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MORE STRESS FROM BIG PHARMA FRAUD

KEYWORDS: Ritalin, Matthew Smith, MBD, "black box warning", Concerta, Dayana, Rett syndrome, prenatal stress, terbutaline, thimerosal, MMR vaccine, Varivax, chickenpox, shingles, FDA Vaccine Adverse Event Report System, Vytorin, *Newsweek*, Lipitor, Dr. Robert Jarvik

Our last Newsletter discussed some of the tragic side effects and deaths in children and teenagers resulting from the use of powerful psychotropic drugs, many of which are not approved for use in this age group. This has been precipitated by an alleged "epidemic" of bipolar disease created by their manufacturers, aided by prominent psychiatrists on their payrolls.

Bipolar disease, formerly called manic-depressive psychosis, has always been considered rare or non-existent in children, much like Alzheimer's disease. U.S. **youngsters are now 40 times more likely to be diagnosed with bipolar disorder compared to just ten years ago.** Yet, there has been no similar explosive rise in Europe or other countries.

Many authorities believe that a comparable situation exists for other diagnoses that have skyrocketed in kids over the past decade, including Attention Deficit Disorder (ADD), Attention Deficit Hyperactivity Disorder (ADHD), Obsessive Compulsive Disorder (OCD) as well as Autism.

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Since the signs and symptoms of these overlap, it is not unusual for children to have two or more of these or other diagnoses, with different psychotropic drugs being prescribed for each. Most of these medications have adverse side effects that are significant and additional drugs may be required that could have other side effects.

As a result, it is not unusual for children six years old or younger to be on 4-6 or more drugs for ADHD. Some of these are approved only for adults, are contraindicated in those taking certain types of antidepressants, and their interactions with other medications have not been fully studied. More importantly, their long-term effects on the rapidly growing brain in this age group have not been delineated and could have tragic consequences.

Ritalin, Amphetamines And ADHD Drugs

The most commonly prescribed drug for ADHD is Ritalin (methylphenidate), which is classified by the FDA as a Schedule II substance. This puts it in the same category as Dexedrine, Percodan, Dilaudid, Demerol, morphine, cocaine, and opium. Ritalin is also one of the most popular "street drugs" that are abused and lead to addiction and dependency problems that contribute to drug related crime in North America. Ritalin is now the number-one street drug in Canada. According to one report, "Vancouver has between 6,000 and 10,000 addicts 'shooting' Ritalin into their veins from three to 20 times/day, often in combination with pain-killers or other drugs.

Ritalin was patented in 1954 and was initially prescribed for treating depression, chronic fatigue, and narcolepsy. In the 1960's, it began to be used in children with symptoms of minimal brain dysfunction (MBD) or hyperactivity, now called ADHD. Not much was known about optimal dosage or duration of therapy but discontinuing it was advised if significant improvement was not seen after a month. One consequence of failing to do this may be sudden death from cardiac complications, as happened to 14-year old Matthew Smith, while he was skateboarding with friends.



Matthew W. Smith
9/11/1985 – 3/21/2000

Matthew's problems started in the first grade, when the school's social worker told his parents that if they did not consider putting Matt on Ritalin for their diagnosis of Attention Deficit Hyperactivity Disorder, that Child Protective Services could charge them with neglecting his educational and emotional needs. She also said there was a possibility that Matthew and their other children could be put in foster care if they refused to have their doctor examine him. His parents later learned this was a common practice for certain teachers dealing with students who are having a difficult time learning or tend to be less obedient than others, since drugs can make them much easier to manage. That opinion was reinforced when they visited the doctor with the school's diagnosis and recommendation for Ritalin. He seemed very frustrated and told them to "let the school know, I am not a pharmacy", suggesting that this situation was not unusual. After a brief exam, a few questions about school and home behaviors, sleeping and eating habits and some blood tests, Matthew was placed on 10 mg. of Ritalin three times daily.

Matthew had always been an energetic child, had few problems at home, and his parents did not consider him to be abnormal. The Ritalin failed to completely subdue him and occasionally his exuberance broke through. When his parents saw him on September 1, 2000, the last birthday of his short life, it was through the bars of a prison in a county jail. Significant or repeated school problems can be a punishable offense in some states and he had been admitted to a state hospital for evaluation. He received injections of Haldol, his Ritalin dosage was doubled, and he was discharged on 20 mg. 3 times a day along with a new prescription for the antidepressant Zoloft. On the court date after his 10-day hospital stay, he was ordered by the judge to continue taking all these medications to avoid being institutionalized.

