IN THE CIRCUIT COURT OF THE NINTH JUDICIAL CIRCUIT,
IN AND FOR ORANGE COUNTY, FLORIDA

ALAN R. YURKO

v.

Case No.: CR 98-1730

STATE OF FLORIDA
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STATEMENT OF AMICI CURIAE IN SUPPORT OF APPELLANT YURKO APPEAL AND STATEMENT OF AMICI CURIAE IN SUPPORT OF RELIEF

Vaccine Brief

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The success throughout the years of vaccines at eradicating epidemics like Polio, Measles, Mumps, Whooping Cough, and other childhood diseases, is undisputed. While vaccines are credited with many triumphs of epidemiological proportions, as with all drugs, they have known risks to a limited number of individuals. These risks have been the topic of research and controversial debates over the last 60 years. While vaccine research has shown correlations to autism[1], autoimmune disorders[2], asthma[3], and other disorders, the benefits of vaccines have always been thought to outweigh the rather purportedly low probability of harmful side effects. Recently several articles have called into question the relationship between vaccines and the diagnosis of Shaken Baby Syndrome. [4] [5] [6] [7] The exact relationship between vaccines and this diagnosis is unknown, and only with the recent rise in allegations of "Shaken Baby Cases" has it begun to be a topic of consideration for the mainstream scientific community. The effects of vaccines on a pre-exisisting subdural hematoma have never been studied, but research indicates that vaccines can produce encephalopathy[8] and blood clotting disorders[9] [10] [11] both of

[1] Wakefield AJ et al, Ileal-lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet Feb. 28, 1998:351:637-641.

[2] Cohen DC, Shoenfeld Y, Vaccine-induced autoimmunity. J Autoimmunity 1996:9:699-703.

[3] Steering Committee, the International Study of Asthma and Allergies in Childhood (ISAAC) Worldwide variation in prevalence of symptoms of asthma, rhinoconjuctivitis, and atopic eczema. Lancet 1998:351:1225-1232.

[4] Barnes, Patrick D. Ethical Issues in Imaging Nonaccidental Injury: Child Abuse Topics in Magnetic Resonance Imaging. 2002:13(2) 85-94.

[5] Goodwin J. Was It Murder Or A Bad Vaccine? Redbook Magazine September 2000:158-175.

[6] Scheibner V. Shaken Baby Syndrome: The Vaccination Link. Nexus Aug-Sep (31). 1993

[7] Clemetson CAB, Barlows Disease, Med. Hypothesis 2002:59(1):52-56. NOTE: This paper is actually a peer reviewed analysis of the instant case of Mr. Yurko.

which can exacerbate existing subdurals or impede their clotting processes. Randall Alexander, the vice president of the National Center on Shaken Baby Syndrome admitted, under oath, that approximately 50% of so called "Shaken Baby" cases have evidence of an old subdural hematoma[12]. Also, because none of the studies on head trauma to date have included vaccination as a variable, very little is known about how vaccines affect the coagulation cascade and the control of intracranial pressure in children who have suffered short falls or minor head traumas in close proximity to their immunizations.

Because some state witnesses during childhood head trauma cases have contended that the presence of retinal hemorrhages is diagnostic of non-accidental trauma, more research needs to be done on the links between vaccines and ocular hemorrhages. A case study by Devin called into question the role of vaccines in the diagnosis of non-accidental trauma in children based on a documented case where retinal hemorrhages appeared in a perfectly healthy adult after the administration of a Hepatitis B vaccine[13]. Several other studies have shown a relationship between ocular disturbances and vaccines. [14] [15] [16] [17] [18] [19]

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[8] Byers R., Moll F Encephalopathies Following Prophylactic Pertussis Vaccine, Pediatrics 1948:1(4):437-39.

[9] Miller, E. et al, Idiopathic Thrombocytopenic Purpura and MMR Vaccine, Archives of Disease In Children 2001:84:227-229.

[10] Urbaschek, Fortschr Med August 14, 1975:93(22-23):1067-1071.

[11] McCuskey et al, Review: the microcirculation during endotoxemia, Cardiovascular Res. Oct. 1996: 32(4):752-763.

