

2001

Ensuring Safe, Effective and Necessary Vaccines for Children

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Recommended Citation

Horwin, Michael E. (2001) "Ensuring Safe, Effective and Necessary Vaccines for Children," *California Western Law Review*: Vol. 37 : No. 2 , Article 4.

Available at: <https://scholarlycommons.law.cwsl.edu/cwlr/vol37/iss2/4>

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COMMENTS

ENSURING SAFE, EFFECTIVE AND NECESSARY

VACCINES FOR CHILDREN

On August 22, 1984 Sean Leary, a healthy nine-month old baby, was administered his third DTP vaccine.¹ Later that afternoon, Sean began to vomit.² The next day, he stopped eating.³ He stayed alert but was no longer active.⁴ That night he cried out every fifteen to thirty minutes.⁵ The following day his mother took him to the pediatrician's office as soon as it opened.⁶ The doctor immediately noted the "obvious circulation collapse."⁷ There at the pediatrician's office, "Sean's eyes rolled back in his head and he stopped breathing."⁸ He was rushed to an emergency room.⁹ Resuscitative efforts failed and Sean was pronounced dead at 1:44 p.m.¹⁰ Sean's parents filed a claim under the National Vaccine Injury Compensation Program and the defendant hired an expert witness named Dr. Jerome Klein.¹¹ Dr. Klein testified that the relationship between the vaccination on August 22, and Sean's death on August 24, was "merely coincidental."¹²

In addition to testifying on behalf of vaccine manufacturers, Dr. Klein is also the chief editor of "pneumo.com" a vaccine website paid for by Wyeth-Lederle.¹³ Wyeth-Lederle is the largest supplier of DTP in the country and

1. *Leary v. Secretary of the Department of Health and Human Services*, 1994 WL 43395, at *1 (Fed. Cl. 1994).

2. *Id.*

3. *Id.* at *2.

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. A claim was filed by Laurie Leary and John Leary on behalf of Sean Leary, deceased, in the United States Court of Federal Claims as required under the National Vaccine Injury Compensation Program. *Id.* at 1. The government declined to concede the case on its pleadings arguing an alternative cause of Sean's death (myocarditis of viral origin). *Id.* A special master subsequently found for the petitioners. *Id.*

12. *Id.* at *6. Contrary to Dr. Klein's testimony, the court held for the petitioners, the Learys. *Id.*

13. <http://pneumo.com/home.html> (last visited October 12, 2000).

also manufactures eight other vaccines.¹⁴ Besides having a relationship with this major vaccine manufacturer, Dr. Klein holds a position on the National Vaccine Advisory Committee. This committee helps the federal government decide what vaccines will be recommended for all children in the United States.¹⁵

One of Dr. Klein's colleagues is James Cherry, M.D. Dr. Cherry has been called "the leading defense expert witness in vaccine litigation."¹⁶ By 1988, Cherry had testified in over eighty cases in which parents sued because their children were allegedly injured or killed by vaccines.¹⁷ Cherry has written that it is a "myth" that pertussis vaccination can cause encephalopathy (brain inflammation)¹⁸, even though a manufacturer lists it under adverse reactions.¹⁹ Furthermore, Cherry has financial relationships with at least four major vaccine manufacturers.²⁰ One manufacturer, Wyeth-Lederle, has paid his department at UCLA Medical Center \$450,000 in unrestricted funds labeled as "gifts."²¹ But most importantly, Cherry has been a member of the Center for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).²² This committee plays a key role in determining U.S. vaccination policy by making vaccine recommendations to the Director of the Centers for Disease Control and Prevention (CDC).²³

14. Michael R. Hugo, *Vaccine Manufacturers and Breast Implant Manufacturers: Same Game, Same Strategies. A Mere Coincidence?*, The Consumer Law Page, October 26, 1996, at <http://consumerlawpage.com/article/vaccine.shtml>. See also PHYSICIANS' DESK REFERENCE 208 (51st ed. 1997) [hereinafter PDR 51]. Lederle manufacturers nine vaccines as of 1997. *Id.*

15. NATIONAL VACCINE ADVISORY COMMITTEE, ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS: QUALITY STANDARDS AND GUIDANCE FOR PROGRAM EVALUATION (2000), <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4901a1.htm> (committee membership list).

16. Hugo, *supra* note 14.

17. Callahan v. Cardinal Glennon Hosp., 863 S.W.2d 852, 869 (Mo. 1993).

From his testimony it was revealed that financial assistance for Dr. Cherry's department and research came through large grants from Lederle. It was also revealed that Dr. Cherry testified for Lederle and other similar companies against plaintiffs in eighty to one hundred products liability or medical malpractice actions.

Id.

18. James Cherry, 'Pertussis Vaccine Encephalopathy': *It Is Time to Recognize It as the Myth that It Is*, 263 JAMA, 1679 (1990).

