

# The Obfuscation of the Confounded Relationship between Vaccines and Autism

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## Abstract

Published research regarding vaccines, particularly safety research, is largely discussed in ways that best serve the interests of the vaccine-producing industry. Benefits to the general public are a secondary consideration. This is a sign of industry capture of the regulatory agencies that validate and make recommendations regarding vaccines.

This article discusses the major flaws in each of four papers on the subject of how vaccines relate to autism-like conditions. These are papers that have been used to justify the claim that vaccines don't cause autism. These papers were selected because they exhibit an apparent deliberate obfuscation of results rather than inadvertent errors and omissions. Each of them illustrates a different way that results could be manipulated to arrive at the industry-desired conclusion—that vaccines are not linked to autism.

## Keywords

Aluminum, industry capture, policy, statistical analysis, thimerosal, vaccines

## Introduction

The CDC estimates that 1 in 36 children<sup>1</sup> has been identified with autism spectrum disorder (ASD). Recently, the CDC reported that 26.7% of 8-year-old children<sup>2</sup> with autism are profoundly autistic. Assuming that 26.7% is a reasonable average for all children, this means that approximately seven in a thousand (0.7%) children in the US are profoundly

autistic. The concern about vaccines and autism dates back to before the 1986 National Childhood Vaccine Injury Act (Public Law 99-660), which included a requirement to study the Pertussis vaccine and autism (Sec. 312. Related Studies)<sup>3</sup>. By now, hundreds of studies have been published with most showing no statistically significant relationship was found, but a significant portion of the public isn't buying that result. "Currently, 10% of U.S. adults believe vaccines cause autism in children, marking a modest increase from 6% in 2015."<sup>4</sup> A survey of 38 countries found "Around one in every five people believe that 'some vaccines cause autism in healthy children,' and 38% are unsure whether it is true or not."<sup>5</sup>

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There is a problem with vaccine research related to its funding that may be the root cause of this disbelief. Published research regarding vaccines, particularly safety research, is largely funded by vaccine manufacturers and discussed in ways that best serve the interests of the vaccine-producing industry. Risks and benefits to the general public are a secondary consideration. This is a sign of industry capture of the regulatory agencies and the academic researchers they fund, in making recommendations regarding vaccines.

Regardless of whether or not such corruption has actually taken place, one result of such an obvious conflict of interest is degrading the public's trust in official information.

### Industry Capture of Regulatory Agencies

Major industrial corporations become the main clients of captured regulatory agencies, providing much of the revenue that funds the agency and showing rewards for cooperating with their wishes by welcoming agency employees into their ranks with lucrative compensation packages for the final years of their careers. It produces an organizational culture akin to systemic racism—an invisible bias that infects decisions throughout the organization. This is a known problem, although the ultimate effect on vaccine research is disputed.

A captured agency is more protective of the industry they regulate than the consumers they are charged with protecting. This leads to situations like the environmental problems caused when 38 cars of a Norfolk Southern freight train carrying hazardous materials derailed in East Palestine, Ohio, United States, on February 3, 2023. The Boeing 737 failures could also be considered unintended consequences of deregulation policies. Our society knows how to prevent those kinds of accidents, but didn't take all the steps necessary to do so. Instead, agencies relaxed requirements which allowed those

corporations to cut costs at the expense of increasing the probability of preventable disasters.

Parents don't get accurate data regarding the questions they want answered about vaccines. This situation was documented in 2013 *The childhood-immunization-schedule-and-safety-stakeholder-concerns-scientific-evidence*<sup>6</sup>:

*"No studies have compared the differences in health outcomes that some stakeholders, i.e., parents, questioned between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule."*

Over a decade later, studies of the entire immunization schedule to provide answers to those questions are still not part of the published research.

## Methods

### The Null Hypothesis

In order to understand why the public isn't buying the scientific evidence regarding vaccines and autism, it's necessary to drill down to the basic questions that are asked and answered in the published research on that relationship. The null hypothesis is the question answered by the statistical test. It is a query about the true state of the world, a mathematical description of our **default assumption** about the true state of the world. When we reject the null, we are able to conclude with high confidence that the null is NOT the true state of the world.

There are two types of possible errors with statistical tests. You can incorrectly reject the null

hypothesis (**Type I error**) or you can incorrectly fail to reject the null hypothesis (**Type II error**). The two types of errors are inversely related and both are dependent on sample size.

