UNIVERSITY OF CALIFORNIA
HASTINGS SCHOOL OF LAW

Vaxxed and CDC Whistleblower

Dorit R. Reiss

Conflict of Interest Statement:

- The family owns stock (regular) in GSK.

Vaxxed's three parts

- CDC Whistleblower
- Vaccines cause autism
- Vaccines' oversight lacking

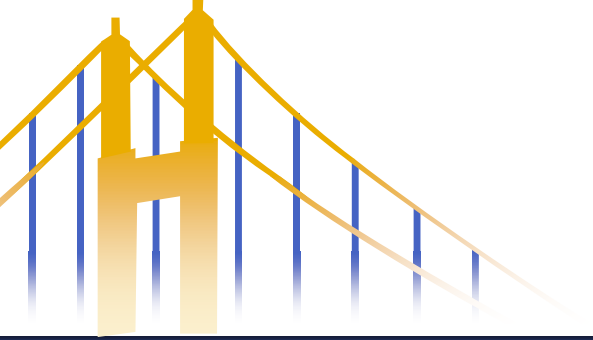
CDC Whistleblower

CDC Whistleblower: The Actors

- Brian Hooker: Biochemical Engineer, believes his son's autism caused by vaccine, VICP claim rejected.
- Andrew Wakefield: Disgraced ex-scientist with history of misrepresentations on MMR and autism.
- William Thompson: senior scientist in CDC, author or co-author on several vaccine safety studies, psychologist by training.

CDC Whistleblower: The claims

- Two alleged results hidden:
  - MMR causes autism in African-Americans
  - MMR causes autism in those with “isolated autism”
- Two claims of wrongdoing:
  - Deviation from analysis Plan
  - Data/documents destroyed to hide wrongdoing.
- None hold up to scrutiny.



ISOLATED AUTISM

The claim:

– Paper omitted a result for isolated autism.

– Isolated autism=children who were not exhibiting problems earlier:

"children of all races who were developmentally normal to age 12 months ('isolated' autism)…"

http://www.ageofautism.com/2016/09/waging-war-on-the-autistic-child-by-andrew-wakefield.html

Correction A:

- Isolated autism result reported in paper – and disappeared in adjusted results.

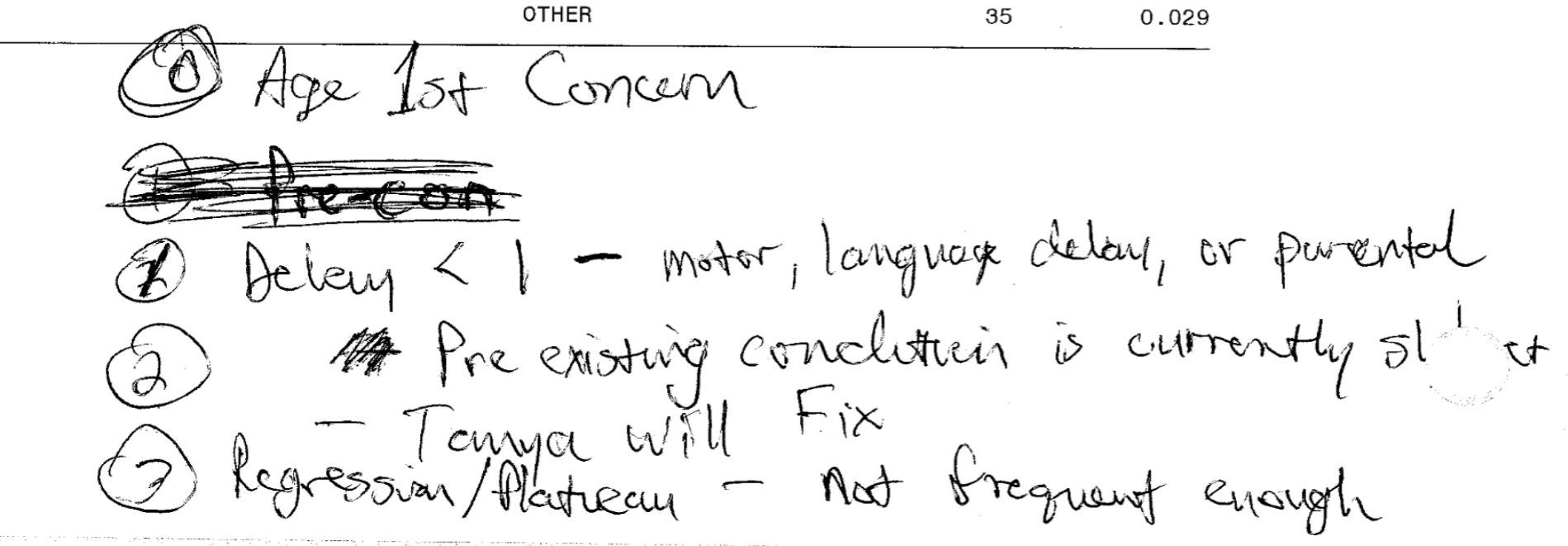
TABLE 4. Associations Between Age at First MMR Vaccination and Autism Case Status Within Selected Clinical Subgroups of Cases for the Total Sample and the Birth Certificate Sample