19. "Neurological complications, such as convulsions, encephalopathy and various mono- and polyneuropathies, including Guillain-Barre syndrome have been reported following administration of preparations containing diphtheria, tetanus, and/or pertussis antigens." PDR 51, *supra* note 14, at 1417.

20. Hugo, *supra* note 14.

21. See *id.* According to Hugo, "This was so designated to allow Dr. Cherry free access to more of the money." *Id.*

22. HARRIS L. COULTER & BARBARA LOE FISHER, A SHOT IN THE DARK 182 (1991). Andrea Rock, *The Lethal Dangers of the Billion-Dollar Vaccine Business*, MONEY MAGAZINE, Dec. 1996 at 148, <http://www.geocities.com/Heartland/Flats/6997>.

23. FACA: *Conflicts of Interest and Vaccine Development: Preserving the Integrity of the Process, Before the Government Reform Committee of the House of Representatives*, 106th

Our legal system entitles pharmaceutical companies to hire expert witnesses to defend their products in court. But a growing number of people who are concerned with the safety of vaccines are fearful that these relationships are jeopardizing the integrity of vaccine policymaking.²⁴ They ascribe their concern to the fact that many of the doctors who enjoy financial connections with vaccine manufacturers are the same individuals who sit on federal advisory committees and make vaccine policy for the country.²⁵

Sean Leary is not alone. Since 1986 there have been over 5,000 claims alleging serious childhood vaccine injury²⁶ including death, paralysis, seizure disorders, and epilepsy.²⁷ And these claims may represent just a fraction of the total number of injuries.²⁸ New vaccines are also bringing new injuries. In March 1999, a vaccine was approved that was designed to prevent diarrhea.²⁹ Within four months it had killed at least one child and critically injured nearly a hundred more by causing intussusception,³⁰ a previously rare

Cong. (June 15, 2000) [hereinafter *Conflicts of Interest and Vaccine Development*] (statement of Dixie E. Snider, MD, MPH, Associate Director of Science, Centers for Disease Control and Prevention (June 14, 2000) at <http://www.house.gov/reform/hearings/healthcare/00.06.15/snider.htm>).

The ACIP provides advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health, and the CDC Director on the most effective means to prevent vaccine-preventable diseases. The ACIP develops written recommendations, subject to the approval of the CDC Director, for the routine administration of vaccines for the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. In addition, as provided by statute, the ACIP designates vaccines for administration in the Vaccines for Children Program (VFC). . . . The overall goal of the ACIP is to provide advice that assists CDC, HHS and the Nation in reducing new cases of vaccine preventable diseases and increasing the safe usage of vaccines and related biological products that provide active and passive immunoprophylaxis.

Id.

24. *Id.*

25. *Id.*

26. Edmund W. Kitch et al., *U.S. Law, in* VACCINES 1175 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

27. Vaccine Adverse Event Reporting System Searchable Database, at <http://www.fedbuzz.com/vaccine/vac.html> (last visited October 18, 2000).

28. See generally Kitch, *supra* note 26, at 1170. Each injury brought in the Court of Federal Claims should be found listed on the vaccine in table. *Id.* at 1174-5. The burden of proof is the preponderance of the evidence. *Id.* If the injury is not on the table, then the burden is proving causation. *Id.* The parameters for the table injuries are strict, i.e. encephalopathy must happen within 72 hours and the table excludes more injuries than it includes when compared to the package inserts. *Id.* See also National Vaccine Information Center, at <http://www.909shot.com/gnscompe.htm>, (last visited Oct. 29, 2000). "I think the vaccine program is an abysmal failure. It is an uncertain, slow, horrible system that is broken." Hugo, *supra* note 14.

29. MAJORITY STAFF OF THE COMM. ON GOVERNMENT REFORM, U.S. HOUSE OF REP., 106TH CONG., CONFLICTS OF INTEREST IN VACCINE POLICY MAKING 9 (Aug. 21, 2000) [hereinafter MAJORITY STAFF REPORT].

30. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 794 (25th ed. 1974). Intussusception

disease.³¹ Three months later it was withdrawn from the market.³²

The House of Representatives Government Reform Committee conducted an investigation into the background of the doctors who participated in the pivotal FDA and CDC vaccine advisory committees that allowed this vaccine to be approved. The investigation culminated in a committee report released on August 21, 2000.³³ According to the report, "The Committee's investigation has determined that conflict of interest rules employed by the FDA and CDC have been weak, enforcement has been lax, and committee members with substantial ties to the pharmaceutical companies have been given waivers to participate in committee meetings."³⁴

Vaccines are the only medical intervention mandated for healthy children.³⁵ Although some exemptions are possible³⁶, children may not be permitted to attend public school and their parents can be charged with neglect or child abuse, if the child is not vaccinated.³⁷ Parents must therefore rely upon the integrity of federal vaccine policymaking. Their children's lives depend on the exercise of careful and prudent decision making devoid of self-interest. The increasing numbers of vaccine injuries and the revelations of the Congressional Investigation raise an important question—how can the law provide children with safe, effective and necessary vaccines when the current system cannot adequately police conflicts of interest and children are obligated to get their shots?

