What if the Consumer Protection Safety Commission Managed VAERS?
By Beth Clay, July 2012
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Consumer product safety is one of the themes utilized in Washington as a reason to pass new regulatory authorities and to increase budgets of regulatory agencies. In recent years Congress passed a massive food safety bill and Dodd-Franks, the major financial regulatory reform while also increasing funding of regulatory agencies such as the Food and Drug Administration (FDA), the agency responsible for assuring the safety of vaccines and other drugs.

The below report is, prompted by the recent report that GlaxoSmithKline pled guilty to both criminal and civil charges and has agreed to pay the largest fine in United States' history to get the Justice Department to close the cases and to keep their corporate executives from going to jail.

For a period between 1999 and 2003, I led a Congressional Committee oversight investigation that looked at reports of vaccine injury including reports that adverse reactions were connected to the epidemic level increases in autism spectrum disorders. For asking questions, there were those in the public health community that attempted to label us as 'anti-vaccine' and deny the concerns of thousands of families and an increasing number of medical professionals. To be clear, there was no 'anti-vaccine' mentality. Rather, there was and remains an earnest desire to get to the truth and to make the truth available to the public. Sadly, it is my observation that the thousands of parents who have spoken up, reported their child's medical injury and expressed their concerns have not been embraced by their government, but have been rejected, insulted, and ridiculed at every turn by the very public health community that has promoted the drug that is linked to their child's injury.

While the FDA and its sister agencies within the public health community have over the last dozen years, repeatedly told the public that vaccines are safe and effective for children, they have collected adverse event reports. A review of the FDA biologics recall page found no recalls of vaccines due to reports of injury. Over the course of the same dozen years, the Consumer Product Safety Commission has taken a much different stance regarding safety concerns of infant car seats. The Commission shows a history of working with the manufacturer of car seats in voluntary recall when a risk is identified, even when no reports of harm or death have been received.

The GlaxoSmithKline Settlement

On July 2, 2012, Deputy Attorney General James M. Cole Speaks in announcing the Settlement Agreement between the US Government and GlaxoSmithKline, stated:

> "*…the Justice Department and our law enforcement partners have reached an historic $3 billion resolution with the pharmaceutical manufacturer GlaxoSmithKline, LLC, to resolve multiple investigations into the company's sales, marketing, and pricing practices. This action constitutes the largest health care fraud settlement in United States history. It underscores our robust commitment to protecting the American people from the scourge of health care*

fraud. And it proves the effectiveness of the strong relationships we've forged with our partners to help ensure the health and safety of the American people, and to safeguard the integrity of our health care system.

Under the agreements announced today, GSK will plead guilty to criminal charges and pay $1 billion in criminal fines and forfeitures for illegally marketing and promoting the drugs Paxil and Wellbutrin for uses not approved by the FDA – including the treatment of children for depression, and the treatment of other patients for ailments ranging from obesity, to anxiety, to addiction and ADHD – and for failing to report important clinical data about the drug Avandia to the Food and Drug Administration. GSK will pay an additional $2 billion to resolve civil allegations that it caused false claims to be submitted to federal health care programs for these and other drugs as a result of the company's illegal promotional practices and payments to physicians. This settlement also resolves a civil investigation of the company's alleged underpayment of rebates that were required under the Medicaid Drug Rebate Program."(US Department of Justice)

The press release form Justice goes into further detail regarding the matters in which GSK has agreed to plead guilty (US Department of Justice). "GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA)."

Paxil

- From April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use.
- GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy.
- GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18.
- GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents.
- GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended.

Wellbutrin

- From January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses.
- GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted.
- To promote Wellbutrin for the unapproved uses GSK used:
    - sales representatives,
    - sham advisory boards, and

- supposedly independent Continuing Medical Education (CME) programs

Avandia

- Between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends.
- The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia.

GSK is among the companies that has liability protection coverage in the Vaccine Injury Compensation Program, a program managed by the Department of Health and Human Services for which the Department of Justice provides legal representation. GSK is also the company that hired CDC epidemiology fellow Thomas Verstraeten before he made a presentation of the thimerosal Vaccine Safety Datalink study to the Institute of Medicine. Dr. Verstraeten remains in their employee and continues to publish in the field of vaccine injury. The latest publication is a post-marketing surveillance study on rotavirus vaccine in Mexico. The study found an increased risk of intersucception within seven days of the first dose. The conclusion of the study as provided on Pub Med:

"This is the largest surveillance study for interssusception after rotavirus vaccination to date. A temporal increase in the risk for interssusception was seen within 7 days of administration of the first vaccine dose. It is still uncertain whether rotavirus vaccination has any impact on the overall incidence of interssusception. This finding has to be put in perspective with the well-documented substantial benefits of rotavirus vaccination." (Velázquez FR)