In the field of quality assurance, these two different probabilities are termed the **producer’s risk** and **consumer’s risk** respectively, which helps to

delineate the dichotomy between the questions vaccine consumers—in particular parents—want answered and the questions vaccine producers want answered. For a familiar example, consider criminal trials in which the jury presumes the defendant is innocent (null hypothesis) and requires strong evidence to convict. See Table 1.

Scenario	Statistical Parallel	Who Suffers the risk?
Convict an Innocent Person	Producer’s Risk Type I Error	Manufacturer
Acquit a Guilty Person	Consumer’s Risk Type II Error	Consumer (Public)

Table 1. Statistical Parallels with Trial Verdicts.

The **p-value** reported for a statistical test is the probability of incorrectly rejecting the null hypothesis when it is actually true. Prior to conducting the test, the researcher decides when this value will be low enough to reject the null and conclude the alternative true. This is represented by the Greek letter alpha ( $\alpha$ ). It is typically set to 0.05 or 5%, but it need not be.

Failing to reject the null is not the same as concluding no relationship exists. The probability of correctly rejecting the null is referred to as the **power** of the test and is represented by the Greek letter beta ( $\beta$ ). The probability of incorrectly concluding the null is true is  $1-\beta$ , which can be much larger than the probability of incorrectly rejecting the null ( $\alpha$ ) to conclude that a relationship exists.

When the null hypothesis of no relationship is not rejected, all the study can or should conclude is that the evidence is insufficient to accept the null hypothesis unless the value of  $\beta$  has been calculated and is sufficiently small.

If we set  $\alpha$  at 5%, then we are 95% certain that the null is incorrect when we reject it. But we don’t know what  $\beta$  is until we calculate it based on a specific alternative being true for a given sample size. These two types of errors are inversely related. For any given sample size, the lower  $\alpha$  is set, the higher  $\beta$  will be. This means that the lower the producer’s risk is set, the higher the consumer’s risk will be.

Going back to the example of a trial in which the jury presumes the defendant is innocent (null hypothesis). In civil trials, where imprisonment or worse is not a potential punishment, only a preponderance of evidence is required. This sets  $\alpha$  lower for criminal trials than for civil trials because the consequence of wrongly rejecting the null is greater for a criminal defendant than a civil suit defendant. See Table 2.

<b>Null Hypothesis: Defendant is NOT guilty</b>	<b>Do not reject Null</b>	<b>Reject Null</b>
Null Hypothesis True	Probability of a Correct Decision ( $1-\alpha$ ) Convict a Guilty Person	<b>Producer's Risk</b> Probability Type I Error: $\alpha$ Convict an Innocent Person
Null Hypothesis False	<b>Consumer's Risk</b> Probability Type II Error: $\beta$ Acquit a Guilty Person	Probability of a Correct Decision = $(1-\beta)$ Acquit an Innocent Person

Table 2. Null Hypothesis (Trial) with all possible outcomes.

Published research papers on vaccines and autism with the null hypothesis assuming no relationship exists will inherently favor (unintentionally but universally) the conclusion that the vaccine is safe by requiring strong evidence before recognizing a potential problem while the probability of incorrectly accepting the conclusion of no relationship is higher. See Table 3.

Parents set their criteria for getting their child vaccinated based on the consequences of a wrong conclusion regarding safety (the consumer's risk) rather than the consequences of wrongly concluding a relationship exists (producer's risk). They can tolerate a lower value for  $\alpha$  in exchange for a higher value of  $\beta$  even if they don't know that terminology to express their preferences.

<b>Null Hypothesis: Vaccines do NOT Cause autism</b>	<b>Do not Reject Null</b>	<b>Reject Null</b>
Null Hypothesis True	Probability of a Correct Decision ( $1-\alpha$ )	<b>Producer's Risk</b> Probability Type I Error: $\alpha$ Incorrectly conclude vaccines cause autism
Null Hypothesis False	<b>Consumer's Risk</b> Probability Type II Error: $\beta$ Incorrectly Conclude Vaccines do not cause autism	Probability of a Correct Decision = $(1-\beta)$

Table 3. Null Hypothesis (Vaccine Safety) with all possible outcomes.