Every child in this country is vulnerable to a system that places financial ties before human life. This note will argue that the pharmaceutical companies play a key role in determining what will be injected into healthy children. It will suggest that this involvement has resulted in the expenditure of millions of dollars for vaccines that may be unnecessary or unsafe. Various solutions will be presented, each designed to protect children's lives.

is a disease in which the intestine collapses into itself—"the prolapse of one part of the intestine into the lumen of an immediately adjoining part." *Id.*

31. "[Prior to the release of RotaShield], on January 1, 1999 there were zero cases of intussusception in the Vaccine Adverse Events Reporting System (VAERS)." MAJORITY STAFF REPORT, *supra* note 29, at 10.

32. *Id.*

33. *Id.*

34. *Id.* at 16.

35. See Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, *Journal of Pharmacy and Law*, 5 JPHARML 249, 250 (1996). See also Robert T. Chen, *Safety of Vaccines*, in VACCINES, *supra* note 26, at 1145. A higher standard of safety is expected with vaccines in comparison to other medical interventions because vaccines are compulsory. *Id.*

36. A State-by-State Summary of Vaccine Exemptions at <http://www.tetrahedron.org/news/contacts.html>, (last visited Oct. 29, 2000). All states, except Mississippi and Virginia permit religious exemptions and philosophical exemptions are available in approximately half of the states. Severyn, *supra* note 35, at 260.

37. Severyn, *supra* note 35, at 259. Severyn discusses *In the Matter of Christine M.*, 595 N.Y.S.2d 606, 607 (N.Y. Fam. Ct., 1992) in which a three-year old child was considered "neglected" by the authorities because the parent refused a measles vaccine. *Id.*

Section I discusses the fact that children are now getting more vaccines at a younger age than ever before. It highlights the concerns of physicians, scientists, and parents, and presents information from federal databases and the medical literature. Section II examines the conflicts of interests uncovered in vaccine policymaking. It provides a brief review of the findings of a recent congressional investigation on the most influential vaccine committees: the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). It also highlights the conflicts of interest associated with the two newest childhood vaccines, RotaShield and Prevnar. Section III will examine various solutions to reestablish integrity in vaccine policymaking, and how children can be protected from abuses. Two different categories of solutions will be offered. The first focuses on strategies to eliminate, reduce, or compensate for conflicts of interest in vaccine policymaking. Various approaches will be discussed, including closing the loopholes in the current law, instituting a more stringent code of ethics, retooling the committees, and adding an oversight or ombudsman role. The second category of solutions takes a remedial perspective and focuses both on protecting children and punishing those who abuse the system. These approaches include utilizing taxpayer derivative actions to induce state agencies to scrutinize federal vaccine recommendations and using Qui Tam litigation under the False Claims Act to encourage manufacturers to reform their vaccine manufacturing and marketing strategies. Section IV will seek to redefine the problem by taking a preventive law approach. Here, the current paradigm, a vaccine for every ill, will be challenged.³⁸ Finally, Section V will provide some concluding thoughts on the steps required to facilitate positive change.

I. MORE VACCINES FOR YOUNGER CHILDREN

A. *Thirty Vaccines in Eighteen Months*

My parents were born in the 1930s. Members of their generation re-

38. E-mail from Barbara Loe Fisher, President of the National Vaccine Information Center. Ms. Fisher has served on the National Vaccine Advisory Committee (1988-1991), the Institute of Medicine Vaccine Safety Forum (1995-1998), and voting consumer member, FDA Vaccines and Related Biological Products Advisory Committee (1999-present) (Oct. 9, 2000) (on file with author).

[Policymakers] see their mission as eradicating most, if not all, infectious microorganisms from the earth. So when drug companies produce a new vaccine that is, in effect, a new weapon in their war on infectious microorganisms, they want everyone to use it. In their minds, the benefits of using this new weapon to achieve their mission always outweighs the risks associated with its use.

Id.

ceived three vaccines.³⁹ I was born in the early 1960s and received vaccines for polio, smallpox and DPT.⁴⁰ A child born today will receive five doses of DPT, four doses of polio vaccine, two doses of measles, mumps and rubella, three injections of hepatitis B, one shot of varicella (chicken pox), four doses of haemophilus influenzae b (Hib), four injections of a pneumococcal conjugate vaccine, and, depending on where the child lives, perhaps one shot of hepatitis A.⁴¹ In addition to getting more shots, children today get vaccines at a younger age. As displayed *infra*, twenty of the twenty-four injections (thirty of the thirty-eight different constituent vaccines)⁴² should be administered to a child before he or she is eighteen months old.⁴³ In addition, some children may also be injected with up to nine different vaccines in a single day.⁴⁴

39. Kathy Koch, *Vaccine Controversies*, 10 CQ RESEARCHER 644 (2000).

40. *Id.*

41. See American Academy of Pediatrics, American Academy of Pediatrics 2000 Immunization Schedule, at <http://www.aap.org/family/parents/immunize.htm>, (last visited October 20, 2000) (lists all the vaccines except pneumococcal conjugate vaccine). See also American Academy of Pediatrics, *AAP Recommends Pneumococcal Vaccine for Children Under Age 2* at <http://www.aap.org/advocacy/archives/junpcv7.htm>, (last visited October 20, 2000) (adds pneumococcal vaccine to schedule).