[12] Randall Alexander Testimony in People v. Lewis. San Diego County 2001. SCD 159354.

13 Devin F, Roques G, Disdier P, Rodor F, Weiller P.J, Occlusion of central retinal vein after hepatitis B vaccination.. The Lancet 1996. 147: 1626.

According to existing literature on the subject, arguments on the relationship between vaccines and a diagnosis of "Shaken Baby Syndrome" (hereinafter "SBS") fall into three categories:

1. Arguments that known side effects of vaccines can exacerbate asymptomatic subdural hematomas or increase the magnitude and effect of a short fall or minor head trauma.
2. Arguments that improper vaccine administration can produce systemic vulnerabilities in children and increase the effects of a minor head trauma.
3. Arguments that the contents or number of vaccines themselves increase vulnerabilities and systemic reactions in children.

(For a more thorough review of the existing literature on vaccines and their relationship to SBS in general, and the case at bar specifically, see Exhibit 1: Declaration of Dr. Harold Buttram, Exhibit 2: Declaration of Dr. Archie Kaikorinos, Exhibit 3: Declaration of Dr. Viera Shciebner, Exhibit 4: Declaration of Dr. Michael Innis, and Exhibit 5: Declaration of Dr. Mohammed Al-Bayati.)

Exhibits:

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[14] Brezin A, Massin-Korobelnik P., Boudin M., Gaudric A., Lehoang P., Acute Posterior Multifocal Placoid Pigment Epitheliopathy After Hepatitis B Vaccine, Archives of Ophthalmology 1995:133:297-200.

[15] Cogan D., Immunosuppression and Eye Disease, American Journal of Ophthalmology 1977:83(6):777-788.

[16] Rochat C., Immunological Profiles in Patients with Acute Retinal Necrosis. Graefe's Archives of Clinical Experimental Ophthamology 1996:234:547-552.

[17] Ribera EF, Polyneuropathy associated with administration of hepatitis B vaccine. New England Journal of Medicine 1983:309:615-615.

[18] Brezin A, Visual loss and eosinophilia after recombinant hepatitis vaccine. Lancet 1993:342:563-564.

[19] Granel B, Disdier P, Devin F, et al. Occlusion of the central retinal vein after vaccination against viral hepatitis B with recombinant vaccines: 4 cases. Presse Med 1977:26:62-65.

1. Known side effects of vaccines can exacerbate asymptomatic subdural hematomas or increase the magnitude and effect of a short fall or minor head trauma.

When doctors and experts are questioned as to whether a child's death could be the result of a vaccine, they generally state that the most common and most severe reactions to vaccines are febrile response and redness at the site of injection. In contrast, vaccine studies reveal that there can be vaccines for which particular kinds of systemic reaction are far more common than local reactions[20]. Studies related to Hepatitis B RECOMBIVAX HB reveal that out of 432 doses administered to 147 infants, only 0.2% of the infants showed redness at the site of injection whereas 10.4% had systemic reactions including the same signs of elevated intracranial pressure that are present in many of the "SBS" prosecutions (irritability, fever, diarrhea, fatigue/weakness, diminished appetite, rhinitis)[21]. Additionally, Prevnar a newer pneumococcal (prophylaxis against *Streptococcus pneumonia* infection) vaccine that uses non-toxic mutant diphtheria toxin as carrier protein or enhancer, lists adverse side effects that closely resemble so called "Shaken Babies" medical histories in the hours and/or days immediately before their respiratory arrest or.

Systemic reactions from vaccines include fever, irritability, loss of appetite, sleepiness and inconsolable crying[22]. Vaccines have also been shown to possibly produce more concerning symptoms such as purpura, ecchymosis, thrombocytopenia[23],

[20] RECOMBIVAX HB Copyright Merck and Co. Issued August 2000.

[21] RECOMBIVAX HB Copyright Merck and Co. Issued August 2000.

