Cal-Oregon Unvaccinated Survey

"We surveyed over 9,000 boys in California and Oregon and found that vaccinated boys had a 155% greater chance of having a neurological disorder like ADHD or autism than unvaccinated boys." -Generation Rescue, June 26, 2007

# Methodology

Generation Rescue commissioned an independent opinion research firm, SurveyUSA of Verona NJ, to conduct a telephone survey in nine counties in California and Oregon. Counties were selected by Generation Rescue. Interviews were successfully completed in 11,817 households with one or more children age 4 to 17. From those 11,817 households, data on 17,674 children was gathered. Of the 17,674 children inventoried, 991 were described as being completely unvaccinated. For each unvaccinated child, a heath battery was administered.

Generation Rescue chose to use telephone interviews with parents to gather data on children, so as to closely mirror the methodology the CDC uses to establish national prevalence for NDs such as ADHD and autism through their national phone survey of parent responses. Generation Rescue chose to focus on children ages 4-17 to match the age range used by CDC.

Are parent responses a reliable indicator of a child's diagnostic status? According to Dr. Laura Schieve, co-author of the CDC's national phone survey study, in discussing the CDC's two phone surveys on autism prevalence, "the consistency of prevalence estimates across the two surveys supports high reliability or reproducibility of parental report of autism and reliability is one important component of validity."

SurveyUSA is a well-known national opinion research firm with unique expertise in canvassing local communities. SurveyUSA has no vested interest in any outcome this or any survey might produce. You can see a copy of the questionnaire used in the survey here. The data the survey intended to capture included:

- -Households with a child or children aged 4-17
- -Whether or not that child had been vaccinated
- -Whether or not that child had any one (or more) of the following diagnosis: ADD, ADHD, Asperger's, PDD-NOS, Autism, Asthma, or Juvenile Diabetes (the final two of which were added to consider other health outcomes).

The results of the survey allowed us to compare the prevalence (what percentage of children have a particular diagnosis) to see if there was any meaningful difference between unvaccinated and vaccinated children.

The most common way to measure prevalence differences is through a calculation known as relative risk or the Risk Ratio, where we compared prevalence amongst unvaccinated children to prevalence amongst vaccinated children. So, if 5% of unvaccinated children have asthma, and 10% of vaccinated children have asthma, that represents an "RR" of 2.0 (10%/5%), or a difference of 100%. We were also able to look at the data by gender, age, and county.

### **Results**

Survey USA gathered data on 9,175 boys and 8,499 girls. Counties surveyed in California included:

San Diego, Sonoma, Orange, Sacramento, Marin

Counties surveyed in Oregon included: Multnomah, Marion, Jackson, Lane

The results of the survey can be accessed as a pdf file here. This is the primary data we received from SurveyUSA and it can be used for anyone to independently analyze our results.

Generation Rescue analyzed the data provided by SurveyUSA, and a copy of our analysis can be found here. The most notable results of our survey are with the boys, which is not surprising considering boys represent approximately 80% of total cases of NDs. Namely:

All vaccinated boys, compared to unvaccinated boys:

-Vaccinated boys were 155% more likely to have a neurological disorder (RR 2.55)

- -Vaccinated boys were 224% more likely to have ADHD (RR 3.24)
- -Vaccinated boys were 61% more likely to have autism (RR 1.61)

Older vaccinated boys, ages 11-17 (about half the boys surveyed), compared to older unvaccinated boys:

- -Vaccinated boys were 158% more likely to have a neurological disorder (RR 2.58)
- -Vaccinated boys were 317% more likely to have ADHD (RR 4.17)
- -Vaccinated boys were 112% more likely to have autism (RR 2.12)

(Note: older children may be a more reliable indicator because many children are not diagnosed until they are 6-8 years old, and we captured data beginning at age 4.)

All vaccinated boys, removing one county with unusual results (Multnomah, OR), compared to unvaccinated boys:

- -Vaccinated boys were 185% more likely to have a neurological disorder (RR 2.85)
- -Vaccinated boys were 279% more likely to have ADHD (RR 3.79)
- -Vaccinated boys were 146% more likely to have autism (RR 2.46)

All vaccinated boys and girls, compared to unvaccinated boys and girls:

- -Vaccinated boys and girls were 120% more likely to have asthma (RR 2.20)
- -No correlation established for juvenile diabetes

All vaccinated girls, compared to unvaccinated girls:

-No meaningful differences in prevalence were noted for NDs (which may be due to the smaller sample size of the study because girls represent about 20% of cases.)

# Commentary

Generation Rescue is not representing that our study proves that the U.S. vaccine schedule has caused an epidemic in neurological disorders amongst our children. We are a small non-profit organization. For less than \$200,000, we were able to complete a study that the CDC, with an \$8 billion a year budget, has been unable or unwilling to do. We think the results of our survey lend credibility to the urgent need to do a larger scale study to compare vaccinated and unvaccinated children for neurodevelopmental outcomes.