42. For example, one dose of Measles-Mumps-Rubella (MMR) is combined in one shot. However, if one were to count the actual vaccine constituents (i.e. one dose of MMR is equivalent to three, one for Measles, one for Mumps, one for Rubella) then the number of separate injections translate into thirty-eight vaccines of which thirty are administered before a child is eighteen months old.

43. *Recommended Childhood Immunization Schedule United States, January - December 2001* is approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). Please note that the schedule reproduced in this article does *not* contain the full directions to clinical practitioners nor does it include the footnoted annotations that provide additional information. Therefore this schedule should not be used to replace an actual schedule provided by the CDC, AAP or AAFP. See <http://www.aap.org/family/parents/immunize.htm>.

44. *Autism: Present Challenges, Future Needs—Why the Increased Rates? Before the Government Reform Committee of the House of Representatives*, 106th Cong. (April 6, 2000) [hereinafter *Autism Hearings*] (opening statement of Chairman Dan Burton) at http://www.house.gov/reform/hearings/healthcare/00.06.04/opening_statement.htm. “[My grandson was administered] DTaP, OPV, Haemophilus, Hepatitis B, and MMR—all at one office visit.” *Id.*

Recommended Childhood Immunization Schedule United States, January - December 2001

Childhood vaccination has been considered one of the leading public

| Age Vaccine ▼ | Birth | 1 mo | 2 mos | 4 mos | 6 mos | 12 mos | 15 mos | 18 mos | 24 mos | 4-5 yrs | 11-12 yrs | 14-18 yrs |
|--------------------------------------|-------|---------|----------|----------|----------|-----------|-----------|-----------|-------------------------|------------|--------------|--------------|
| Hepatitis B | Hep B | | | | | | | | | | Hep B | |
| Diphtheria, Tetanus, Pertussis | | Hep B | | Hep B | | | | | | DTaP | Td | |
| H. influenzae type b | | | Hib | Hib | Hib | Hib | | | | | | |
| Inactivated Polio | | | IPV | IPV | IPV | | | | | IPV | | |
| Pneumococcal Conjugate | | | PCV | PCV | PCV | PCV | | | | | | |
| Measles, Mumps, Rubella | | | | | | MMR | | | | MMR | MMR | |
| Varicella | | | | | | Var | | | | | Var | |
| Hepatitis A | | | | | | | | | Hep-A in selected areas | | | |

Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

health measures of the twentieth and twenty-first centuries.⁴⁵ Vaccines have been credited with controlling dangerous diseases and reducing the associated mortality and morbidity.⁴⁶ Nonetheless, there is a growing number of physicians, scientists and parents who strongly believe that the increasing numbers of these unavoidably unsafe products⁴⁷ administered at younger

45. INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY I (Kathleen R. Stratton et al. eds., National Academy Press 1994).

46. Susan L. Plotkin & Stanley A. Plotkin, *A Short History of Vaccination*, in VACCINES, *supra* note 26, at 1.

47. Severyn, *supra* note 35, at 267 (citing THE RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965)); “There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he [she] has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.”)

ages are damaging and sometimes killing healthy children.⁴⁸

In the 1970s and early 1980s, the number of lawsuits and the size of damage awards for vaccine injury grew at an alarming rate.⁴⁹ The response from manufacturers was to encourage lawmakers to pass the National Childhood Vaccine Injury Act.⁵⁰ This Act, passed in 1986, requires that all vaccine injuries first be brought forward in the Federal Court of Claims.⁵¹ Only after such a claim is filed and the plaintiff is unhappy with the result can a civil action be filed.⁵² The Act insulated manufacturers from tort liability and put a cap on monetary damages of \$250,000 when a child dies from a vaccine injury.⁵³ Additionally, it created an excise tax on every vaccine that finances a fund that is used to pay damage awards so that vaccine manufacturers are not held financially liable.⁵⁴

In addition to providing a fund to compensate victims of vaccine injury, the Act also called for the creation of the Vaccine Adverse Events Reporting System (VAERS).⁵⁵ This reporting system requires that health care providers report selected adverse events occurring after vaccination.⁵⁶ Because this is a passive system, only a "fraction" of events are thought to be reported.⁵⁷ Serious adverse events, however, are considered to be accurately diagnosed.⁵⁸

48. See *infra* note 72 and accompanying text.

49. See generally Kitch, *supra* note 26, at 1168-69.

50. See Severyn, *supra* note 35, at 261-62.

51. *Id.*

52. 42 U.S.C. § 300aa (2000) (The National Childhood Vaccine Injury Act was enacted in 1986). 42 U.S.C. § 300aa-11(a) states in part:

(2)(A) No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death.