Consumer Product Safety Commission

The Consumer Product Safety Commission is a federal agency responsible for monitoring products that may pose a fire, chemical, electrical or mechanical hazard to children. One of the areas they have been very active in monitoring is the area of car seats and carriers. Like vaccines, infant car seats are mandated by law to protect the child from the possibility of harm while traveling in an automobile. The Commission does not have a reputation of taking the side of industry over that of the parent. A review of information on their website found that since 2000, eight product recalls of car seats have been conducted. In two of the eight cases, no reports of injuries were received. Overall, less than 500 reports of injuries were received. Most of the reports were for cuts and scrapes. There were no reports of deaths for these products or related to the recalls. This information is provided in Table 1.

Table 1

Reports of Car Seat Recalls From 2000 to 2012
(US Consumer Product Safety Commission)

Date	Recall Report Title	Injury-Incident Reports	Approximate Number of products Recalled
December 2011	Bugaboo Car Seat Adapter Recalled Due to Fall Hazard	One report of minor injury.	64,000
November 2010	Infant Car Seats Recalled by Britax Due to Laceration and Choking Hazards	Three reports of injury - which included minor lacerations and scratches to arms and a finger; and one report involved an infant placing the clip in his mouth.	23,000
December 2009	Fall Hazard Prompts NHTSA, CPSC and Dorel Juvenile Group to Announce Recall of Infant Car Seat/Carriers	At least three injuries to infants including bumps, bruises and a head injury.	447,000
May 2007	Fall Hazard Prompts NHTSA, CPSC and Evenflo to Announce Recall of Embrace™ Infant Car Seat/Carriers	Reports of 160 injuries to children including a skull fracture, two concussions, cuts, scrapes and bruises.	450,000
June 2003	CPSC, NHTSA, and Dorel Juvenile Group Inc. Announce Extended Recall of Infant Car Seats/Carriers	Reports of nine injuries to children. These reports include bruises and scratches to the head and face. According to the reports, some injuries occurred to children restrained in the seat.	2,000,000
May 2002	CPSC, NHTSA, and Dorel Juvenile Group Inc. Announce Recall to Repair Infant Car Seats/Carriers	No injuries were reported.	26,000
May 2001	CPSC, NHTSA, Evenflo Announce Recall to Repair Evenflo® Joyride® Car Seats/Carriers	Report of 97 injuries. These reports include skull fractures, concussions, a broken leg, and numerous scratches and bruises.	3,400,000
October 2000 and September 2003	CPSC, NHTSA and Century Announce Recall of Infant Car Seats/Carriers	Received over 200 reports of injury, including concussions, skull fractures, lacerations, broken bones, bruises, and scratches as a result of such handle-related problems.	4,000,000

How does this aggressive action to protect infants when a risk is identified compare to the response of federal regulators responsible for monitoring vaccine injury reports?

VAERS Reports of Deaths in the United States for Children Five and Under Since 2000

Using the Center for Disease Control and Prevention (CDC) Wide-ranging On-Line Data for Epidemiologic Research (WONDER) access to the Vaccine Adverse Event Reporting System (VAERS), a search was conducted looking for reports of deaths in the United States in children five years and under since 2000. An important caveat to keep in mind regarding this data, as with any adverse event reporting system managed by the government is that the report of an incident is not proof that there is an absolute connection between the product and the injury or death. Rather, this system of reporting is intended to be an 'early warning system' for regulators through which they can quickly identify new or unexpected adverse reactions. The results of the report are provided at Table 2.

Table 2

VAERS Reports of Deaths in Children 5 Years an Under By Year for GlaxoSmithKline Vaccines

Year	DT ADSORBED (DITANRIX)	DTAP (INFANRIX)	DTAP + HEPB + IPV (PEDIARIX)	DTAP + IPV (KINRIX)	HEP A (HAVRIX)	HEP B (ENGERIX-B)	HIB (HIBERIX)	INFLUENZA (SEASONAL) (FLUARIX)	ROTAVIRUS (ROTARIX)
2000	1	32	0	0	0	17	0	0	0
2001	0	53	0	0	1	22	0	0	0
2002	0	41	0	0	0	13	0	0	0
2003	0	25	9	0	0	4	0	0	0
2004	0	6	25	0	0	9	0	0	0
2005	0	6	23	0	0	5	0	0	0
2006	0	2	23	0	0	5	0	0	0
2007	0	4	44	0	2	3	1	1	0
2008	0	1	43	1	2	3	1	0	1
2009	0	1	9	0	3	11	0	0	6
2010	0	2	7	0	4	13	0	0	7
2011	0	0	5	1	1	8	1	0	3
2012	0	0	5	0	1	3	1	0	4
Total	1	173	193	2	14	116	4	1	21

The search of VAERS found 525 reports of deaths in GlaxoSmithKline Vaccines Between 2000 and 2012. The three highest reports were for Infanrix (trivalent vaccine for diphtheria, tetanus and pertussis), Pediarix (diphtheria, tetanus, pertussis, hepatitis B and polio) and Engerix-B (hepatitis B).

