplan-to-bachmann-prove-hpv-claim/>

<sup>5</sup> ACIP proceedings recommending Gardasil: <http://www.cdc.gov/vaccines/recs/acip/downloads/min-archive/min-jun06.txt>

<sup>6</sup> From 2006-2009 there were many reports of adverse events associated with Gardasil reported to the governments Vaccine Adverse Event Reporting System (VAERS). There were a total of 13,115 adverse event reports, 269 of which involved life-threatening injuries, 1444 hospitalizations and 456 involving some type of disability. Souayah, Nizar et al. 2011. "Guillain-Barré syndrome after Gardasil vaccination: data from Vaccine Adverse Event Reporting System 2006-2009." *Vaccine* 29(5):886–889

the vaccine, because of concerns about safety, which have never been adequately evaluated. Even one of the scientists who helped develop the vaccine, Diane Harper of Dartmouth University, raised serious questions about the safety of the first and most commonly administered HPV vaccine, Gardasil, because of concerns about adverse events associated with the vaccine.<sup>7</sup>

Rep. Bachmann referred to an HPV vaccine causing “mental retardation”, a very unlikely event since HPV vaccines are recommended for girls 9 years of age and older. “Mental retardation” is not a condition that is likely to occur in an individual who has reached an advanced age without previous evidence of cognitive or learning problems. Rather, it is likely that cognitive deficits afflict some individuals who have been injured by the Gardasil vaccine, and these have been documented.<sup>8</sup>

Interestingly, the pundits and professors displayed considerable zeal in claiming that vaccines are safe, expressing outrage and doubt about a claim that a vaccine could cause “mental retardation” or even other types of serious cognitive problems in children. These comments relate, no doubt, to claims that vaccines have caused “autism” in children, a controversy that has been raging for at least a decade. The claim has reportedly, been “debunked by science” as it was explained by a media commentator.<sup>9</sup>

In our recent law review article, *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, we uncovered many cases where children with “autism” and other cognitive disorder were compensated for vaccine injury. We questioned the dismissal of the claim that vaccines can

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<sup>7</sup> <http://www.actions-traitements.org/spip.php?breve4601>

<sup>8</sup> ACIP proceedings recommending Gardasil:  
<http://www.cdc.gov/vaccines/recs/acip/downloads/min-archive/min-jun06.txt>

<sup>9</sup> AC – 360 “Has Michele Bachmann told her last lie”,  
[http://www.youtube.com/watch?v=1gQuZL1rMmc&feature=player\\_embedded](http://www.youtube.com/watch?v=1gQuZL1rMmc&feature=player_embedded) (accessed September 18, 2011).

cause “autism” and pointed to documented and verified instances that contravened the evidence that claimed to “debunk” the association.<sup>10</sup>

On reviewing the most recent controversy, we conducted a preliminary examination of the legal literature reporting whether vaccines can cause “mental retardation”, something that pundits rebutting Rep. Bachmann seem very sure about. We easily found clear examples of reported cases in the legal literature showing that there has existed credible evidence, going back 50 years, that vaccines have had a causal relationship with “mental retardation”. While the legal process employs standards that are different from a focused scientific inquiry, the cases we found provide support for the claim, based on the evidence provided by medical doctors, that vaccines have, indeed, caused “mental retardation.”

In presenting what we have found we acknowledge that our data raises more questions than it resolves. But this is the point. “Science” cannot point to studies showing that vaccines are completely safe. Credible information supported by medical experts, to the contrary, shows that vaccines can cause serious neurological injury, like “mental retardation.” “Science” has not revealed to date the precise mechanism by which such injuries occur. The scientific evidence is incomplete, as reflected in a recent Institute of Medicine review of specific issues related to the safety of selected vaccines, which reported that for most questions regarding vaccine safety scientific investigation is incomplete and inconclusive.<sup>11</sup>

We have cited four cases below, selected from many that are easily located, that clearly show the connection between vaccine injury and "mental retardation". Some of these

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<sup>10</sup>Mary Holland, Louis Conte, Robert Krakow, and Lisa Colin, *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 Pace Evol. L. Rev. 480 (2011). Available at: <http://digitalcommons.pace.edu/pelr/vol28/iss2/6>

<sup>11</sup> IOM (Institute of Medicine). 2011. *Adverse Effects of Vaccines: Evidence and Causality*. Washington, DC: The National Academies Press. Available at: <http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

cases go back decades. Notably, the decisions finding that vaccine injury caused "mental retardation" are supported by expert medical testimony. It has long been understood that vaccine injury can result in permanent neurological damage.