It is also the opinion of Generation Rescue that we are over-vaccinating our children, and we encourage parents to use caution in how they choose to vaccinate their children, particularly boys. In the vaccine section of our website, we provide additional detail on vaccines and vaccinating safely and provide three alternative vaccine schedules parents may want to consider for their children.

### Background:

In 1983, the Centers for Disease Control ("CDC") recommended a total of 10 vaccines for our children up to the age of 5. In 2007, the CDC recommends 36, an increase of 260%, or 3.6x. (See a comparison here).

During this time period, we have witnessed an epidemic of childhood neurological disorders ("NDs"). Today, the CDC estimates that 1 in 13 U.S. children has been diagnosed with ADHD and 1 in 150 has been diagnosed with autism. In the 1980s, ADHD was almost unheard of and autism was estimated to affect 1 in 10,000 children. Boys are significantly more affected by NDs, accounting for approximately 80% of all cases.

Unfortunately, the mainstream media still misreports that the explosive growth in NDs is the results of "better diagnosis" despite the considerable published scientific research to refute this position. As one example, Department of Developmental Services in California, known for keeping the best autism data in the country, issued this report regarding the growth of autism rates in California where they stated:

"There is no evidence that a loosening in the diagnostic criteria has contributed to increased number of autism clients...we conclude that some, if not all, of the observed increase represents a true increase in cases of autism in California...a purely genetic basis for autism does not fully explain the increasing autism prevalence. Other theories

that attempt to better explain the observed increase in autism cases include environmental exposures to substances such as mercury; viral exposures; autoimmune disorders; and childhood vaccinations."

Many parents blame vaccines for their children's ND, and many published biological studies seem to support this position, because vaccines contain ingredients capable of causing neurological damage. Yet, no studies have ever been done to compare ND rates of unvaccinated children to vaccinated children. Until now.

(Note: Neurolological disorders include ADD, ADHD, Asperger's, PDD-NOS, and Autism.)

#### Brief commentary:

There is a lot of misreporting that would lead parents to believe that vaccines have already been scientifically proven to be unrelated to the epidemic of NDs. This is simply not true.

- -U.S. children have been analyzed to compare those who received some mercury in their vaccines with those who received more mercury in their vaccines for the outcome of autism (not ADHD). The conclusion of the study was neutral, meaning a link could neither be confirmed nor denied. This study, conducted by the CDC, is the only study ever done using data of U.S. Children.
- -Children in several European countries have been analyzed to compare those who received mercury in their shots with those who received no mercury in their shots for the outcome of autism. The conclusions of these studies was that no association was found, although these studies have been disputed. See <a href="http://www.putchildrenfirst.org/">http://www.putchildrenfirst.org/</a> for more details.
- -Further, in 2006 the National Institute of Environmental Health Sciences, at the request of Senator Joseph Lieberman, issued this report which effectively conceded that both the CDC study of U.S. children and the "Danish Studies" were of poor study design and not reliable in determining whether or not Thimerosal causes autism. As this article from UPI reporter Dan Olmsted noted following the report's release: "For three years, the CDC has used a study conducted on its own Vaccine Safety Datalink to reassure parents that mercury in vaccines does not cause autism. Now a panel of government-appointed experts says there are "serious problems" with exactly the approach the CDC took." Olmsted interviewed the Chairperson of the NIEHS Committee who was quoted as saying:

"It's an 'open question' whether anything about vaccines -- timing, dose, preservative -- is related to the rise in diagnoses [of autism]. Some studies are stronger than others. The Verstraeten [Pediatrics] study was an improvement on other studies including the two in Denmark, both of which had serious weaknesses in their designs that limit what we can learn from them."

- -No studies have ever been done to compare ND rates of children who received vaccines with those who received no vaccines, which is what our survey accomplished. Moreover, no studies have ever explored a link between vaccines and ADHD, despite the fact that 1 in 13 U.S. children have this diagnosis (versus 1 in 150 for autism).
- -Even the Institute of Medicine, which is often cited in the media for issuing a 2004 report refuting the relationship between mercury and autism, held a 2007 workshop on "autism and the environment" that featured "presentations and discussions on strategies for research focusing on the potential relationship between autism and an array of environmental exposures."

The glaring absence of a study to compare vaccinated and unvaccinated children for ND rates caused Congresswoman Carolyn Maloney (D-NY) to introduce this bill to compel the National Institutes of Health to do such a study.

#### **Potential Criticisms**

The question of whether or not vaccines have played and role in the epidemic of neurological disorders is an explosive topic with many passionate voices on both sides of the debate. Our survey results will most assuredly be challenged and criticized. Some of the more likely challenges (and our responses) include:

**Criticism:**Parents who do not vaccinate their children are less likely to seek an ND diagnosis, which explains the difference in prevalence you found.

