Talking Points on Vaccine-Injury Concerns 2/16/2012

1. Framework of vaccine-injury concerns
   a. An increasing # of vaccine-injuries resulting in successful lawsuits in 1980's
   b. Congress passes NCVIA (National Childhood Vaccine Injury Act) law in 1986
   c. Beginning in late 1980's, # vaccines for USA child in 1st 15 months of life has increased from 8 to 25
   d. Since late 1980’s, USA has experienced dramatic increases in allergies, asthma, ADHD, and autism
   e. USA has highest # of mandated vaccines for children under 5 in the world (36, double the Western word average of 18), the highest autism rate in the world, but only places 34th in the world for its mortality rate in children under age 5
   f. Most developed countries do not include several vaccines on the US schedule
   g. Vaccines aren't tested for long-term chronic health outcomes prior to approval
   h. Generally, long-term health outcomes not tested in children who receive vs don’t receive a vaccine
   i. Parents are concerned: a 2010 survey found that 54% of parents are concerned about the adverse effects of vaccines and 25% think some vaccines cause autism in healthy children, and a 2010 poll found that 89% of parents rate vaccine safety as a top priority in children’s health research

2. Potential vaccine-injury rates are very high, and yet there is a strong resistance by public health officials to undertake the study of long-term health outcomes
   a. The one health condition that has been extensively studied is asthma, with research showing as high as 1 in every 13 USA children develops vaccine-induced asthma. Interestingly, research showed that this risk went away if the vaccine was delayed by 4 months.

3. SafeMinds posed the question: do vaccine-injuries from the current USA vaccination schedule now outweigh benefits of vaccines for USA children, and if how can the necessary research be performed to determine what causes vaccine-injuries so that vaccines can be made both safer and more effective?
   a. SafeMinds analysis found research supporting as high as a 1 in 13 risk of vaccine-induced asthma, with an insufficient research on allergies, ADHD, or autism to determine a risk; but weighing that against the risk of vaccine-preventable diseases in the USA in 2012, we found:
   b. If a child didn't vaccinate until age 5 in a highly-vaccinated population, we found the incremental risk of the diseases to range from about 1 in 500,000 to 1 in 30B for injury, and about 1 in 100,000 to 1 in 18B for death
   c. If a child didn't vaccinate until age 5 in a low-vaccinated population (where many others did not vaccinate), we found the incremental risk of the diseases to range from about 1 in 3400 to 1 in 63M for injury, and about 1 in 16,000 to 1 in 20M for death
   d. The take-away from that analysis was that urgent research is needed to understand vaccine-injuries in order to make vaccines safer and more effective, and that in parallel parents need tools to assist them in making informed decisions about vaccines.

4. What about vaccines and autism?
   a. The vaccine-autism link has generally not been studied, despite assertions to the contrary by some public health officials. Only one of the 7 vaccines administered to children in first year of life has been studied for autism rates in children who received vs did not receive the vaccine -- and that one, the Hepatitis B, was shown in recent research to be associated with a 3x increased risk of autism
   b. EBELA study found that 83 children with autism have quietly been paid settlements from the government-run Vaccine Injury Compensation Fund
   c. What has been studied is one vaccine (Measles-Mumps-Rubella) administered after 1 year of age, and one ingredient (the mercury-based preservative called thimerosal that is still included in some flu vaccines). Population studies have not found an association, although animal studies have suggested a link in regards to mercury. SafeMinds & others (Cochrane Collaboration, Congressional epidemiology panel) have raised significant questions about the validity of the population studies.
   d. Several plausible hypotheses haven't been studied, e.g. conjugate vaccines and/or aluminum adjuvants contributing to autism

5. What can parents do?
   a. SafeMinds has developed the SmartVax website (www.smartvax.com) that includes the analysis above and provides parents with tools to assist them in making informed decisions on each vaccine. SmartVax does not recommend a particular vaccination schedule, but instead provides a downloadable "Individual Vaccine Schedule" that helps step the parent through a decision on whether to administer, delay, or forgo each vaccine by having them consider the risks vs benefits of each. (see A SmartVax Approach to Vaccines)
   b. To attend daycare or school in Georgia, a child needs to either be immunized per the recommended schedule or provide a medical or religious exemption form. In Georgia, the religious exemption requires the parent to state that they are exercising their right to vary the immunization schedule based on religious beliefs but does not require any explanation of what those religious beliefs are. Parents can also become involved in ensuring that they have these rights get strengthened as a general philosophical exemption. More information at SmartVax website & SmartVax Facebook page