To the specific point about "mental retardation" and vaccines raised by Rep. Bachmann the evidence dates back 50 years.

### Case 1

In the early 1960's physicians at the Mayo clinic diagnosed a little boy with *retardation in mental and motor development*, visual impairment, and infantile spasms or myoclonic jerks with atypical hypsarrhythmia. They recommended treatment that was completed in 1962. After the treatment, the boy's seizures ceased. After a second treatment the boy suffered a permanent spastic diplegia rendering him fully dependent on his parents. The parents brought a lawsuit years later when their son was in his 30's.

The Chief Special Master presiding over the case determined that the evidence showed actual causation. In particular, the Chief Special Master relied on new evidence showing Quadragen's propensity to cause myoclonic seizures, encephalopathies, and other neurological insults in infants. The Claims Court adopted the Chief Special Master's recommended compensation award.

A panel of the U.S. Court of Appeals determined that the claimants produced a sufficient evidence to show actual causation. In addition, the appeals court panel pointed out that the reviewing judges in the lower courts determined that there was insufficient evidence that the child's injury was caused by factors unrelated to the vaccine.

*Grant v. Sec'y of Dept. of Health & Human Services*, 956 F.2d 1144, 1146 (Fed. Cir. 1992)

### Case 2

In this case, a court reported the following in connection with a claim regarding

seizures associated with vaccine injury,

Many experts in vaccine cases have testified that mental retardation and other neurological deficits are likely to accompany intractable seizure disorders in young children, although not in every case. The outcome of convulsive status epilepticus (SE) is variable, however, a series of studies by renowned epileptologist, Jean Aicardi, found a high incidence of mental deficits following SE. Studies by Fujiwara, *et al.*, found similar results and a high incidence of motor damage as well. In the Aicardi series, seizures occurring after SE were mainly of a type “usually associated with brain damage.” Aicardi concluded: ‘Convulsive seizure may end in death or may leave *severe mental and/or neurological sequelae* that appear to result, at least in part, from the convulsive activity itself, irrespective of its causes.’ Jean Aicardi, *Epilepsy in Children*, Raven Press, N.Y., at 243, 258. According to Aicardi, poor prognosis in some types of seizure disorders is often associated with early age of onset. *Id.* at 6, 36, 52, and 160.

*Lurtz v. Sec'y of Dept. of Health & Human Services*, 90-1703 V, 1998 WL 321926 (Fed. Cl. June 4, 1998)

### Case 3

In Case 3, a child met developmental milestones for a period after his initial seizures that an expert found consistent with vaccine causation. Initial seizures, which were relatively brief, had little impact on his neurological development, but subsequent seizures, which “became intractable and uncontrolled by medication,” caused much more significant cognitive deficits. The Court cited Case 2 above, *Lurtz*, that noted that “[m]any experts in vaccine cases have testified that *mental retardation* and other neurological deficits are likely to accompany intractable seizure disorders in young children”). In *Almeida*, for example, the special master explicitly rejected the government's contention that evidence of brain injury from the DPT vaccine will manifest itself immediately. Instead, the special master credited the testimony of the claimant's expert who explained that:

In cases of severe seizure disorders, the initial MRI is more commonly negative than it is positive, regardless of the cause of the disorder. In vaccine injury, both MRI's and CT scans will be normal initially. Over the years, one might expect to observe cerebral atrophy, but one would not observe it right away. *Customarily, one will observe no immediate markers to identify a DPT injury other than its clinical course....* If the condition continues, pathology can be later identified ... but would not

indicate what caused the injuries.

*Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Services*, 569 F.3d 1367, 1381-82 (Fed. Cir. 2009)

#### Case 4

In this case parents brought a claim for damages for the vaccine-related injury of their son. They alleged that as a result of the administration of a DPT vaccine he suffered a hypotonic-hyporesponsive collapse and/or encephalopathy and residual seizure disorder. The parents further maintain that the injuries resulted in permanent disabilities involving significant developmental delay, moderate autistic characteristics, and *mental retardation*...

The court found that the claimants were entitled to compensation, concluding that the DPT was the presumed cause.

*Sorenson v. HHS*, 1990 WL 290491 (Cl. Ct.)