Matthew's sudden death was unanticipated since he had no history, signs or symptoms of heart disease and had never experienced problems while skateboarding or engaging in much more strenuous activities. The autopsy performed by the County's chief pathologist, found that the heart weighed over 400 grams, compared to 350 grams for an average adult heart. It also showed small blood vessel damage that was described as being very similar to the type caused by amphetamines. Despite severe pressure to find some other explanation, the pathologist's Certificate of Death listed his diagnosis as "Death caused from Long Term Use of Methylphenidate, (Ritalin)."

The reaction from various authorities funded by drug manufacturers was swift and predictable. In an Associated Press release, Harvard's Dr. Joseph Biederman, a longtime Ritalin proponent said, "It is a free country and people can have whatever opinion they want. But **Ritalin has a long history of safety unparalleled by any other drug** and that it was not unusual for people to take Ritalin their entire lives. It is given to millions of children. I don't know why this boy died, but we have no known knowledge of people dropping dead on Ritalin." Dr. David Rosenberg, a Detroit child psychiatrist, was a little more cautious, noting "There have been reported increases in blood pressure and pulse that aren't clinically significant, but I would want to avoid it in someone with an underlying heart condition."

By 2006, the FDA had been made aware of at least 19 other cases of sudden death due to Ritalin in children, some as young as six. The number was undoubtedly much higher since it has been established that well over 90% of adverse drug complications are not reported. There were also concerns about a study showing chromosomal abnormalities associated with increased risk of malignancy in children taking Ritalin for more than three years. In February 2006, the FDA Drug Safety and Risk Management Advisory Committee voted overwhelmingly to place a "black box" warning label on Ritalin and all other ADHD prescriptions about possible

cardiovascular complications. The Agency's response was to quickly convene a meeting of its recently formed Pediatric Advisory Committee. One month later, as anticipated, this panel concluded that Ritalin did not need such a warning, since it did not appear to pose any cardiovascular risk for "normal" children. What they meant by "normal" is not clear. Ritalin would not be prescribed for a "normal" child and none of the children who died suddenly while taking it had any history or evidence of heart disease.

A "black box" warning is the most serious warning that can be added to a drug's label information. Amphetamines like Dexedrine and Adderall already had a black box warning indicating dangers and risk of abuse. Ritalin, and other methylphenidate products, like Concerta, a sustained release tablet and Daytrana, a transdermal patch, are not amphetamines and were therefore exempt. All the FDA did was to add to the amphetamine black box warning, "Misuse of amphetamines may cause sudden death and serious cardiovascular events." One year later, they also directed the manufacturers of all drug products approved for the treatment of ADHD "to develop Patient Medication Guides to alert patients to possible cardiovascular risks and risks of adverse psychiatric symptoms associated with the medicines."

None of this is likely to have any effect since patients and even doctors seldom see or read such warnings. Many believe that black box warnings are simply a convenient way to for the FDA to avoid banning dangerous drugs. By resorting to such warnings, that are generally ignored, the agency is essentially shifting the responsibility for any harm to consumers. The side effects listed for Ritalin include: palpitations, stomach pain, insomnia agitation, nervousness and that it is contraindicated in patients taking certain types of antidepressants. However, there is growing evidence that Ritalin can cause suicidal depression, neurological disorders, including Tourette's Syndrome and epilepsy, drug abuse and dependence, stunted growth, and psychotic states "indistinguishable from schizophrenia." It is estimated that up to 4 million children are currently taking methylphenidate products, some as young as two. Anti-Ritalin web sites with numerous horror stories have increased public awareness of its dangers. This may be why, if you want to look up its side effects, Ritalin no longer appears in the PDR listing of brand and generic names for prescription drugs. Nor can it be found under Novartis products, as in previous years.