Sadly, because FDA appears to take a much different stance regarding consumer protection than the Consumer Protection Safety Commission, the public is not typically informed of the reports of these deaths. If the agency was concerned that a published report on these reported deaths would create fear and reduce immunization rates, did they reach out to the medical community with this information and encourage VAERS reports they way the FDA has done on other products followed under their MEDWATCH system?

A review of MEDWATCH reports on the FDA website finds a recommendation in 2008 to suspend use of Rotarix, not because of the death reported, but because of a report of the presence of DNA from porcine circovirus type 1 (PCV1). Within the year, the FDA informed doctors that it recommended that Rotarix use be resumed and a conclusion that PCV1 does not cause illness in humans. In February 2007, FDA issued an alert to the medical community and consumers about 28 post-marketing reports of intersucception (a condition of the bowel in which it accordions in itself, often requiring surgery to repair) following administration of RotaTeq, Merck's rotavirus vaccine.

Rotavirus Vaccine Death Reports

The rotavirus vaccine is the only vaccine in recent history in which the FDA has moved to alert the public of adverse event reports. This follows their aggressive action in 1999 to restrict the use of Rotashield after reports of adverse reactions were received including two deaths soon after Rotashield was approved for use in the United States. Both Merck and GSK now have products in the marketplace. GSK employee, Dr. Thomas Verstraeten is co-author of a recent study from Mexico showing a continued risk of intersucception within seven days of the first dose of the vaccine. Dr. Paul Offit, the pharmaceutical front man who attacks those who raise concerns about vaccine safety is part of the 3 man team that patented the Rotateq vaccine.

Frustrating to many parents is the failure of the media to inform the public of his deep financial benefits from the promotion of immunizations when they give Dr. Offit a public platform. He admits to making about $6 million when Children's Hospital of Philadelphia sold the patent rights of Rotateq for $182 million. In an email made public by *Age of Autism* Dr. Offit opines that he created the vaccine "…because it's fun and because you think you can contribute…"(Offit) This $6 million compensation is only one portion of the compensation he received for his role in developing the vaccine. It is likely that his true compensation on Rotateq is over $20 million. He also has numerous other financial conflicts of interest that are seldom disclosed to or by reporters. They include being paid by Merck and likely others to promote vaccines through paid speeches to medical professionals.

Table 3

VAERS Reports of Deaths in the United States from Rotavirus Vaccines in Children Age 5 Years and under since 2000

Year	ROTAVIRUS (ROTARIX) (GlaxoSmithKline)	ROTAVIRUS (ROTATEQ) (Merck)	ROTAVIRUS (ROTASHIELD) (PFIZER\WYETH)
2000	0	0	0
2001	0	0	0
2002	0	0	0
2003	0	0	1
2004	0	0	0
2005	0	0	0
2006	0	15	0
2007	0	49	0
2008	1	55	0
2009	6	27	0
2010	7	21	0
2011	3	30	0
2012	2	8	0
Totals	**19**	**205**	**1**

A review of reports of death to VAERS for all rotavirus vaccines in the United States for children ages five years and under finds that 225 deaths have been reported since 2003. While two reported deaths resulted in Rotashield being pulled from the market, reports of 205 deaths between 2006 and 2012 have brought no such action for Dr. Offit's Rotateq sold by Merck.

It should be noted that while Table 3 includes the years 2000 forward to 2012, Rotateq was not approved until 2006. Rotarix was approved in 2008, and Rotashield which originally entered the marketplace in 1998 and was withdrawn in 1999 was re-approved in 2006.

While the VAERS system reports 225 deaths in the United States, an article published in 2011 by CDC personnel states only 38 "rotavirus-coded deaths identified in the national multiple cause-of-death database" between 1999 and 2007. (Desai R, 2011) This is dramatically different than earlier estimates by the public health community that have promoted the importance of recommending the rotavirus vaccine because 20-60 children were dying each year in the United States from rotavirus.

This is Not Intended to Fear Monger

This article is put forward to stimulate discussion and future research. I am not suggesting that parents not immunize their children. The vaccine decision, like all medical decisions is one that parents should make. It should be an informed decision based on the best information available in conjunction with family medical history and personal philosophical and religious beliefs.