53. Kitch, *supra* note 26, at 1174. See also *Childhood Vaccine Excise Tax Reduction to 25 per dose Recommended*, 59 (No. 51) THE PINK SHEET 5 (1997) ("In general, the vaccine manufacturers' risk of liability has decreased since the inception of the VICP [Vaccine Injury Compensation Program] of 1988 according to a survey by the Office of the General Counsel."); *Lederle-Praxis DTP Vaccine Price Drops 52% Due to Decreased Liability*, 52 (No. 49); THE PINK SHEET (1990) (Claims for injuries allegedly resulting from Lederle's DTP went from 255 complaints in 1986 to only 50 in 1989 and approximately 25 in 1990.).

54. Rebecca Porter, *Vaccine Injury Compensation Reaches Nearly \$1 Billion*, TRIAL, Dec. 1998, at 99.

55. Kitch, *supra* note 26, at 1170.

56. Severyn *supra* note 35, at 267.

57. See David A. Kessler, *Introducing MedWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems*, 269 JAMA 2765 (June 2, 1993). This former commissioner of the FDA has written that "only a fraction" of serious adverse events are reported to the FDA." *Id.*

58. Chen, *supra* note 35, at 1151.

Even with the presumed underreporting, there are over 108,000 reports of adverse reactions and death allegedly resulting from vaccination amassing in the VAERS database.⁵⁹

C. The Medical Literature

The medical literature provides evidence that vaccines may be dangerous to some children.⁶⁰ The possibility that vaccines can cause neurological complications in children was recognized as early as 1919⁶¹ when “amyotrophic paralysis and polyneuritis were definitely recognized as complications [of vaccination].”⁶² Since that time several hundred medical studies have reported a variety of severe neurological complications associated with vaccination.⁶³ These complications have included: encephalitis, myelitis, Guillain-

59. Vaccine Adverse Event Reporting System, Frequently Asked Questions About VAERS, What is VAERS?, <http://www.vaers.net/vaers.htm>, (Data from 1986 to the present) (last visited October 15, 2000). The following examples are from the Vaccine Adverse Event Reporting System Searchable Database, at <http://www.fedbuzz.com/vaccine/vac.html>, (last visited October 18, 2000): A healthy baby boy was vaccinated with DTP on December 10, 1997. Four days later he had a fever and became weak. The following day his temperature increased. He had convulsions and difficulty breathing. He was rushed to the hospital and died two days later. Another baby boy was administered the measles, mumps and rubella vaccine. Following the vaccination the child had encephalitis (inflammation of the brain) and was hospitalized. The child died a short time later. A biopsy revealed the presence of “measles inclusion bodies” in the brain. A nine-year old boy received the hepatitis B vaccine and soon developed tics. Later, when he was administered a booster shot the tics became worse and the child was ultimately diagnosed with Tourette’s disease. Two weeks after another apparently healthy infant was vaccinated she was taken to the doctor because her foot dropped and her ribs were pulled inward. One week later she stopped eating. She was rushed to the ER in cardiopulmonary arrest. There she was revived and diagnosed with muscular dystrophy. Soon after a healthy five-year old boy was vaccinated with diphtheria and tetanus he had nausea, vomiting and fever as high as 103 degrees for three days. He was unable to smile. He was taken to the doctor and subsequently diagnosed with Bell’s Palsy.

60. In Congressional testimony, Marcel Kinsbourne, M.D. summarized three ways that a vaccine may be harmful to some children including:

[1] Toxic: Killed bacteria [in vaccines] may release toxins when their cell bodies break down . . . [2] Infectious: A vaccine that consists of attenuated virus particles may cause the very infection it was intended to prevent . . . [3] Autoimmune: The body responds to a vaccine with an immune reaction that also attacks a constituent of the body which bears some chemical resemblance to a constituent of the vaccine.

Vaccines: Public Safety and Personal Choice Before the Government Reform Committee of the House of Representatives, 106th Cong. [hereinafter *Vaccines: Public Safety and Personal Choice*] (statement of Marcel Kinsbourne, M.D.) (Aug. 3, 1999) at <http://www.house.gov/reform/hearings/healthcare/99.08.03/kinsbourne.htm>. See generally VIERA SCHEIBNER, *VACCINATION: 100 YEARS OF ORTHODOX RESEARCH SHOWS THAT VACCINES REPRESENT A MEDICAL ASSAULT ON THE IMMUNE SYSTEM* (1993).