It's not all bad news. A January 28 2007 press release indicated that Florida Medicaid is now reviewing the use of antipsychotics for ADHD. **The taxpayer bill for these drugs jumped from \$9 million seven years ago to nearly \$30 million in 2006.** Florida Medicaid records show that the number of children - some just months old - receiving these drugs, doubled to over 18,000 during this same period. And even as drug makers were

being told to issue warnings about risks, a Florida Legislature-directed program partly funded by Big Pharma was recommending these drugs for treating ADHD despite the fact that there is no FDA approval for this. A University of South Florida study found the most common diagnosis for antipsychotic treatment for youngsters in Florida's Medicaid program between July and December 2005 was for ADHD. **Over half were for children 5 years old and younger** although the state's Agency for Health Care Administration guidelines specifically states that "antipsychotics should not be used primarily to target ADHD symptoms" and **"The use of antipsychotics in children under the age of six is generally not recommended."** As a result, the Florida attorney general is considering whether to file a lawsuit. Critics claim that there is no proof that "attention deficits" in children are anything more than normal variants in behavior that often disappear with age. Some believe that the same may be true for many children labeled as having autism, and that both disorders are being over diagnosed because there are no clear criteria and the diagnosis is based on a subjective opinion that is often not shared by other physicians.

Stress, Autism, Asperger's And PPD-NOS

Autism is a disorder characterized by an inability to communicate and interact properly with others, along with inappropriate and repetitive behaviors. It has a strong genetic component, is usually diagnosed before the age of three, and persists throughout life. There are other disorders with similar signs and symptoms of impaired social skills that sometimes surface at a later age, and are part of an autistic spectrum categorized as Pervasive Developmental Disorders (PDD). In addition to autism, these include: Asperger syndrome, Rett syndrome, Childhood Disintegrative Disorder and Pervasive Developmental Disorder Not Otherwise Specified. As with bipolar disease and ADHD, the diagnostic criteria for each of these are not precise, there is considerable overlap, with some children being diagnosed with one and then another, or having multiple diagnoses. This is obviously stressful for parents seeking answers as to what to do. Few cases are identical and although there is no cure, the prognosis can be different.

Asperger's Syndrome is named after the Austrian physician Hans Asperger, who in 1944 described children who lacked communication skills, failed to exhibit empathy with their peers and tended to be clumsy when engaging in physical activities. They would often curl up in a fetal position in their chair, chew clothing, usually a sleeve, exhibit repetitive rocking, spinning or tapping behaviors and have difficulty sleeping. They usually have some circumscribed area of interest that they focus on to the exclusion of everything else, some examples being: cars, trains, French literature, door knobs, cappuccino, hinges, meteorology and astronomy. Asperger described his young patients as "little professors".

Rett Syndrome is due to a genetic mutation and is primarily seen in girls, since male fetuses with this abnormality rarely survive. Development is usually normal until 12-18 months when language and motor milestones regress and there is a loss of purposeful hand movement. There is a deceleration of bone growth resulting in a small head as well as small hands, and feet. Stereotypic, repetitive hand movements such as mouthing or hand wringing are frequently seen, as well as cognitive impairment and problems with socialization. Scoliosis, growth failure, and severe constipation are common; up to 80% have seizures, half are confined to wheelchairs and most do not live past the age of 40. There are marked variations in the severity of the disease and it can be difficult to distinguish from autism because of similar symptoms, such as: inconsolable crying, screaming fits, panic attack, avoidance of eye contact, lack of social/emotional interactions and poor communication skills. No two patients are alike and some resemble children suffering from cerebral palsy or Down's syndrome. As a result, many physicians are reluctant to make a definitive diagnosis and classify questionable cases as having Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) or Autistic Disorder. Since this is a **category**, not a diagnosis, such children are often listed as having autism.

This may have contributed to the current alleged epidemic of autism. According to the Centers for Disease Control and Prevention, **fifteen years ago the incidence of autism was 1 in 5,000, compared to today's rate of 1 in 150.** According to the anthropologist David Grinker, there is no autism epidemic. In his book, *Unstrange Minds: Remapping the World of Autism*, Grinker claims that 50% to 75% of the increase in diagnoses is coming from these milder categories of Asperger's and PDD-NOS. In addition, U.S. schools are required to report data on students who receive special education services but **autism wasn't added until 1992. That explains why the numbers skyrocketed from 22,445 in 1955 to 140,254 for school children receiving special services for autism.** Another factor is that parents are seeking more help because there is less stigma associated with autism than decades ago, when the disorder was blamed on chilly "refrigerator" mothers and poor parenting skills. There are also financial incentives, since in some states, parents of children with autism can apply for Medicaid even if they are well above the poverty line. A diagnosis of mental retardation does not always provide this benefit.