## Lies, Damned Lies, and Statistics

The consistent denial of a causal relationship between vaccines and autism by health authority figures has resulted in a serious miscommunication<sup>7</sup> with the public regarding what scientific studies actually show regarding the relationship between vaccines and autism. That claim of no relationship is a far stronger claim than the published evidence supports.

The reason the stronger claim isn't actually established by the published scientific research is due to this difference between rejecting the null hypothesis and concluding the null hypothesis is true. The scientific literature concludes that we cannot reject the null hypothesis that the vaccine is safe. That is frequently interpreted as concluding that vaccines are safe but those two things are not the same.

Scientific knowledge rests on setting up very explicit hypotheses for statistical testing. The reason for doing so is to set the risk of wrongly concluding the existence of a relationship to be very low. One reason for this is because statistical testing requires that the null hypothesis contains the equality; this means that mathematically it must contain the boundary of the solution set. In order to alter the null to put the original boundary outside of the range for the null hypothesis requires a rather specialized rewriting of the statistical test to accommodate this alteration of the null solution set in order to define the probability of the consumer's risk rather than the producer's risk when analyzing the data.<sup>8</sup> It requires that a minimum detectable difference be established by that analyst in conjunction with the research committee designing the study.

## Confounded Variables

In statistics confounding refers to two or more variables whose effects are not mathematically separable. An example of this is ice cream cone sales at Coney Island being strongly correlated with drownings. Was eating ice cream causally related to drowning? Do drownings increase ice cream cone sales? The answer is that one doesn't cause the other, but that temperature was a causal factor for both. We can have confidence in this conclusion based not just on the statistical relationships, but also due to our knowledge of how temperature affects human behavior. Temperature can explain the correlation between ice cream cone sales and drownings. Statisticians say that temperature is confounded with ice cream cone sales in determining causes of drownings. Predictive models for drownings are better with just one of those two **confounded** variables included.

Confounding variables make sussing out causality more difficult, but confounding variables **do not negate** the correlation that exists. We determine which ones are causally connected (temperature and drownings) and which are not (ice cream cone sales and drownings) based on our non-mathematical understanding of causes and effects. But if we don't know which confounded factors are causal, the models can get quite complex with all of them included. Diagnostics have to be examined carefully to ensure the model is appropriate.

## Example of Cultural Bias in a Published Scientific Paper.

Scientists are making the right call to look for confounders and, when confounders are found, they rightly conclude that they cannot conclude the relationship exists based on correlation alone. But establishing a confounding variable exists does not provide grounds for concluding that there is no

causal relation. All the statistics can establish is that certain variables are correlated. In vaccine studies, this correlation may be dismissed when a plausible confounder is hypothesized, despite the fact that this relationship cannot be tested because they lack the data to do so. Sometimes they go further and conclude the null is true despite their evidence suggesting otherwise. As in this peer-reviewed paper on vaccines and allergies<sup>9</sup>:

*“In summary, although our results in an observational cohort study demonstrated a positive association between vaccination and allergic disease, this association can be explained by ascertainment bias. These data, together with other published evidence, suggest that current vaccination practices do not have an adverse effect on the incidence of allergic disease.”*

**\*Ascertainment bias\*** was a hypothesized confounding variable that data was not available for. It was considered a plausible explanation for the statistically significant positive association found in their dataset. While that is a legitimate reason to caveat the finding and reserve judgement about any causal relationship, it is not sufficient to conclude there was no causal relationship. More investigation is needed to determine if this correlation was due to the vaccines or the hypothesized variable instead. This paper demonstrates cultural obfuscation of the answer to the question regarding harm due to vaccines. The conclusion is a logical outcome expected from current scientific practices, not a deliberate attempt to disguise findings. This was confirmed via contact with the corresponding author. The current conventional approach, which focuses on reducing the producer’s risk of an incorrect conclusion, results in a consistent bias that raises the consumer’s risk of an incorrect conclusion.

## Results

Industry capture leads to a dilemma for researchers and the journals that publish their research. Publishing a paper that links vaccines to autism will likely result in a drop in vaccination rates, leading to a drop in herd immunity, and an increase in both frequency and severity of outbreaks.<sup>10</sup> This is universally discouraged by public health organizations. Industry capture of regulatory agencies also means that research is only funded if the answers are expected to be of benefit to the industry. The result is a strong publication bias against studies that report any negative findings regarding vaccination.<sup>11</sup>

Looking deeply into the relationship between vaccines and autism is not of benefit to the vaccine industry. It's better for them if no relationship is found to exist. Meanwhile the experiences of the public continue to be at odds with the claim of no relationship. Thus, the relationship between vaccines and autism remains a contentious issue despite the multitude of expensive high-quality peer-reviewed published scientific papers that show no relationship and the sparsity of those claiming otherwise.