SafeMinds produced the SmartVax website to encourage a new discourse on vaccines as medical treatments with both benefits & risks that must be weighed and researched. By pursuing scientific research on vaccine injuries, a new immunological paradigm can be discovered that could lead to a safer and more effective vaccination program as well as treatments for many disorders.
6. Influenza vaccine
   a. Cochrane 2006 evidence-based review, flu vaccine was similar to placebo in children < 2 and "...we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, and community transmission of influenza" and that "Decision makers' attention to the vaccination of very young children is not supported by the evidence summarized in our review."
   b. The largest study on 50K pregnant women (by Black) over 5 years found no benefit from flu vaccine
   c. SmartVax analysis, based on Cochrane, found no increased risk from not vaccinating
   d. Average 35 flu deaths annually in 2007/08 < 5 per 21M children = about a 1 in 600,000 risk
   e. Flu vaccines are a “Category C drug”, meaning that they are not tested for safety on pregnant women
   f. Paper published this month (Patterson et al, Maternal immune activation yields offspring displaying mouse versions of autism) indicates that there might be risk to fetus by exposing pregnant women to flu vaccines
   g. About 47% of flu vaccines contain mercury preservative ‘thimerosal’, which animal studies have shown can enter the brain and interrupt brain development
   h. Over 200 antigens can cause “influenza-like illness”; a CBS investigation in 2009 found that about 90% of persons diagnosed with H1N1 flu didn’t have any kind of flu at all based on lab testing
   i. Safeminds.org has a special section with flu vaccine information, and SmartVax website has further info

7. HepB vaccine
   a. Vaccine recommended by CDC at birth, 1-2 months, and 6 months
   b. Vaccine is a benefit to a newborn if the mother is HepB-positive (1 in 480 chance); otherwise, the risk factors begin during teen years (unsafe sex and illegal intravenous drug use)
   c. Immunity from the vaccine administered in first 6 months may wane prior to the teen years
   d. 2009 study indicated that boys who received HepB vaccine had a 3x greater risk of developing autism and a 9x greater risk of needing special education services
   e. Many countries screen pregnant women for HepB and administer HepB to infants only if mother is HepB-positive (such as UK, Denmark, Netherlands, Switzerland, Sweden, Norway, Finland, Iceland, Japan)
   f. SmartVax analysis of risk to a child if not vaccinated by age 5 and mother tested negative for HepB: 1 in 8M injury and 1 in 7.6M death in high-vax population, 1 in 33K injury and 1 in 127K death in low-vax population
   g. SmartVax website has further info

8. DTaP vaccine
   a. Diphtheria, Tetanus, & Pertussis (whooping cough, “hooping”) vaccine recommended at 2, 4, 6, 12, & 48 mos
   b. Diphtheria & Tetanus are low disease risks in modern-day USA, so risk focus is on pertussis
   c. Incremental risk if a child doesn’t vaccinate until age 5: 1 in 432K death (high-vax), 1 in 99K death (low-vax)
   d. Historically, high numbers of vaccine-injuries from pertussis vaccine led to NCVIA act in 1986
   e. Large Canadian study indicated a 1 in 13 risk of developing vaccine-induced asthma from administering pertussis vaccine per recommended schedule, but that this risk goes away if delayed by 4 months
   f. Despite record high vaccination rates, pertussis outbreaks remain cyclical because vaccine is not very effective
      i. CDC representative has stated in Atlanta newspaper that more effective vaccine is needed
      ii. CDC indicated that California pertussis rates were similar in highest-vax and lowest vax counties; there’s no evidence that pertussis outbreaks were related to unvaxed (vaccinated individuals commonly carry and can spread pertussis bacteria because vaccine doesn’t clear person of bacteria)
      iii. DTaP vaccine has suppressed pertussis bacteria, which has encouraged parapertussis to proliferate
   g. Recent research indicating that pertussis bacteria is developing resistance to the vaccine
   h. SmartVax website has further info