Sample	Case Subgroup	Cases	<18 Months, OR (95% CI)	<24 Months, OR (95% CI)	<36 Months, OR (95% CI)
Total sample Unadjusted analyses*	No preexisting conditions <1 y‡	390	1.07 (0.83–1.39)	1.14 (0.82–1.59)	1.51 (0.96–2.37)
	Regression or plateau	80	1.37 (0.78–2.41)	1.30 (0.64–2.66)	1.45 (0.54–3.93)
	With MR§	376	1.06 (0.82–1.38)	1.09 (0.79–1.51)	1.21 (0.79–1.84)
	Without MR	248	1.23 (0.87–1.73)	1.46 (0.93–2.30)	2.45 (1.20–5.00)
Birth certificate sample Adjusted analyses†	No Preexisting Conditions <1 y‡	187	1.05 (0.68–1.61)	1.02 (0.56–1.86)	1.82 (0.77–4.31)
	Regression or Plateau	31	0.83 (0.23–3.09)	0.41 (0.07–2.29)	0.69 (0.14–3.30)
	With MR§	179	1.13 (0.72–1.79)	0.96 (0.54–1.71)	0.82 (0.38–1.79)
	Without MR	132	0.68 (0.40–1.16)	1.02 (0.47–2.22)	3.55 (0.74–17.07)

* Conditional logistic regression model stratified by the matching variables (age, gender, school).
† Conditional logistic regression model stratified by the matching variables (age, gender, school) and adjusted for birth weight, multiple gestation, maternal age, and maternal education.
‡ Includes children without any indication of developmental delay at <12 months, a major defect, co-occurring developmental disability, or a major perinatal or postnatal insult.
§ Defined as an IQ of ≤70 on the most recent psychometric test.

Correction B:

- Isolated autism=/= children who had no problem before 12 months.



Correction B:

- Isolated autism=/= children who had no problem before 12 months.

Isolated	229	MMR < 18	1.21	0.84	1.73
		MMR < 36	**2.53**	**1.18**	**5.41**
		MMR Categories			
		0 - 11 mo	1.27	0.24	6.81
		12 - 15 mo	**2.77**	**1.28**	**5.99**
		16 - 18 mo	**2.28**	**1.02**	**5.09**
		19 - 23 mo	**1.83**	**0.72**	**4.67**
		24 - 35 mo	2.59	0.98	6.82
		36+ mo	1.00	1.00	1.00
Non-Delayed	443	MMR < 18	1.22	0.96	1.56
		MMR < 36	**1.67**	**1.09**	**2.57**
		MMR Categories			
		0 - 11 mo	1.29	0.48	3.46
		12 - 15 mo	**1.83**	**1.17**	**2.85**
		16 - 18 mo	1.54	0.97	2.47
		19 - 23 mo	1.41	0.82	2.43
		24 - 35 mo	1.71	0.96	3.04
		36+ mo	1.00	1.00	1.00

AFRICAN AMERICAN MALES

The claim:

- Initial results showed statistically significant link MMR/Autism in full sample group of African Americans.

			Matched Analyses			Unmatched Analyses								
Sample	Cases	Variable	All Subjects			White Model			Black Model			Other Model		
			OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI
Total	596	MMR < 18	1.14	0.92	1.40	0.96	0.71	1.29	1.23	0.91	1.67	1.41	0.63	3.13
		MMR < 36	**1.61**	**1.10**	**2.34**	0.89	0.52	1.52	**2.25**	**1.25**	**4.03**	1.97	0.64	6.09
		MMR Categories												
		0 - 11 mo	1.16	0.51	2.65	1.08	0.37	3.16	1.42	0.36	5.59	NA	NA	NA
		12 - 15 mo	**1.74**	**1.18**	**2.56**	0.99	0.58	1.70	**2.17**	**1.18**	**4.00**	2.33	0.72	7.57
		16 - 18 mo	1.42	0.94	2.15	0.69	0.39	1.24	**2.68**	**1.43**	**5.05**	1.71	0.46	6.35
		19 - 23 mo	1.55	0.96	2.49	0.83	0.41	1.67	2.02	1.00	4.10	3.00	0.63	14.17
		24 - 35 mo	1.61	0.97	2.68	0.96	0.45	2.08	2.03	0.99	4.14	1.11	0.11	11.43
		36+ mo	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

The claim:

- This result was replicated by a published analysis by Hooker.