Having a child with autism or some other developmental disorder is very stressful, since there is no cure despite a baffling array of treatment recommendations ranging from psychiatric approaches to nutritional supplements. Desperate parents will grasp at any straw that might help. Caring for a child with autism is also very expensive. A recent report from the Harvard School of Public Health estimated that direct medical costs, such

as physician and outpatient services, prescription medications, and behavioral therapies averaged more than \$29,000 per year. Non-medical costs for special education, camps and child care were over \$38,000 annually for those with low levels of disability and over \$43,000 for more severely disabled children. The average cost for lifetime care is \$3.2 million. This combination of emotional and financial stress takes a toll on the entire family and has been responsible for higher rates of divorce and separation.

Although autism is largely genetic, prenatal stress may also play a role, according to one recent report from Ohio State University Medical Center researchers. Their study of 188 women who had delivered autistic children found that they were much more likely to have experienced a major stressor during the 24th through 28th weeks of their pregnancy compared to 212 controls who had normal children and 92 who had children with Down's syndrome. The number of women experiencing major stress during any certain four-week period in their pregnancies remained fairly constant during the study for normal and Down's syndrome pregnancies. However, **stress levels for mothers of autistic children were nearly twice those of the other mothers** in the study. The Social Readjustment Rating Scale, which measures the significance of life change events, was used to gauge the impact at four-week intervals. A "major stressor" was defined as a life-altering event in the woman's life, such a loss of a loved one or losing a job. As the lead investigator explained, "What we were looking for was this rise in the numbers of who had a major stressor during this time period (before 32 weeks) and that these women also had more autistic children." The timing of the stressful events meshes with the periods of development of the fetal cerebellum - a key portion of the brain that is structurally different in autistic children. These results are also consistent with animal studies suggesting that stress experienced at specific periods during pregnancy can lead to structural changes in the brain that have been linked to autism.

Exposure to toxins, infections and other stressors during pregnancy could also contribute to autism. One mother of triplets was devastated when she learned that all of her 15-month triplets had autism. A previous child was perfectly normal and she doubted that the problem was genetic. After combing the literature, she found that terbutaline caused damage to brain regions involved in learning and memory in experimental animals that had been exposed to it before birth. Terbutaline (Brethine) is a drug used to treat asthma by relaxing smooth muscle in the bronchi. It also relaxes muscles in the uterus and is frequently used during multiple pregnancies to prevent premature labor. However, the dose here is much higher than the recommended maximum for asthma, there can be numerous side effects since other muscles can be stimulated to contract, and the FDA has warned against this unapproved off-label use. The manufacturer also discourages it,

since terbutaline has been shown to cross the placenta and have an equal chemical concentration in the fetus as in the mother. In addition to the harmful effects to the fetus, there is a long list of side effects to the mother, including chest pain and hypertension.

In addition to terbutaline, this mother of triplets had also been given magnesium sulfate to prevent premature labor, which is even more toxic to brain tissue. Johns Hopkins researchers subsequently confirmed a higher than expected incidence of autism in twins whose mothers took terbutaline during pregnancy. The identical twin of an autistic child has a 75 to 90 percent chance of also having autism whereas a fraternal twin has only 5 to 10 percent likelihood. A research physician's wife had given birth to fraternal twins, but only one, who was much smaller, subsequently developed autism. After further investigation, he found that terbutaline leads to autism by effects on the B2AR gene. This over stimulates receptors that then produce a barrage of cell-to-cell signals that interfere with normal development, but this can differ in fraternal twins. His wife also received terbutaline as well as magnesium sulfate. He is now convinced that **these two toxins, along with being bombarded with over 200 micrograms of mercury poisoning from vaccinations in the first few years of life, were responsible for retarding this twin's development and autism.**