[22] PREVNAR Manufactured by Lederle Laboratories. Marketed by Wyeth Lederle Vaccines. Revised on April 15, 2002.

neuropathy[24], retinal hemorrhage[25], anaphylaxis[26 27], hypotonic hyper-responsiveness[28], cyanosis[29], vasodilation, asthma[30], seizures[31], erythema[32 33], encephalitis[34 35 36], encephalomyelitis[37], and death[38]. Most important to this appeal is that some vaccines are reported to occasionally produce encephalopathy[39], encephalitis [40 41 42], and other

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[23] Miller, E. et al, Idiopathic Thrombocytopenic Purpura and MMR Vaccine, Archives of Disease in Children 2001:84:227-229.

[24] Ribera EF, Polyneuropathy associated with administration of hepatitis B vaccine. New Engl Jmed 1983:309:615-615.

[25] Devin F., Roques P. Disdier F., Rodor P., Occulsion Of Central Retinal Vein After Hepatitis B Vaccination. The Lancet 1996:347:1626.

[26] VARIVAX (Oka/Merck) Copyright Merck and Co.; Issued November 2000.

[27] Munoz JJ, Peacock MG, Hadlow WJ, Anaphylaxis or so-called encephalopathy in mice sensitized to an antigen with the aid of pertussigen (pertussis toxin). Infection and Immunity 1987:55:1004-1008.

[28] Olin P., Rasmussen F., Gustafsson L. Hallander H. and Heijbel H., Randomized Controlled Trial Of Two, Three, and Five-Component Acellular Pertussis Vaccines Compared With Whole-Cell Pertussis Vaccine. The Lancet 1997:350:1569-1577.

[29] TRIVAX HIB SmithKIine Beecham Pharmaceuticals, Mundells, Welwyn Garden City, Hertfordshire AL7 IEY. Jan. 11, 1996.

[30] Odent M., Culpin E., Kimmel T., Pertussis Vaccination and Asthma: Is There a Link? JAMA 1994:272:592-3.

[31] RECOMBIVAX HB Copyright Merck and Co. Issued August 2000.

[32] TRIVAX HIB SmithKIine Beecham Pharmaceuticals, Mundells, Welwyn Garden City, Hertfordshire AL7 IEY. Jan. 11, 1996.

[33] Goolsby PL, Erythema nodosum after Recombivax HB hepatitis B vaccine. New England Journal of Medicine 1989:321:1198-1199.

[34] Flexner S, Post vaccinal encephalitis and allied conditions. JAMA 1930:94:305-311.

[35] Gorter E, Post vaccinal encephalitis. JAMA 1933:101:1871-1874.

[36] Anon. Post-infectious encephalitis: a problem of increasing importance. JAMA 1929:92:1523-1524.

[37] Munoz J., Bernard C., Elicitation of Experimental Allergic Encephalomyelitis in Mice with the Aid of Pertussigen. Cellular Immunology 1983:83:92-100.

[38] Niu MT, Salve ME, Ellenburg SS, Neonatal deaths after hepatitis B vaccine the vaccine adverse event reporting system. Arch Pediatr Adolesc Med 1991-1998:199:153:1279-1282.

[39] Behan PO, Moore MJ, Lamarche JB, Acute necrotizing hemorrhagic encephalopathy . Postgraduate Medicine 1973:54(4):154-160.

conditions that cause brain swelling[43] [44] [45] [46] or increased intracranial pressure[47] [48] [49] in a recognized percentage of children[50]. Swelling in the brain increases vascular permeability, which in turn can increase a child's vulnerability to a head injury or can produce conditions that would cause a subdural to rebleed. While the adage by the American Academy of Pediatrics is that short falls do not kill, some children can and do have died from short falls. Common sense tells us that a swollen brain is more fragile than a brain that is not under some sort of neurological stress.

Some vaccines have also been shown to produce clotting disorders (coagulopathies)[51]. Coagulopathies cause alterations in blood viscosity and reduce a subdurals ability to clot and increase its tendency to rebleed. This can be problematic for children with undiagnosed or asymptomatic subdural hemorrhages. Children with birth

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[40] Flexner S, Post vaccinal encephalitis and allied conditions. JAMA 1930:94:305-311.

[41] Gorter E, Post vaccinal encephalitis. JAMA 1933:101:1871-1874.

[42] Anon. Post-infectious encephalitis: a problem of increasing importance. JAMA 1929:92:1523-1524.