Table 2

Fisher's exact analysis for African American children only

	Total cohort			Males only			Females only		
Age cut-off	**Relative risk**	**95% CI**	**p-value**	**Relative risk**	**95% CI**	**p-value**	**Relative risk**	**95% CI**	**p-value**
18 months	1.24	0.90-1.70	0.184	1.36	0.95-1.95	0.0880	0.855	0.44-1.68	0.649
24 months	1.47	0.99-2.19	0.0562	1.73*	1.09-2.77	0.0200	0.861	0.40-1.88	0.707
36 months	2.30*	1.25-4.22	0.0060	3.36*	1.50-7.51	0.0019	1.01	0.38-2.68	0.982

- Note: Hooker's analysis was retracted. Movie doesn't say that.

Correction A: Thompson

- Initial association appears spurious:
  - No biological basis
  - African Americans generally receive lower rates of autism diagnosis than Caucasians.
  - Disappeared in birth certificate model that allowed controlling for confounders.
  - Explanation: result of enrollment in early intervention plans that require MMR.

Correction B: Hooker

- Results significant only in African American males that got MMR **late**.
- Numbers supporting result very small.
- Wrong statistical tool.
- No controlling for confounders.
- Retracted: Non-disclosure of COIs and bad methods.

Even if issues ignored -

Honda et al, Japan, 2005, over 300,000 children

Madsen et al, Denmark, 2002, 537,303 children

Jain et al, United States, 2016, 95,727 children

Destefano et al, 2004, 2448

Fombonee et al, Canada, 2006, 27,749 children

Smeeth et al, U.K., 2004, 5,763 children

Mäkelä et al, Finland, 2002, 535,544 children

Wrongdoing 1:

DEVIATION FROM ANALYSIS PLAN

The claim:

- To hide result linking early MMR to autism in African Americans, authors deviated from analysis plan, by only publishing analysis for birth certificate group.

Analysis Plan, April 2001 I:

Burfle

DRAFT
Autism and Childhood MMR Vaccine
Analysis Plan

April 3, 2001

Introduction

Autism is a serious life-long developmental disorder characterized by marked impairments in social interactions, and communication skills; and repetitive, restrictive, or stereotyped behaviors. A recent review of studies conducted since 1985, shows an estimate of the prevalence to be 1-1.4 per 1,000 for classic autism, and possibly as high as 4-5 per 1,000 for all autism spectrum disorders (ASD) combined (1,4). While these rates are 3-4 times higher than rates found in studies conducted 15-20 years ago (1), there are several recent studies, including a study done by Baird et al. (2000) and an investigation in Brick Township NJ, which suggested that the rate of autism may be higher still with rates of 3.1 per 1,000 and 4 per 1,000, respectively (CDC

Analysis Plan, April 2001 II:

We will use conditional logistic regression stratified by matched sets to estimate the odds ratios for the association between age at MMR vaccination and autism. In the main analyses, we will include all ASD cases. The factors that will be examined in the analyses will be race, age of MMR vaccination, thimerosal exposure (DTP and hepatitis B), weight adjusted thimerosal exposure, and number of vaccines received.

Each of the above variables will be individually evaluated for their association with the ASD case definition. Those with an odds ratio p-value ≤ 0.20 will be included as covariates in a conditional logistic regression model to estimate adjusted odds ratio for the association between age at vaccination and ASD.

For the children born in Georgia for whom we have birth certificate data, we will perform several sub-analyses similar to the main analysis, and will included several additional potentially confounding variables. The variables that will be evaluated will include:

- Birth weight (< 1500; 1500-2499; 2500+)
- Gestational age (< 32; 32-36; 37+)
- Birth type (singleton, twin, ~~triplet~~)
- Birth order (1, 2, 3 or higher)
- APGAR scores (1 and 5 minutes)

Comments Analysis Plan:

- According to Thompson's statement, analysis of race started September 2001 at the earliest.
- Analysis plan: April 2001.
- Should authors have included and explained results for full sample, after seeing?
  - Maybe.
  - Professional disagreement≠fraud.

Wrongdoing 2:

DATA/DOCUMENTS DESTROYED TO HIDE WRONGDOING

The claim:

- Authors got together and threw documents/data in trashcan.