Other scientists suspect that maternal viral infections can be a major cause of non-inherited autism. Studies have shown an increased incidence in offspring whose mothers were exposed to the rubella (German measles) virus early in pregnancy. California Institute of Technology researchers reported that when pregnant mice were infected with a modified human-flu virus, they produced offspring that later behaved in ways very similar to those of many autistic children. Compared with a control group, the affected mice interacted less and were unusually anxious under mildly stressful situations and when around unfamiliar objects. They also had unusually low numbers of Purkinje cells that are critical signaling components in the brain. Autopsies of people with autism have revealed similar findings, but it is not clear if this is due to viral infection in the fetus, or the mother's immune system responses. As one researcher explained, "Some of the molecules that the mother uses to fight the virus may be crossing the placenta and affecting brain development in the fetus. If so, the problem wouldn't be specific to the flu virus. Lots of kinds of infection could lead to the same effect." Indeed, any influence outside the womb, including toxic drugs, infections that activate immune system responses, a mother's hormonal response to stress, or anything that affects pregnancy, could have similar effects. Newborns and infants are especially vulnerable to the damaging effects of such stressors because the human nervous and immune systems undergo considerable remodeling during the first 2 years of life.

Vaccination Stress, Gardasil And Zostavax

As noted previously, one physician felt that his son's autism was partly due to "being bombarded with over 200 micrograms of mercury poisoning from vaccinations during his first few years of life." Whether vaccinations can cause autism has been a highly controversial topic for the past two decades. Suspicions arose because autism is often diagnosed around the time small children receive a series of routine vaccines containing a mercury-based preservative called thimerosal. Mercury is a known neurotoxin that can damage the cerebellum, basal ganglia and other parts of the brain, resulting in motor slowing, clumsiness, tremor and the mental dulling often seen in autism. The type of mercury used in thimerosal is generally cleared from the body within six weeks, but some researchers point out that babies were often injected with many times the "safe" level determined by the FDA and that some could not clear mercury from their bodies due to genetic factors.

In response, authorities launched several investigations that they claimed had completely absolved the mercury in thimerosal as a contributor to autism. Unfortunately, the hearings on this were held in secret and critics protested that studies showing a definite link had not been reviewed. A widely acclaimed 2006 book by David Kirby, *Evidence of Harm: Mercury in Vaccines And the Autism Epidemic: a Medical Controversy*, was a balanced presentation based on four years of research by this respected, frequent contributor to the *New York Times*. It clearly showed that the FDA had seriously underestimated the amount of mercury being injected into small babies and described what appears to have been a conspiracy between health authorities and vaccine manufacturers who were leery of lawsuits. As Kirby later wrote, "Many of the public health officials who discount the thimerosal theory were unwilling to be interviewed for this book (or prohibited from speaking by superiors). Readers are invited to reach their own conclusions on the evidence."

A *Rolling Stone* article by environmentalist Robert Kennedy Jr. stated that thimerosal in pediatric flu and other vaccines shipped abroad had probably caused millions of autism cases, including 1.3 million children in China where **autism did not exist until they started receiving vaccines**. In an independent study of autism in the U.S. Amish population, which does not allow vaccinations, there was virtually no autism. **Of the four Amish children diagnosed as autistic, all had been vaccinated**, some prior to adoption. He also claimed that public health officials, including the Centers for Disease Control, pharmaceutical companies, and high public officials had fudged numbers and refused to release the epidemiological raw data conclusively proving that vaccines had caused a U.S. epidemic of autism. Thimerosal has gradually been phased out of vaccines in the past few years and thimerosal-free vaccines are now available across the board.

A different issue is the question of harm from the mumps/measles/rubella (MMR) vaccine that has never contained thimerosal or mercury. However, it does include a dose of three live viruses and is given to children at an age when stressors are more likely to cause autism. Most vaccines are based on live or dead viruses, but what makes MMR different is that it contains not one, but three different sets of viruses, and is given to children when they are around the age when autism is likely to become evident. It also contains aluminum, which has been found to be increased in the brain in Alzheimer's disease. Concerns began when a British gastroenterologist tested youngsters with and without autism and found a possible link between measles virus in the gut and autism. He and others also suspect that this may precipitate an immune system response that damages brain tissue in susceptible individuals, some of whom exhibit a gradual but progressive deterioration. Government officials strongly deny such a link and point out that the incidence of autism is just as high when three separate injections are given, showed no change in Japan when MMR was banned, and it is still recommended for all children at 12-15 months, with a second dose later on.