[43] Levine S., Lowinski R., Hyperacute Allergic Encephalomyelitis, Amer J. Pathol 1973:73:247-250.

[44] Munoz J., Bernard C., Elicitation of Experimental Allergic Encephalomyelitis in Mice with the Aid of Pertussigen, Cellular Immunology 83:92-100.

[45] Iwasa, S., Swelling Of The Brain In Mice Caused By Pertussis Vaccine. J.Med.Sci.Biol., 1985:38:53-65.

[46] Ishids, Akama K., Swelling of the brain caused by pertrussis vaccine: it's quantative determination and the responsible factors in the vaccine. Japan J Med Sci Biol 1985:38(2):53-65.

[47] Jacob J, Manning F, Increased intracranial pressure after diphtheria-pertussis-tetanus immunization. J Dis Child 1979:133:217-218.

[48] Gross TP, Milstein JB, Kuritsky JN, Bulging fontanelle after immunization with diphtheria-pertussis-tetanus vaccine and diphtheria-tetanus vaccine.

[49] Mathus R, Kumari S, Bulging fontanelle following DPT. Indian Pediatr 1981:18:417-418.

[50] Byers R., Moll F Encephalopathies Following Prophylactic Pertussis Vaccine. Pediatrics 1948:1(4):437-39.

[51] Miller Supra.

injuries or prior falls or other minor head traumas who receive injections can develop coagulopathies, which can ultimately prove fatal. These injuries may appear shortly after the well-baby visit, with signs of an old and new subdural and an old impact site, but with no signs or indications of a recent trauma. Pediatricians or treating physicians will report that the child appeared fine at the time of the vaccination, and the parents will usually report decreased activity and increased signs of intracranial pressure (lethargy, vomiting, failure to feed and inconsolable crying) subsequent to the immunization. Because more than 50% of the cases currently being prosecuted as shaken baby cases have evidence of an old subdural, the effects of immunizations on the clotting and rebleeding of chronic subdurals should not be dismissed without significantly more research.

2. Improper Vaccine Administration can produce systemic vulnerabilities in children and increase the effects of a minor head trauma.

The Department of Health and Human Services issued a recommendation in 1998 that children should be vaccinated at 2, 4, and 6 months. Unfortunately, many hospitals have, in order to increase compliance with government vaccination programs, continued the practice of vaccinating children at birth and at their 2 and 4 month well-baby check ups. This more rigid schedule can ultimately be dangerous for infants because not all children are appropriate for vaccinations at birth or their well-baby check ups. Some children will manifest disorders that are contraindicated for inoculation. No drug or pharmaceutical treatment is 100% safe. Reactions can occur in perfectly healthy

patients[52]. With vaccines, children and infants with pre-existing clinical or sub-clinical conditions are much more susceptible to injury[53]. Premature infants with predisposing conditions that would indicate immunosuppression or immunocompromise are more susceptible than other infants[54] [55] [56]. Vaccines are generally indicated only for healthy people. Vaccines are contraindicated for people with seizures[57], people with respiratory illnesses, and people who are allergic to eggs, gelatin, and neomycin[58]. Vaccines are contraindicated for people with blood dyscrasias, leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic systems[59]. Merck recommends for vaccinations to be deferred for at least 5 months following blood or plasma transfusions, or following the administration of immune globulin or varicella zoster immununoglobulin. While vaccines are generally safe for the majority of healthy individuals, because hospitals do not test for all of these disorders at birth or prior to vaccinations, hospitals that inoculate at birth risk injuring infants who are contraindicated for vaccines.

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[52] Devin F., Roques P. Disdier F., Rodor P. Occulsion Of Central Retinal Vein After Hepatitis B Vaccination The Lancet 1996:347:1626.

[53] Plotkin, SA, Vaccines, (eds. Plotkin et Mortimer) 1-12 Philadelphia:WB Sandders Company 1994.

[54] CDC, Update: Vaccine Side Effects, Adverse Reactions, Contraindicators and Precautions Morbidity and Mortality Weekly Report Vol.45:September 6, 1996.