Response: We think the data disproves this, because we found no meaningful difference in

prevalence for NDs between vaccinated and unvaccinated girls. If this was simply an issue of parent behavior, the girls would have shown wide discrepancies in prevalence, too, and they did not.

It's also interesting to consider a study completed by the CDC and published in Pediatrics, Children Who Have Received No Vaccines: Who Are They and Where Do They Live? The study noted:

"Unvaccinated children tended to be white, to have a mother who was married and had a college degree, to live in a household with an annual income exceeding \$75,000, and to have parents who expressed concerns regarding the safety of vaccines and indicated that medical doctors have little influence over vaccination decisions for their children."

## And, it continues:

"Why do some parents avoid vaccinating their children? Our results indicate that parents of unvaccinated children are much more concerned about vaccine safety than are parents whose children receive Your browser may not support display of this image.1 vaccine dose. In a survey of parent's beliefs and practices regarding vaccinations and autism, siblings in families in which there was an autistic child were 3 times more likely to be unvaccinated, compared with siblings in families in which there was a child with attention-deficit/hyperactivity disorder. In response to concerns about the perceived risk of autism resulting from vaccinations, parents might have avoided having their sons vaccinated at a higher rate than their daughters, as a result of knowing that they have risk factors for autism and knowing that the rate of autism is 4 times greater for boys than for girls."

**Criticism:**The ratio of diagnosed to undiagnosed children in this survey may be too high, indicating a potential response bias.

Response: The survey does not attempt to newly establish the prevalence of autism in the general population. The survey attempts only to shed preliminary light on any relationship between vaccination status and diagnosis. It is not surprising and not unexpected that parents with children who have received a diagnosis may have been more willing to complete the health battery included in this survey than parents of children who have not been diagnosed. However, that does not make the parents who did participate in this study likely to lie about, or forget about, the vaccination status of their children. The only way a possible "response bias" in favor of those households with a diagnosed child would invalidate the results of this research is if asking about vaccination status of a child independently produced a bias and that bias interacted with the bias caused by asking about NDs. For the concern to be valid: somehow, the main group of vaccinated families would have to be more likely to respond if there was an ND in the family, without also affecting the response of unvaccinated families in the same way. While such an interaction is possible, this criticism can be addressed by further, more elaborate research. Such a potential interaction does not invalidate this research.

It's also worth considering that if there was response bias, we should have received a disproportionate share of our responses from parents of boys, who represent 80% of NDs, and we did not. Boys were 51.9% of responses and girls were 48.1%. (We hope there was some response bias, because our numbers show a prevalence of autism of 1 in 43, far higher than the CDC's reported number of 1 in 150.)

**Criticism:**Parent responses is not a reliable way to gauge either a child's diagnosis or whether or not a child has been vaccinated.

**Response:**We would point to our "Methodology" section above and cite the CDC, who also uses a parent phone survey to gauge prevalence of NDs in children. We generally mimicked their approach.

# **Final Thought**

Why hasn't a larger scale study comparing ND rates of vaccinated and unvaccinated children already taken place? We don't know. We credit Dan Olmsted, a reporter for United Press International, with giving us the idea to do this study. At a press conference in the summer of 2005, Mr. Olmsted had a chance to ask Julie Gerberding, the Director of the CDC, a simple question. Mr. Olmsted asked:

"Has the government ever looked at the autism rate in an unvaccinated U.S. population, and if not, why not?"

Ms. Gerberding's answer:

"In this country, we have very high levels of vaccination as you probably know, and I think this year we have record immunization levels among all of our children, so to (select an unvaccinated group) that on a population basis would be representative to look at incidence in that population compared to the other population would be something that could be done.

But as we're learning, just trying to look at autism in a community the size of Atlanta, it's very, very difficult to get an effective numerator and denominator to get a reliable diagnosis.

I think those kind of studies could be done and should be done. You'd have to adjust for the strong genetic component that also distinguishes, for example, people in Amish communities who may elect not to be immunized (and) also have genetic connectivity that would make them different from populations that are in other sectors of the United States. So drawing some conclusions from them would be very difficult.

I think with reference to the timing of all of this, good science does take time, and it's part of one of the messages I feel like I've learned from the feedback that we've gotten from parents groups this summer (in) struggling with developing a more robust and a faster research agenda, is let's speed this up. Let's look for the early studies that could give us at least some hypotheses to test and evaluate and get information flowing through the research pipeline as quickly as we can.

So we are committed to doing that, and as I mentioned, in terms of just measuring the frequency of autism in the population some pretty big steps have been taken. We're careful not to jump ahead of our data, but we think we will be able to provide more accurate information in the next year or so than we've been able to do up to this point. And I know that is our responsibility.

We've also benefited from some increased investments in these areas that have allowed us to do this, and so we thank Congress and we thank the administration for supporting those investments, not just at CDC but also at NIH and FDA."

Is Ms. Gerberding genuinely interested in getting an answer? We will let the reader decide.

Generation Rescue June 26, 2007