When I entered practice, children routinely received DPT (sometimes called DTP) shots of a triple vaccine to prevent diphtheria, pertussis (whooping cough) and tetanus and were inoculated with smallpox vaccine. Injectable or oral vaccines to protect against polio subsequently became available. Adults rarely received any vaccines save for a booster shot of tetanus toxoid if they suffered an injury that might put them at increased risk for tetanus.

Things have changed considerably since then. Inoculation with smallpox vaccine, which had been around in some form for over 200 years, has not been mandatory since 1972, when smallpox was eradicated in the U.S. It is no longer even available except for researchers and laboratory workers at high risk of infection. However, in addition to DPT, all children now receive vaccines for chickenpox, measles, mumps, influenza, hepatitis A, hepatitis B, rubella, polio, meningococcal polysaccharide vaccine (MPSV) to protect against four microbes that cause meningitis, Hib vaccine to prevent meningitis from *Haemophilus influenzae*, pneumococcal conjugate vaccine (PCV) to prevent pneumococcal pneumonia, influenza vaccine and rotavirus to prevent gastroenteritis from this organism. There are also single dose combinations, such as MMR. Many of these are given as a series of injections at specific intervals, although flu shots are given yearly since the strains of the virus vary. Children under seven can now receive diphtheria/tetanus/acellular pertussis (DTaP) vaccine. DTaP can also be given as part of two different combination vaccines; one includes DTaP, polio, and hepatitis B vaccines, and one contains DTaP and Hib vaccines. Children sensitive to the pertussis component of the combined vaccine can receive a DT (diphtheria/tetanus) combination. Two new tetanus toxoid-

diphtheria-acellular pertussis (Tdap) vaccines are also now available for children older than seven.

With respect to adults, in addition to annual flu shots, pneumococcal polysaccharide vaccine (PPV) is indicated for anyone 65 or older or adults with chronic health problems, (alcoholism, diabetes, cardiac, respiratory or liver disease), sickle cell anemia, spinal fluid leaks, any disease or drug that decreases immune system resistance, Alaska Natives and certain Native Americans. A booster shot is recommended every five years. An anthrax vaccine is also available for adults at increased risk for this infection and is compulsory for military personnel serving in Iraq, Afghanistan or South Korea. Millions of anthrax vaccine doses have been stockpiled here to protect against terrorist attacks. However, it has been the subject of considerable controversy because of severe side effects and several deaths. Vaccines for varied pollens, animal dander and other allergens have long been available. Some for malignancies like melanoma are also in the works.

Many believe that the two latest vaccines, Gardasil, to prevent cervical cancer and Zostavax to reduce shingles (herpes zoster) and painful post herpetic neuralgia, illustrate the triumph of marketing over science. There is little doubt that both could be cash cows. An injection of Zostavax costs \$150 and unlike flu or pneumonia shots, is not covered by Medicare, the population it is targeted for. Gardasil is the most expensive vaccine ever, well over twice the price of Zostavax. Since three shots are required, the total cost of treatment can be up to \$1000 when the \$50 fee for injection is added. It might be worth it for some patients if these vaccines were effective and safe and provided life long protection, as some other vaccines do, but neither vaccine satisfies these criteria. With respect to Zostavax (Varivax for children), serious side effects are uncommon but a booster shot may be required depending on age. And there are questions about efficacy as well as the recommendation that is required for everyone over 60.

Shingles is a reappearance of chickenpox, which is usually a trivial childhood infection. Any recurrence is most likely to be seen six or more decades later and never happens in people who have not had chickenpox. Herpes-varicella virus should not be confused with herpes simplex virus, which causes recurrent cold sores in the mouth or genital region. Herpes simplex is present in over 80 percent of the population, but there may be no symptoms until immune system defenses are lowered by some stressful event. In contrast, **the incidence of shingles in U.S. senior citizens is only 19 per 1000, or 1.9 percent. In addition, only 1.4 out of 1000 cases of shingles ever develops postherpetic neuralgia, or 0.14 percent. The efficacy of Zostavax in preventing herpes zoster was 51 percent in the 60-69 age group, 41 percent in those 70-79 and only 18 percent**

in patients over 80. In vaccinated patients who later developed shingles, **post herpetic neuralgia was reduced by only 3 days (21 days compared to 24 days for a placebo).** Many correctly question whether Zostavax should be required for everyone over 60.