61. Henry G. Miller & John B. Stanton, *Neurological Prophylactic Inoculation*, 23 Q. J. MED. 1, 2 (1954).

62. *Id.*

63. Various neurological complications including encephalitis, myelitis, Guillain-Barre syndrome, radicular, polyneuritic and mononeuritic syndromes were associated with vaccina-

Barre syndrome, radicular, polyneuritic and mononeuritic syndromes, Reye syndrome (which has a 50% mortality rate⁶⁴), and encephalopathy.⁶⁵

In addition to permanent and severe neurological reactions, some scientists are studying how vaccines may be responsible for the tremendous increase in autoimmune diseases.⁶⁶ In 1967, a paper was published in the *British Medical Journal* that suggested three possible methods in which various vaccines could cause or contribute to multiple sclerosis in children and adults including: introducing a viral organism, triggering a latent condition or causing the disease by itself.⁶⁷ A study in New Zealand found that vaccinated children had a 23% rate of asthma episodes and a 30% rate for consultations for other allergic diseases.⁶⁸ However unvaccinated children had a 0% rate for both allergies and asthma.⁶⁹ On-going studies in Europe and the U.S. have found a possible correlation between the measles vaccine and subsequent Crohn's disease.⁷⁰ In addition, autism rates have risen dramatically. In California, the rate has increased 210% from 1987 to 1998.⁷¹ Scientists,

tion in 1954. *See id.* at 24. A 1977 study conducted by the UCLA School of Medicine found that Guillain-Barre syndrome could follow a tetanus-diphtheria vaccination. R. Bakashi and MC Graves, *Guillain-Barre Syndrome After Combined Tetanus-Diphtheria Toxoid Vaccination*, 147(2) J. NEUROLOGICAL SCI. 201 (1977). A 1979 study found that vaccination with live virus vaccines (i.e. measles, mumps, rubella, oral polio), "may occasionally serve as cofactors in the etiology of Reye syndrome through undefined mechanisms." David M. Morens, M.D. et al, *Reye Syndrome Associated with Vaccination with Live Virus Vaccines*, 18 CLINICAL PEDIATRICS 42 (1979). Reye's syndrome has a mortality rate of approximately 50%. *See infra* note 64. In a 1983 letter to the medical journal *The Lancet*, Dr. Gordon Stewart drew attention to a British study that demonstrated a small but statistically significant number of temporary and permanent neurological disorders related to the pertussis vaccine. Gordon T. Stewart *Reactions to Pertussis Vaccine*, LANCET, May 28, 1983, at 1217-18. In 1985, *Science* reported that, "Encephalitis, myelitis, and neuritis are well-known complications of certain viral infections and vaccines. . ." *See* Ulrike Jahnke et al., *Sequence Homology Between Certain Viral Proteins and Proteins Related to Encephalomyelitis and Neuritis*, SCIENCE, July 19, 1985. In 1991, a report released by the Institute of Medicine found "a possible causal relation between DTP vaccine and acute encephalopathy." *See* L.D. Cowan et al., *Acute Encephalopathy and Chronic Neurological Damage After Pertussis Vaccine*, 14 VACCINE 1371 (1993).

64. Reyes syndrome is characterized by vomiting followed by stupor which progresses to generalized convulsions and coma. Kurt J. Isselbacher & Daniel K. Podolsky, *Infiltrative and Metabolic Diseases Affecting the Liver*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, pt. 11 § 2, at 1719 (Anthony S. Fauci, M.D. et al., eds, 14th ed 1998). The mortality rate is 50%. *Id.*

65. *See* Kitch, *supra* note 26, at 1170.

66. *See generally* *Autism Hearings*, *supra* note 44 (statements of Vijendra K. Singh, Ph.D., Andrew Wakefield, MD) at <http://www.house.gov/reform/hearings/healthcare/00.06.04/index.htm>.

67. Henry Miller et al., *Multiple Sclerosis and Vaccination*, BRIT. MED. J., 212 (1967).

68. T. Kemp et al., *Is Infant Immunization a Risk factor for Childhood Asthma or Allergy?*, 8 EPIDEMIOLOGY, 678 (1997).

69. *Id.*

70. Andrew Wakefield, et al., *Perinatal Measles Infection and Subsequent Crohn's Disease*, LANCET, Aug. 20, 1994, at 508; *Autism Hearings* (statement of Vijendra K. Singh, Ph.D.) *supra* note 66. *See also* R. Ray et al., *Direct In Situ Transcriptase Polymerase Chain Reaction in Detection of Measles Virus*, J. VIROLOGICAL METHODS, 1 (1996).

71. California Health and Human Services Agency, Department of Developmental Ser-

medical doctors and parents have testified before Congress that they believe vaccines are responsible for the increase.⁷²

Even Sudden Infant Death Syndrome (SIDS) has been associated with vaccination by a very small number of physicians and scientists.⁷³ In 1982 a presentation was made in Dallas, Texas at the “Session on Child Neurology” in which Dr. William Torch reported his findings related to DPT vaccination and SIDS.⁷⁴ He wrote, “In conclusion, these data show that DPT vaccination may be a generally unrecognized major cause of sudden infant and early childhood death, and that the risks of immunization may outweigh its potential benefits.”⁷⁵ A year later, Dr. L. Baraff et al. studied SIDS death in Los

vices, *Changes in the Population of Persons with Autism and Pervasive Developmental Disorders in California's Developmental Services System: 1987 through 1998*, March 1, 1999, at 7.