[55] Munyer TP, Mangi FJ, Dolan T, Kantor FS, Depressed lymphocyte function after measles-mumps-rubella vaccination. J Infect Dis, 1975:132:75-80.

[56] Beckenhauer WH, Gill MA, Immunosuppression with combined vaccines. J AM Vet Med Assn, 1983:183:389-390.

[57] RECOMBIVAX HB Copyright Merck and Co. Issued August 2000.

[58] VARIVAX (Oka/Merck) Copyright Merck and Co. Issued November 2000.

[59] VARIVAX (Oka/Merck) Copyright Merck and Co. Issued November 2000.

Lastly, the government's Vaccine Adverse Events Reporting System (VAERS) database has over 20 reports of vaccination being associated with SBS[60].

[60] www.vaers.org

3. The contents or numbers of vaccines themselves increase vulnerabilities and systemic reactions in children.

Millions of infants that are born in the U.S. every year have a total of 7 vaccines at the 2 month, and the 4 month, and the 6 month well-baby check ups (that is 21 vaccines before 6 months of age and 35 vaccines before the age of 5)[61]. As no vaccine is 100% safe and the risk of reaction varies greatly, it is pertinent to realize that although reactions are comparatively rare, they do exist. Most research and clinical trials on vaccines test new vaccines with only 1 or 2 other vaccines, even though babies are currently given up to 35 shots by the age of 5. The effects of the number of vaccines have not yet been fully studied.

The study and knowledge of the timing of vaccine reactions is greatly limited. In some cases, delayed onset or gradual onset of post vaccination reactions can take up to 14 days or more to be clinically visible[62], which compounds the difficulty in recognizing reactions. In recognition of adverse reactions to vaccines, in 1986 the U.S. government created the National Vaccine Injury Compensation Program to compensate for injuries caused by vaccines and to insulate pharmaceutical companies from liability so that vaccine production could remain consistent. In an attempt to track vaccine reactions, Title 42, 300 (aa) of the National Vaccine Injury Compensation Act mandates physicians to report suspected reactions to vaccines. Unfortunately, it is thought that only 10% of actual reactions are reported under this passive reporting system. A review of the Vaccine Adverse Event Reporting database reveals that, despite the notoriously

[61] Advisory Committee of Immunization Practices, Centers for Disease Control, Atlanta, GA, USA, Infant Immunization Schedule 2002.

[62] Stratton KR, Howe CJ, Johaston RB Jr. eds. Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. Washington DC: National Academy Press, 1994.

unreliable passive reporting procedures and the short time frame for reactions, approximately 10,000 vaccination reactions are reported each year.

Vaccines are currently being produced with a variety of chemicals and through a variety of processes. With some vaccines, more reactions seem to be associated with certain lots or batches than with others. The term "Hot Lot" has been used to represent these seemingly more reactogenic lots. The "Hot Lot" fear combined with the increase in the number of vaccines given to children, has caused an increase in public concern over vaccines. Recalls for mercury laden vaccines and "hot lots" have been the subject of recent public debate[63]. In 1999 the production of vaccines that use mercury as a preservative, were banned due to concerns of dangerous side effects. However, many such vaccines are still being manufactured and administered to our children today. Sadly, documented cases of vaccine injuries have often caused doctors and officials to accuse caretakers of abuse[64].

Conclusion:

While research on vaccines and allegations of non-accidental trauma to children is in it's genesis, preliminary studies suggest that vaccines can produce conditions that exacerbate prior subdural hematomas and cause retinal hemorrhages. Research also suggests that some children who have been recently vaccinated may be more vulnerable to short falls or minor head injuries as a result of conditions caused by vaccines. It is clear that some children should not be vaccinated. Children should be screened for contraindications prior to inoculations and children should be monitored closely after

[63] Drug Makers tell Congressional Staff they will not produce vaccine without amendment granting immunity from Mercury Vaccine Lawsuits. PR Newswire, November 17, 2002.

[64] Goodwin J. Was It Murder Or A Bad Vaccine? Redbook Magazine September 2000:158-175.

shots. Finally, more research needs to be conducted on the cumulative affects of vaccines and on their contents and production processes.

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