Looking closely at the data in published scientific papers discussed below, it’s clear that some relationship exists. This may not be a causal relationship—remember, ice cream cones and drownings have a relationship, but they are not causally related. This correlation of the two is either not mentioned at all or is addressed and dismissed in one brief paragraph. These examples support a broader conclusion of how current vaccine research benefits vaccine-producing corporations and regulatory agencies rather than the public as a whole.



It is a sad fact of mathematical analysis that statistical analyses and predictive models require a lot of subjective choices to be made by the analyst. These choices can be used to obscure some findings and promote a desired outcome. Each of the papers analyzed below for obfuscation illustrates a different way that results could have been manipulated to arrive at the desired conclusion—that vaccines are not linked to autism—and a lack of evidence to the contrary.

If the data from these papers was available (it is not), then an independent expert could determine which explanations for that relationship are unlikely and which are probable. For each of these papers, the corresponding author was contacted about how to obtain access to their dataset, with proper blinding to protect individual identities of the study subjects, in order to verify their analyses and exclude the hypotheses of researchers deliberately misleading their readers. In all cases, this request was either unacknowledged or denied. Studies that do not allow the data analysis to be reproduced by independent researchers are suspect as they lack both transparency and reproducibility.

### **Apparent Deliberate Obfuscation of Meaningful Conclusions**

The choices made for a complex analysis can be used to obscure true findings by dishonest researchers. Each of the papers below illustrates a different way that results could have been manipulated to arrive at the desired conclusion—that vaccines are not linked to autism.

Two of the papers show an unsuspected statistically significant relationship, indicating that unvaccinated children had a higher probability of also having an autism diagnosis. While this does not imply a causal relationship between vaccines and autism, the unexpected findings imply that some relationship exists between the two variables. If we

want to understand autism and what might influence it, these findings need further investigation.

In practice, industry capture appears to skew research funding toward studies whose findings are anticipated to benefit the vaccine industry. Finding links between vaccines and autism is not of benefit to the vaccine industry. This pattern of scientific obfuscation is one reason why the claim of a relationship between vaccines and autism remains a contentious issue despite the many published peer-reviewed scientific papers that claim no causal relationship between them.

## **Discussion**

### **Thimerosal and Autism Technical Report Volumes I<sup>12</sup> and II<sup>13</sup>**

This was an important paper, providing the first detailed and thorough analysis of the relationship between thimerosal in vaccines and autism. It was prepared for the National Immunization Program Centers for Disease Control and Prevention, Atlanta, Georgia. A lengthy two volume report that provides the results of many different models looking at different factors. The results showed a statistically significant positive relationship between thimerosal in vaccines and autism in males. [Vol I, section 9.4.2.6] The authors rejected this result as a concern with one brief paragraph insufficient to justify that decision:

*“The parameter estimates for cumulative exposures birth to seven months and birth to 20 months were in a direction suggesting that increased exposure was related to decreased risk of either AD or ASD. Although these results were statistically significant, we are not aware of a plausible biological mechanism that would lead to this result. We therefore interpret this result as a chance finding.”*

This conclusion was not appropriate because in models of this type, the sign of parameter estimates can be reversed if some covariates included in their models are highly correlated:

*“When you have two variables in a model that are highly positively correlated, you often find that one will have a positive coefficient and the other will be negative. Likewise, if two variables are highly negatively correlated, the two regression coefficients will often be the same sign.”<sup>14</sup>*

This appears to have been a deliberate choice to publicly dismiss the correlation, with the aim of obfuscating the statistically significant relationship found, rather than recommending support for additional time and resources to understand what lay behind that unexpected positive correlation.

Complex models can make use of many different covariates in an attempt to winnow out the effect of the variable of interest—in this case, the contribution of vaccines to the incidence of autism—by accounting for the effects of the covariates known to be associated with the variable of interest. The choice of confounders to be included in the analysis is one place where a researcher could manipulate findings to be in alignment with the desired result. Including covariates that result in changing the sign of the correlation, which is then dismissed as a chance finding due to the direction of sign, is one way to do that.