9. MMR (MMRV)
   a. Measles, Mumps, Rubella (& Varicella) vaccine recommended at 12 & 48 mos
   b. Mumps, rubella, and varicella (chicken pox) have very low risk to children <5, so the risk focus is on measles
   c. Incremental risk from measles if a child doesn’t vaccinate until age 5:
      i. 1 in 16M injury and 1 in 19M death in highly vaccinated population
      ii. 1 in 15,851 injury and 1 in 18,924 death in low vaccinated population
   d. Dec 2011 Canadian study (Wilson et al) found a 33% increase in emergency room visits or hospital admissions 4-12 days post 12-month vax, which equated to a 1 for every 168 children vaccinated. Study also found an additional 20 febrile seizures for every 100,000 vaccinated at 12 months (a 1 in 5,000 risk)
   e. SmartVax website has further info

10. Thimerosal (mercury preservative)
    a. Is still in about 47% of flu vaccines
    b. Doree Jun 2011 review of neurotoxicity thimerosal studies – animal research has shown that thimerosal can lead to accumulation of inorganic mercury in brain & that doses in vaccines pose the potential to affect human neuro-development; thimerosal not studied with co-occurring aluminum adjuvant in vaccines
    c. Epidemiology studies show increased risk of tics and speech language delays
    d. Elevated levels of mercury in women of child-bearing age, research linking environmental mercury to autism
    e. Possibility of milder cases when exposed to aluminum-adjuvant vaccine w/o thimerosal (should be studied)
f. Unnecessary risk – vaccines are available without preservative or with non-mercury preservatives

Details: Incremental Infectious Disease Risk to a Child who doesn’t Vaccinate until age of five:

<table>
<thead>
<tr>
<th>Disease</th>
<th>Highly Vaccinated Population</th>
<th>Low Vaccinated Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Permanent Injury</td>
<td>Death</td>
</tr>
<tr>
<td>Hepatitis B¹</td>
<td>8,000,000</td>
<td>7,600,000</td>
</tr>
<tr>
<td>Polio</td>
<td>820,000,000</td>
<td>4,000,000</td>
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<tr>
<td>Pertussis²</td>
<td>No Incremental Risk</td>
<td>432,000</td>
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<tr>
<td>Tetanus</td>
<td>No Incremental Risk</td>
<td>759,000</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>No Incremental Risk</td>
<td>108,000</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>No Incremental Risk</td>
<td>483,000</td>
</tr>
<tr>
<td>Influenza (flu)</td>
<td>No Incremental Risk</td>
<td>508,000</td>
</tr>
<tr>
<td>Mumps</td>
<td>19,000,000</td>
<td>19,000</td>
</tr>
<tr>
<td>Measles</td>
<td>16,000,000</td>
<td>19,000</td>
</tr>
<tr>
<td>Hib</td>
<td>No Incremental Risk</td>
<td>3,400,000</td>
</tr>
<tr>
<td>Rubella</td>
<td>30,000,000,000</td>
<td>1,900,000</td>
</tr>
<tr>
<td>Varicella</td>
<td>74,000,000</td>
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</tr>
<tr>
<td>Diphtheria</td>
<td>No Incremental Risk</td>
<td>99,000</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>No Incremental Risk</td>
<td>108,000</td>
</tr>
<tr>
<td>Measles</td>
<td>16,000,000</td>
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</tr>
<tr>
<td>Mumps</td>
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<td>2,400,000</td>
</tr>
<tr>
<td>Measles</td>
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<td>19,000</td>
</tr>
<tr>
<td>Rubella</td>
<td>63,000,000</td>
<td>1,000,000</td>
</tr>
</tbody>
</table>

¹ Risk to infant if mother has tested negative for HepB
² Incremental risk excludes deaths & injury risks before vaccination series is completed

Most Vaccines not studied for Autism in children who received vs didn’t receive the vaccine

Studied (no association found, but studies deemed inadequate)³

Studied (up to 3x risk of vax-induced autism)¹

USA Vaccine Schedule 2011
Most vaccines have been added since the 1986 NVICIA law that protects vaccine manufacturers from lawsuits (includes first year of routine use)

MMR (1963)
Polio (1955)
DTaP (1988)
HepB (1991)
Hib (1988)
PCV (2001)
Varicella (1995)
Influenza (2004)
Rotavirus (2005)
HepA (2005)

1986: NVICIA law protected vaccine manufacturers from lawsuits

California Dept of Developmental Services
Autism Prevalence per 10,000

1988: autism rates began accelerating with children born in 1988, per 2010 EPA study

1986 federal law protected vaccine manufacturers from vaccine-injury lawsuits
1990 change in MMR vaccine formula
1991 new Hepatitis B Vaccine at birth