To be clear, I am not suggesting that every death that is reported through VAERS is confirmed to be related to the vaccine included in the report. However, as Smokey the Bear taught the Baby Boomer generation of which I am a member – *Where there is Smoke there is Likely Fire!* Certainly, all 525 of the deaths reported in children five years and under for GSK vaccines given in the United States since 2000; and all 205 of the deaths reported in children five years and under since 2006 for the (Offit-Merck) Rotateq given in the United States are not confirmed to be linked to the vaccine. However, I am concerned that so little is being discussed in a forum where the average consumer or medical professional would be aware. Seven hundred children have died.

With the GSK agreement with the US Department of Justice in which they pled guilty to failing to truthfully inform the FDA of research outcomes and misrepresenting the facts in studies they paid to have published, it is impossible to presume that their reporting on vaccine adverse events has been complete or entirely truthful. Merck the maker of Rotateq and other children's vaccine has also been found guilty of the same type of behavior, not by the Justice Department, but through civil law suits for their drug Vioxx.

Because Congress in their desire to protect the vaccine supply provided liability protection to the manufacturers (and presumably the developers) of the vaccines, and the manufacturers have not been required to provide full discovery in the Vaccine Injury Compensation Program, the American public (and the world) has been denied access to the full truth about what is known about vaccine adverse reactions.

This is compounded because the public health mantra continues to be that the benefits of immunizations far outweigh the risks. Because the government and industry control the research resources, too little independent and unbiased analysis takes place. Immunization policies cloud true scientific inquiry and the public has been left in the dark about the actual number of adverse event reports received for vaccines, including in young children. I observed this when the

Institute of Medicine was looking at the neurodevelopmental delays/autism vaccine injury evidence and see this repeated as part of the conclusion of any study such as the latest Verstraeten study on rotavirus vaccines.

I am concerned that too often medical examiners or coroners list SIDS as the cause of death. Such a conclusion may dissuade further research into vaccine adverse reaction as the possible cause of death. The *A.D.A.M. Medical Encyclopedia* defines Sudden Infant Death Syndrome (SIDS) as "the unexpected, sudden death of a child under age 1 in which an autopsy does not show an explainable cause of death."

Death is not the only reported adverse reaction in the VAERS system. In 2011, there were more than 351 vaccine adverse event reports in the United States in the categories of death, life threatening, permanent disability in children under the age of 1 year. There were 373 in 2010 and 308 in 2010 and in 2012 there have already been 91 reports. More than 1,100 babies under the age of one year in the United States have been reported to the FDA to have died, suffered a life threatening injury and/or suffered a permanent disability from their mandated vaccines over the last three and one half years.

Where are the headlines? Where is the Consumer Protection Safety Style investigation? A search in VAERS across all age groups and years available in the system found that more than 1,400 reports have been submitted to VAERS for autism spectrum disorder as an adverse event from vaccines. These reports go back to 1981and is provided at Table 4.

How many death reports does it take for a vaccine to be recalled when less than 38 deaths from the disease it is given to protect against have occurred in an eight year span? Other questions come to mind as well. Where is the research to develop a standard to personalize vaccine schedules to take into account family medical history and possibly genetics so that an informed decision can be made whether to inoculate a baby on their first day outside the womb? Information is power.

I urge parents and soon to be parents to do their own research, to ask questions and to protect your rights to make medical decisions for yourself and your children. Treat a vaccine like you would any other medical decision, read the package insert, ask questions and take into account your family medical history.

If the Consumer Protection Safety Commission was responsible for managing VAERS, given their track record with infant car seats, would we have seen recalls or a different strategy? The evidence indicates that we might have. If true discovery were available within the Vaccine Injury Compensation Program both for the federal government and the vaccine manufacturers and related parties, would the outcomes be different? Would the actual truth be made available to the public about what is known about vaccine adverse events?

Table 4	
VAERS Reports of Autism or Autism Spectrum Disorder in the United States by Year	
Year Vaccinated	**Events Reported**
1981	2
1983	1
1984	1
1985	2
1986	4
1987	1
1988	7
1989	5
1990	8
1991	18
1992	27
1993	31
1994	44
1995	56
1996	68
1997	89
1998	128
1999	98
2000	83
2001	85
2002	75
2003	59
2004	37
2005	43
2006	56
2007	35
2008	21
2009	10
2010	4
2011	3
Unknown	398
Total Reports	1,499

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Beth Clay, Senior Vice President, Capitol Strategy Consultants, Inc. Email: bclay@dc-strategy.com