72. For example of scientists see *Autism Hearings*, *supra* note 44 (statement of Vijendra K. Singh, Ph.D., Department of Biology & Biotechnology Center, Utah State University) at <http://www.house.gov/reform/hearings/healthcare/00.06.04/singh.htm> (“the data will lead to inescapable conclusion that these vaccines can potentially cause autoimmunity in autism.”); *Mercury in Medicine: Are We Taking Unnecessary Risks? Before the Government Reform Committee of the House of Representatives* [hereinafter *Mercury Hearings*], 106th Cong. (July 18, 2000) (statement of Stephanie Cave, MD) at <http://www.house.gov/reform/hearings/healthcare/00.07.18/cave.pdf>. (“I believe that the introduction of the Hepatitis B vaccine in 1991 has sparked this recent epidemic [of autism] because of the thimerosal [form of mercury].”). For an example of a parent see *Autism Hearings* (statement of Congressman Dan Burton) *supra* note 44

(I don't have to read a letter to experience the heartbreak. I see it in my own family. My grandson Christian was born healthy. He was beautiful and tall. We were already planning his NBA career. He was outgoing and talkative. He enjoyed company and going places. Then, his mother took him for his routine immunizations and all of that changed. He was given what so many children were given—DTaP, OPV, Haemophilus, Hepatitis B, and MMR—all at one office visit. That night Christian had a slight fever and he slept for long periods of time. When he was awake he would scream a horrible high-pitched scream. He would scream for hours. He began dragging his head on the furniture and banging it repeatedly. Over the week-and-a-half after the vaccinations, Christian would stare into space and act like he was deaf. He would hit himself and others, which was something he had never done. He would shake his head from side to side as fast as he could. He lost all language. [He has subsequently been diagnosed as autistic]).

73. William C. Torch, *Diphtheria-Pertussis-Tetanus (DPT) Immunization: A Potential Cause of the Sudden Infant Death Syndrome (SIDS)*, 32 *NEUROLOGY* A169 (1982); Baraff LJ, et al., *Possible Temporal Association Between Diphtheria-Tetanus Toxoid-Pertussis Vaccination and Sudden Infant Death Syndrome*, 2(1) *PEDIATRIC INFECTIOUS DISEASES* 7-11 (1983); Bernier RH, et al., *Diphtheria-Tetanus Toxoids-Pertussis Vaccination and Sudden Infant Deaths in Tennessee*, 101(3) *J. PEDIATRICS* 419-21 (1982). SCHEIBNER, *supra* note 60, at 13-71.

74. Torch, *supra* note 73. Dr. Torch's study was inspired by reports of eight DPT-associated SIDS in Tennessee and four SIDS within 3 ½ to 19 hours of inoculation in Nevada. *Id.* Subsequent to these reports, Dr. Torch analyzed 200 randomly selected SIDS cases. *Id.* He found that “6.5% died within 12 hours of inoculation; 13% [died] within 24 hours; 26% [died] within 3 days, and 37%, 61%, and 70% within 1, 2, and 3 weeks, respectively.” *Id.* Dr. Torch was formerly Director of Child Neurology, Department of Pediatrics, at the University of Nevada School of Medicine. *Id.*

75. *Id.*

Angeles and concluded that “These SIDS deaths were significantly more than expected were there no association between DTP immunization and SIDS.”⁷⁶ Although other studies have not found any association between vaccination and SIDS, the fact that results have been inconsistent between studies is disturbing to some scientists.⁷⁷

The numerous warnings and adverse events reported in the manufacturer’s inserts that accompany each vaccine also raise concerns.⁷⁸ These inserts are careful to draw a distinction between adverse events caused by the vaccine and those merely associated with the vaccine.⁷⁹ One reason for this distinction is the lack of studies undertaken on causation.⁸⁰ According to a 1994 Institute of Medicine review of adverse events associated with childhood vaccines, “[During the review], the committee encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines.”⁸¹ Even with this gap, the inserts list a number of dangerous and deadly adverse reactions associated with vaccines, including: neurological complications, convulsions, encephalopathy (degenerative disease of the brain), shock, apnea, Guillain-Barre Syndrome (nerve inflammation), collapse, orchitis (inflammation of the testes), abnormal liver function, Bell’s Palsy, multiple sclerosis and SIDS.⁸²

D. Carcinogens and Toxins in the Vaccines

Concerned scientists and physicians are trying to discern the biological mechanisms that explain how vaccines can cause these injuries or deaths.⁸³

76. Baraff LJ, et al., *Possible Temporal Association Between Diphtheria-Tetanus Toxoid-Pertussis Vaccination and Sudden Infant Death Syndrome*, 2(1) PEDIATRIC INFECTIOUS DISEASES 7-11 (1983).