16. Sometime soon after the meeting where we decided to exclude reporting any RACE effects, also between August 2002 and September 2002, the coauthors scheduled a meeting to destroy documents related to the study. Dr. Coleen Boyle was not present at the meeting even though she was involved in scheduling that meeting. The remaining 4 coauthors all met and brought a big garbage can into the meeting room and reviewed and went through all our hard copy documents that we thought we should discard and put them in the large garbage can. However, because I assumed this was illegal and would violate both FOIA laws and DOJ requests, I kept hard copies of all my documents in my office and I retained all the associated computer files. This included all the Word files (agendas and manuscript drafts), Excel files with analysis and results, and SAS files that I used to generate the statistical findings. I also kept all my written notes from meetings. All the associated MMR-Autism Study computer files have

Correction I:

- Data not destroyed:
  - Used by Hooker for reanalysis.
  - Available for qualified researchers under conditions:

https://www.cdc.gov/ncbddd/developmentaldisabilities/maddsp-data-sets.html

Correction II:

- Thompson claimed he kept original documents & provided them.
- Provided documents don't show wrongdoing.
- If duplicates of meeting notes, etc., trashed, that's not wrongdoing.

Conclusion:

A. No good evidence of anything that needed to be hidden.

B. No good evidence of wrongdoing.

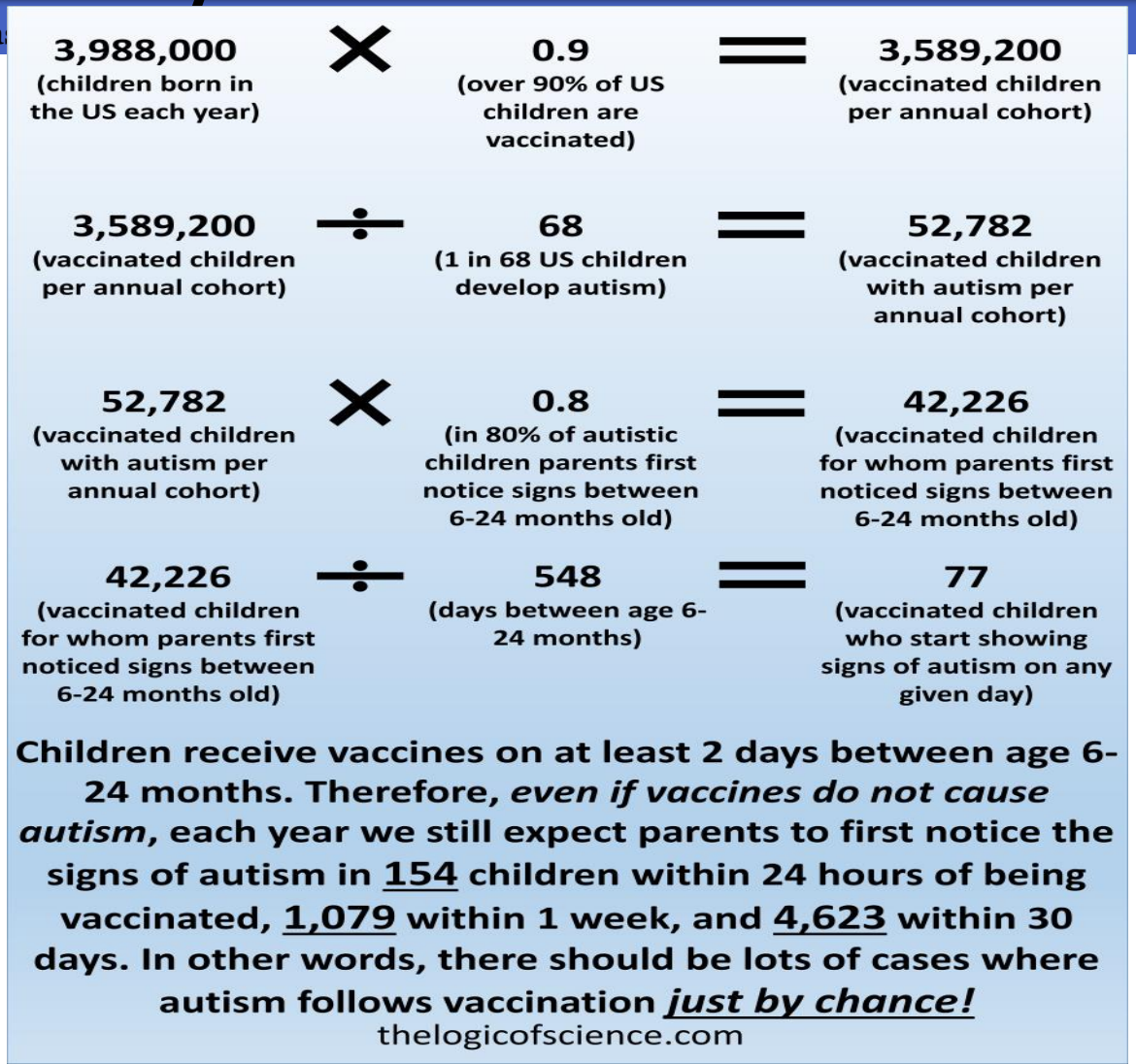
C. Numerous studies on MMR and autism: lack of link demonstrated even without this study.