Requiring a series of Gardasil injections to all females aged 11 to 26 is even more controversial. There is no proof that it prevents deadly cervical cancer and appears to be much more dangerous than advertisements suggest.



Although Merck doesn't claim Gardasil prevents cervical cancer, this is implied in a blitz of ads that simply trumpet "One Less". This could apply to anything, but obviously suggests that you will be one less cancer victim. The facts are that Gardasil simply targets four of the well over 100 strains of the human papilloma virus that cause genital warts, which can be precancerous. Promotional literature describes it as safe, with only mild local reactions or flu like symptoms, but it has been linked to at least 11 deaths and serious side effects including paralysis, Bell's Palsy, seizures, as well as fetal abnormalities and miscarriages in pregnant women.

Since its approval 18 months ago, over 3,500 complaints about Gardasil have been filed with the FDA's Vaccine Adverse Event Report System. The number is probably several times that since it is well known that the vast majority of adverse side effects are not reported. Some women died shortly after receiving an injection or suffered from blood clots. Three weeks after her first shot, one 14 year-old developed disfiguring lesions all over her legs that ended her career as a star cheerleader and caused severe emotional distress. A biopsy revealed vasculitis, an autoimmune disorder, and she was warned by a rheumatologist not to continue with the remainder of the series. There is also doubt about the vaccine's ability to prevent cancer. The FDA stated in a March 2003 news release that **"most HPV infections are short-lived and not associated with cervical cancer."** What is worse, is the FDA admitted in May 2006, that in women previously exposed to the virus, **"the vaccine has been found to increase the risk of developing high-grade precancerous lesions by 44.6%."** Vaccinated women believe they are protected from genital warts that might cause cervical cancer, but the findings show **that 129 women would have to be vaccinated with Gardasil to prevent one possibly precancerous genital wart.**

Nevertheless, the "jab everyone with Gardasil" juggernaut rolls on because of parents frightened by deceptive advertising that gives them false hopes. Last February, the Governor of Texas issued an executive order to make Gardasil mandatory for 6th graders entering school next September. It was overruled by the legislature but over 20 states are considering similar bills. New Hampshire doctors can't keep up with the demand and the state spent

\$5 million last year to make Gardasil available to them free for 11 to 18 year-old girls. South Dakota began providing Gardasil free to the same age group one year ago, with \$1.7 million approved by the Legislature and \$7.5 million in federal funds. Washington has a similar program. Virginia is the only state with a law that requires all girls entering the sixth grade to get Gardasil but permits their parents to refuse this. Although the vaccine has not been shown to prevent cancer and is not approved for boys or men, some are receiving it. Studies are underway to get approval to prevent possible precancerous lesions in males from oral sex. Sales exceeded \$1.4 billion in the first nine months of 2007, and if approved for males, Gardasil could eventually bring in up to \$10 billion/year. That may depend on the outcome of growing lawsuits since monetary awards may be limited because Gardasil is now included in the National Vaccine Injury Compensation Program.

The Collapse of Cholesterol And *Sayonara* To Statins?

Oops – wanted to include a section on this, since it is the best example of Big Pharma fraud and deceptive advertising, but I have run out of space. In addition there have been so many recent developments, with more to come over the next few weeks, that it may be necessary to devote an entire Newsletter to this. Among other things, the Vytarin fiasco has revealed that the combination drug has no advantages over a generic, although it lowers cholesterol more, that this information was concealed, and that principals sold off stock in advance. Congress is investigating, the Attorney General of New York and Connecticut are planning to sue for Medicaid fraud, and others are sure to follow. *Businessweek* just ran a cover story showing that the benefits of Lipitor and other statins had been hyped and that LDL was "irrelevant". This was echoed in lead articles in the *New York Times*, *Wall Street Journal* and other prominent publications that also commented on how serious side effects and the potential for cancer had been suppressed.

Even some prominent pro statin physicians have now changed their tune and admit that benefits are not related to lowering LDL or cholesterol. Congress is also investigating the appropriateness of Dr. Robert Jarvik to be a spokesperson for Lipitor as well as his financial arrangements with Pfizer, which is facing still more lawsuits for false advertising. There is much, much more to be said about the crumbling of the cholesterol cartel, the conniving of Big Pharma and their collusion and conspiracy with FDA — so stay tuned!

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