Without more documentation, no assessment can be made about whether confounding affected the direction of the relationship between thimerosal and autism. With access to the dataset, the model could be evaluated and the hypothesis of a dishonest researcher could be tested.

Since this paper was published by the CDC, the data should theoretically be available to the public. But

to gain access to even a limited dataset including only variables used in the published analysis and blinded regarding the medical information for the individuals included, the CDC requires that the requester provide—at their own expense—an “Institutional Review Board (IRB) approved protocol and an IRB approval letter.” To demand IRB approval to have access to a database to verify the validity of the models presented in a study when the data was already obtained with IRB approval creates an unnecessary financial hurdle to independent researchers validating the results. This researcher was not able to obtain any further information.

**Measles, Mumps, Rubella Vaccination and Autism:  
A Nationwide Cohort Study by Anders Hviid,  
Jørgen Vinsløv Hansen, Morten Frisch, and Mads  
Melbye<sup>15</sup>**

*“Survival analysis of the time to autism diagnosis with Cox proportional hazards regression was used to estimate hazard ratios of autism according to MMR vaccination status, with adjustment for age, birth year, sex, other childhood vaccines, sibling history of autism, and autism risk factors (based on a disease risk score).” This method involved examining “person-years of follow-up,” wherein children “contributed person-time to follow-up from 1 year of age and until a first diagnosis of autism, death, emigration, unexplained disappearance from the source registers, diagnoses of autism-associated conditions or syndromes, or end of the study on 31 August 2013.”*

This study lists a primary funding source as the Novo Nordisk Foundation, which owns Novo Holdings A/S, a holding company that is the majority shareholder of Novo Nordisk, a major Danish pharmaceutical corporation.



The authors of this paper fail to mention the fact that the children included in the study are 1.7 times more likely to be diagnosed with autism if not vaccinated with MMR. This appears to be a deliberate obfuscation of the most statistically significant finding of this paper: the drastic

difference in the autism rates between the children vaccinated with MMR and those who were not. A 2 x 2 chi-squared test on this data shows that autism is not randomly distributed between MMR vaccinated and MMR unvaccinated children. See Table 4.

Hviid paper data	Unvaccinated	Vaccinated	Total
Cases included in Final analysis	31,619	625,842	657,461
Cases with autism Diagnosis	525	5,992	6,517
% autism diagnosis	1.66%	0.96%	0.99%

Table 4. Hviid Paper Data for Autism Diagnoses.

The chi-squared test results on this data give this difference in autism rates occurring by chance of  $7.944 \times 10^{-35}$ . Autistic children are far less likely to have received the MMR vaccine. This difference cannot be due to random chance. In fact, this result was due to having 525 cases of autism in unvaccinated children when, under the null hypothesis, we had an expectation of only 313 cases. *This is a strong indication of a relationship of some kind between autism and the MMR shot.*

The fact that we ended up with such imbalance in the sample with regard to autism rates is both concerning and suspicious. Why were parents that declined the MMR vaccine for their child so much more likely to have their child receive an autism diagnosis? Why did this finding not spur some further research regarding what could cause this difference in autism rates?

With over 650,000 children included in the study, curating the entire dataset requires subjective

decision making by the researchers. There were 5,775 children excluded from the study at the start and an additional 6,518 that were censored during follow up. Less than 2% of the total cases were excluded, which is a reasonable amount of data to be excluded.

This process of exclusion and censoring is a necessary part of any well-run study of this size. It also requires some subjective judgments on the part of the individuals tasked with doing this. The data has to be reviewed and bad data must be identified and removed.

The exclusion criteria is an area where a dishonest researcher could manipulate findings. Given the extremely large samples size, the difference between the general population rate of autism in Denmark (1.65%) and the rate of autism in the included subjects (0.99%) is suspicious.

Without more documentation, no assessment can be made about the potential bias resulting from the excluded children. But if the authors were to provide data regarding the autism rate of the excluded/censored cases for vaccinated and unvaccinated children, this hypothesis of a dishonest researcher could be tested. If there are far more vaccinated children with autism in the excluded sample than expected, we could conclude that the results of the study support the hypothesis that the study results were manipulated via the method of choosing exclusion parameters to suit the final outcome.