#### Comment on “Causation” and the Limitation of Science and Its Terminology

In offering these examples of support for the proposition that vaccines can and have caused “mental retardation” along with neurological deficits and other cognitive problems, we are mindful of the difference between “causation” in law and “causality” in science. In particular, we are mindful of the standards applicable in the Vaccine Injury Compensation Program (“VICP”). But these are the sources of data available to us, as citizens, doctors, lawyers, and most importantly parents, as we strive to make responsible decisions regarding the health of our children. It is the absence of understanding by scientists of the nature and cause of vaccine injury, something that indisputably occurs, that has required us to employ standards other than absolutist scientific ones, to make judgments regarding safety. It is the absence of science – something that must be resolved – that was one factor motivating Congress to establish the VICP so that justice would be available to victims of vaccine injury.<sup>12</sup>

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<sup>12</sup> [H.R. Rep. 99-908](#), at 1, 6-7, reprinted in 1986 U.S.C.C.A.N. 6344, 6344, 6347-48. (“While it is true that some children, because of their physical condition, are more likely to

We also observe, as we have done in the case of “autism” that imprecise definitions often confuse understanding. There is no doubt that the emerging data shows that the Gardasil vaccine, similar to most vaccines, has caused various forms of brain injury, or “encephalopathy”.<sup>13</sup> “Mental Retardation”<sup>14</sup> has a generalized definition and manifests in multiple ways and to varying degrees, all relating to deficits in cognitive ability and intellectual functioning. The term is in disfavor among those who work in the disabilities field, with the phrase “intellectual disability” more favored. This highlights the moving target presented by a debate of the question whether vaccines cause “mental retardation” and some of the unresolvable confusion inherent in any discussion of the issue. That definitional

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react to a vaccine, vaccine

H.R. REP. 99-908 Page 3

H.R. REP. 99-908, H.R. Rep. No. 908, 99TH Cong., 2ND Sess. 1986, 1986 U.S.C.C.A.N. 6344, 1986 WL 31971. Congress said, “While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely foreseeable. There is today no 'perfect' or reaction-free childhood vaccine on the market. A relatively small number of children who receive immunizations each year have serious reactions to them. But it is not always possible to predict who they will be or what reactions they will have. And since State law requires that all children be immunized before entering school, most parents have no choice but to risk the change--small as that may be--that their child may be injured from a vaccine.”

For a discussion of the perils of proving causation in the VICP and its backdrop of the absence of scientific examination of causation issues, see, Gray, Betsy J., *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 Harvard Journal on Legislation 343 (2011). Available at:

[http://www.harvardjole.com/wp-content/uploads/2011/07/Grey\\_Article.pdf](http://www.harvardjole.com/wp-content/uploads/2011/07/Grey_Article.pdf)

<sup>13</sup> “**Encephalopathy**” is defined as “any degenerative disease of the brain”, Dorland’s Electronic Illustrated Medical Dictionary, 32d edition, electronic. Accessed at: <http://www.dorlands.com//def.jsp?id=100035088> . In the Vaccine Injury Compensation Program, as we have noted in our article, *Unanswered Questions*, “encephalopathy” has a more specialized definition.

<sup>14</sup> “**Mental retardation**”: a mental disorder characterized by significantly subaverage general intellectual functioning associated with impairments in adaptive behavior and manifested during the developmental period. It is classified on the basis of severity as mild, moderate, severe, and profound; a fifth subgroup. Dorland’s Electronic Illustrated Medical Dictionary, 32d edition, electronic. Accessed at: <http://www.dorlands.com//def.jsp?id=100092387>



ambiguity creates a linguistic imprecision that should not be laid at the doorstep of anyone, like Michele Bachmann, who publicly suggests that vaccines can cause “mental retardation.” The confusion in the discussion leaves parents to make the call over the safety of an invasive medical intervention like vaccination, in the absence of clear-cut evidence of safety. If the benefit outweighs the risk, as public health vaccine advocates repeatedly proclaim, the safety risk can be openly and freely weighed by parents, without the need for media talking heads and bioethicists to gloss over a complicated medical issue.

We offer the foregoing information, therefore, in the interest of avoiding simplistic assertion or condemnation, and to counter overzealous punditry that advances misleading assurances regarding vaccine safety. Ignorance of the precise cause of vaccine injury does not justify grandstanding proclamations, whether by campaign advocates, or bioethicists, when their claims are profoundly grounded in ignorance. “Absence of proof is not proof of absence.”<sup>15</sup> While Michele Bachmann could have been more accurate in her choice of words she is not so nearly as wrong as the media pundits and bioethicists would have you believe. There is some evidence that she is correct and her critics are wrong.

/s/ Robert J. Krakow and the Coauthors of “Unanswered Questions”

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<sup>15</sup> Attributed to William Cowper 1731-1800,