Vaccines Cause Autism

Claim Based on:

- CDC Whistleblower claims.
- Parental Testimony.
- Claims from:
  - Doreen Granpeesheh
  - Stephanie Seneff

Parental Testimony by the numbers: https://thelogicofscience.com/2016/06/28/why-are-there-so-many-reports-of-autism-following-vaccination-a-mathematical-



Recollection issues:

- Brian Hooker: Case Dismissed at Vaccine Injury Compensation Program –
  - Claim: Child suddenly regressed.
  - Medical records show:
    - Child had developmental problems from infancy.
    - No indication of sudden regression during the time period it allegedly occurred.

Vaccine Oversight Lacking

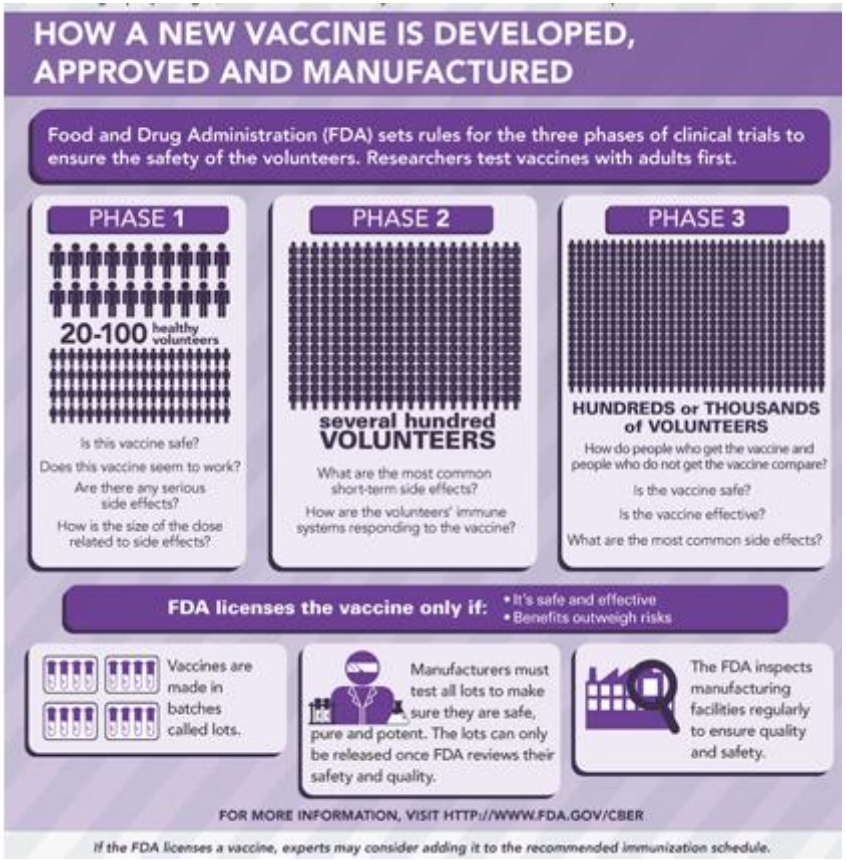
The claims:

- Vaccines are not as thoroughly tested as other products:
  - No placebo-based testing.
  - No testing with the rest of the schedule.

- Liability protections=no accountability.

Vaccine testing:

- Placebo-based for modern vaccines.
- Tested with schedule.
- Extensive testing before & monitoring after.



Accountability:

- Liability protections not absolute.
- Liability protections≠no accountability: heavy regulation and monitoring.
- Liability protection part of compromise that makes compensation easier.

Vaxxed's Omissions:

- Additional MMR/Autism studies.
- Retraction of both Hooker and Wakefield's papers.
- Changes in diagnostic criteria for autism.
- MMR Wakefield discusses never used in United States.
- Children in Wakefield's study recruited through litigant group.

Thank you!

Questions? Comments?

reissd@uchastings.edu
415-565-4844