The request to the corresponding author for further information about their dataset was declined. This researcher was not able to obtain any further information about the diagnostics for the model presented in this paper or any additional information about the excluded children.

### **Blood and Hair Aluminum Levels, Vaccine History, and Early Infant Development: A Cross-Sectional Study<sup>16</sup>**

Objective: To evaluate relationships between whole blood (B-Al) and hair aluminum (H-Al) levels in healthy infants and their immunization history and development.

This study was supported by the Gerber Foundation (to A.D.W. and M.P.K.) and the Agency for Toxic Substances and Disease Registry (ATSDR), cooperative agreement award number 1U61TS000238-01.

This paper has been used to justify the assumption/conclusion of no association between the aluminum contained in childhood vaccines and the child's development, but it does not make this claim. This study does not conclude anything about the relationship between the aluminum in vaccines (CAL) and a child's motor, language, and cognitive

development (BSID score) because that analysis wasn't included in the paper.

Did the authors simply neglect to do an analysis linking the main independent variable of interest (CAL) with the main dependent variable of interest (BSID scores)? Or were analysis results not included because the authors were concerned about the potential effect of scaring parents away from vaccines, a supposition which carries with it an implication of negative findings? It is difficult to believe that the authors were not aware of the need to directly compare those two variables.

If there were significant positive correlations between CAL and the measured BSID scores, that would be a piece of evidence linking vaccinations to potential neurological damage in young children. If that doesn't appear, it would be a piece of evidence supporting the safety of using Al adjuvants in vaccines. The lack of this analysis from the results reported in Table 2 of that paper leaves the reader without any assessment of the safety of that vaccine ingredient given the total number of vaccines received over the first year of life. That is a currently unstudied question with regard to the scientific literature. This study could have helped to fill that gap. It didn't, but is often cited as support for the safety of Al adjuvants in vaccines routinely given to infants. Concluding that the direct analysis was deliberately excluded to obfuscate the finding is reasonable, particularly given the other suspicious analysis and reporting choices detailed below.

This lack is a major analysis flaw that should have been identified and corrected prior to publication. That the B-Al and H-Al levels show little correlation with the BSID scores does not imply anything about the relationship between CAL and BSID scores.

There are two other suspicious analysis choices, also issues of what wasn't included in the paper.

1) Nearly 10% of the dataset was identified as outliers and the analysis results were reported both with and without the outliers in Table 2, but more information about the outliers would be appreciated. There is no sense of scale regarding the outliers or any way to determine the distribution of the outliers compared with the remaining dataset. Do they form a distinct cluster that could be separately identified or are they simply the result of a long and drawn-out tail of the overall distribution? Outliers may contain crucially important information about the dataset. 2) Lack of clarity regarding the inclusion or exclusion of outliers in the reported correlation between CAL and B-AI and H-AI levels. Reporting both values, as was done in Table 2 for the other comparisons, would have been sufficient to quell concerns on both the exclusion of outliers and clarify the reported results.

Requests to the corresponding author for further information about their dataset were never acknowledged. A listing of the CAL, H-AI, B-AI, and the BDIS scores for each of the 85 participants, scrubbed of any identifying information of course, would allow reproduction of their model, checking the diagnostics, and inspecting the outliers for patterns.

**Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism.<sup>17</sup>**

Objective: To evaluate the association between autism and the level of immunologic stimulation received from vaccines administered during the first 2 years of life.

This study was funded by a contract from the Centers for Disease Control and Prevention to America's Health Insurance Plans (AHIP), published in the *Journal of Pediatrics* in April 1, 2013.

The authors analyzed the effect of cumulative vaccinations using only the antigen level. This, by the way, can vary by many orders of magnitude between vaccines. They did not include the number of individual shots or the cumulative amount of any of the other ingredients of the vaccines. There were some questionable choices made regarding the statistical analysis that was performed. Why were antigens assumed to be the only “immunologic stimulation” to be examined when vaccines include multiple ingredients, including adjuvants, which are included specifically to increase the immunologic response?

This isolation of the experiment to asking the question regarding one ingredient only is a way to reduce the overall producer's risk, which means that the consumer's risk is increased. Restricting the analysis to the number of antigens rather than looking at the number of vaccines obfuscates the information that parents want. Parents don't care about whether it is antigens or some other ingredient that might cause a problem for their child. They want to know the overall risk of adverse effects when getting their child multiple vaccines, not the risk for the cumulative number of antigens. This is another example of how vaccine producers' interest dominates the published research.

Rather than concluding no relationship exists, the only proper conclusion is that this study was unable to identify any effect of the vaccine antigens from the noise given the analysis choices they made regarding what to test (only one ingredient) and how to group the levels of antigens at the different ages. The choices they made for those aspects of design decreased the probability of detecting a statistically significant effect compared with other choices. The effect of any other vaccine ingredient or combination of ingredients was not included in the analysis. No conclusions can be drawn regarding any other aspect of the vaccines and the risk of autism.

The choice of what measure to represent cumulative vaccines and how to group the different cumulative levels of antigens are avenues that a dishonest researcher could use to manipulate findings. With access to this dataset, the hypothesis of a dishonest researcher could be tested by examining other measures of cumulative vaccines, such as the total number of vaccines given or the total amount of Al contained in those vaccines.

The request to the corresponding author for further information about their dataset or the reasoning for their choice of analysis methodology was declined.

### Conclusion

Taken together, these papers suggest a consistent pattern of selective analysis and reporting that obscures the relationship between vaccines and autism.

Statistically significant results are unmentioned. Important analyses were not done. There is no transparency with regard to their data to verify the findings. See Table 5. The analysis choices produce published results that better serve industry interests than helping the public make an informed

choice about the risks versus the benefits of vaccines for their children.

It would be useful to see the bare bones correlation between vaccines and autism. If it wasn't significant, then the authors could simply report the lack of a relationship. No need to look at confounders. Published papers should report that correlation and, if significant, then discuss the confounders that might be responsible. Instead, confounding variables are included in the published results without any assessment of a correlation without those confounding variables included. This approach results in a bias in favor of vaccinations as discussed above.

Science that is used to develop public policies must be accurate, unbiased, and verifiable to earn the support of the population for any public policies based on that science. Given that the published studies regarding the relationship between vaccines and autism are not unbiased or verifiable (can't discuss accuracy without it being verifiable), it is not a surprise that much of the public rejects the claim that "vaccines do not cause autism"<sup>7</sup> and concludes they cannot trust the agency telling them so.

Paper	Methodological Flaws	Validation
Thimerosal and Autism Technical Report Volumes 1 & II	Statistically significant correlation dismissed due to sign of correlation without adequate reason or documentation. The inclusion of correlated covariates in model could have caused the sign to be negative.	An independent researcher given access to dataset could validate whether the dismissal of the correlation was appropriate.

Paper	Methodological Flaws	Validation
Measles, Mumps, Rubella Vaccination and Autism: A Nationwide Cohort Study	Did not mention statistically significant lower rate of autism of vaccinated children compared with unvaccinated children. This could have been caused by a bias resulting from the exclusion criteria chosen.	An independent researcher given access to dataset could validate whether the exclusion criteria caused bias with regard to autism rates.
Blood and Hair Aluminum Levels, Vaccine History, and Early Infant Development: A Cross-Sectional Study	Failure to provide direct analysis of the two main variables, the aluminum in vaccines and development scores. Excluded data may have resulted in a change in results.	An independent researcher given access to dataset could both conduct the direct analysis and validate whether the exclusion criteria resulted in a change in results.
Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism	Choice of dependent variable was only of interest to vaccine producers, not parents. Choices made for grouping the data decreased the probability of detecting a statistically significant effect compared with other choices.	An independent researcher given access to dataset could conduct a new analysis based on total number of vaccines and validate whether grouping choices affected the outcome.

Table 5. Papers and their methodological flaws.

## Policy Recommendations

Transparency would be improved by requiring publication of the Data Analysis Plan prior to the beginning of the analysis data from a study and requiring datasets to be fully shareable for re-analysis after publication. Blinding to maintain patient privacy is acceptable, but all other data

should be available for independent analysts to verify the results.

Trust would be improved by reporting both producer's and consumer's risk for the null hypothesis based on extending to a larger population and including diagnostic test results for the model selected in the supplemental materials.



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**Conflict of Interest:** The author has no financial entanglements of any sort with any commercial enterprises that either produce or advocate for vaccines or advocate for improving vaccine safety.

**Institutional Review Board Statement:** The study did not require ethical approval.

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