77. See SCHEIBNER, *supra* note 60, at 13-71.

78. The adverse reactions listed for Acel-Imune—the acellular DTP vaccine manufactured by Lederle—include: vomiting, anaphylactic reactions (i.e. difficulty breathing, shock) neurological complications, convulsions, and encephalopathy (degenerative disease of the brain). PDR 51, *supra* note 14, at 1415-17. Adverse reactions listed for Smith Kline’s DTP includes: shock, apnea (breathing stops), anorexia, vomiting, convulsions, encephalopathy (degenerative disease of the brain), Guillain-Barre Syndrome (nerve inflammation), collapse, and SIDS (“Sudden Infant Death Syndrome has occurred in infants following administration of DTP.”). *See id.* at 2650-53. Adverse reactions listed for SmithKline’s hepatitis B vaccine (“Engerix”) includes: Tinnitus (ringing in ears), earache, vomiting insomnia, tachycardia/palpitations (rapid heart beat), abnormal liver function, Guillain-Barre Syndrome (nerve inflammation), Bell’s Palsy, and multiple sclerosis. *See id.* at 2656-58.

79. *See generally* INSTITUTE OF MEDICINE, *supra* note 45, at 5, 17, 317.

80. *Id.*

81. *Id.* at 317.

82. *See, e.g.*, Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein) Package Insert [hereinafter Package Insert] at <http://www.pneumo.com/vaccine/Pl.html> (last visited on Sept. 13, 2000).

83. *See Autism Hearings* (statements of Vijendra K. Singh, Ph.D., Mary Megson M.D., Bernard Rimland, Ph.D.) at <http://www.house.gov/reform/hearings/healthcare/00.04.06/index.htm>; Harold Buttram, M.D., Vaccine Scene 1999: Overview And Update, at <http://www.whale.to/vaccines/buttram1.html> (last visited February 17, 2001); National Vac-

Some have concluded that the mercury used as a preservative in many vaccines needs to be eliminated.⁸⁴ Dr. Vasken Aposhian, an expert in molecular and cellular biology, has testified, "I am rather amazed that [mercury] has been a constituent of vaccines for children. There is no need of endangering any child with any form of mercury. Many countries . . . have banned [its] use. . ."⁸⁵ In fact, according to the congressional testimony of one medical doctor, the two-month dose of mercury a child is exposed to through vaccines, "is at least 30 times higher than the recommended daily maximum exposure as set by the EPA."⁸⁶

In addition, to mercury, the dissolved aluminum in vaccines is also potentially dangerous. According to the journal *Pediatrics*, "[a]luminum is now being implicated as interfering with a variety of cellular and metabolic processes in the nervous system and in other tissues."⁸⁷ There are other ingredients that raise concerns that are either in the shots themselves or used in the manufacturing process. These substances include: formalin (a type of formaldehyde), monkey kidney cells, human fetal tissue (from abortions), pig enzymes, sheep red blood cells, calf serum, yeast, fetal cow serum, chicken embryos, ammonium sulfate, and monosodium glutamate.⁸⁸

E. Are All These Vaccines Necessary?

Given the potential danger of vaccine ingredients and the association between vaccination and injury cited in the medical literature, critics challenge the necessity of some vaccines especially when they are designed to prevent diseases that children are not at risk for or are not dangerous. For example, the chicken pox vaccine is targeted against a "disease" that is very seldom dangerous or deadly.⁸⁹ The rotavirus vaccine is designed to prevent a virus that causes diarrhea, takes the lives of approximately twenty children

cine Information Center, Professor of Cell Biology Investigates Hep B Vaccine Damage at <http://www.909shot.com/profcellbio.htm> (last visited February 17, 2001) (discussing the research by Professor Bonnie Dunbar, Ph.D. into the adverse effects caused by the hepatitis B vaccine); R. Riikonen, *The Role of Infection and vaccination in the Genesis of Optic Neuritis and Multiple Sclerosis in Children*, 80(5) ACTA NEUROL SCAND 425-31 (1989).

84. *Mercury Hearings*, *supra* note 72 (statement of H. Vasken Aposhian, Ph.D., Professor of Molecular and Cellular Biology, The University of Arizona) at <http://www.house.gov/reform/hearings/healthcare/aposhian.pdf>; (statement of Stephanie Cave, MD), *supra* note 72 (Dr. Cave's testimony also lists the 17 vaccines currently containing mercury).

85. *Mercury Hearings* (statement of H. Vasken Aposhian), *supra* note 84.

86. *Mercury Hearings* (statement of Stephanie Cave), *supra* note 72.

87. *Aluminum Toxicity in Infants and Children (RE9607)*, 97 PEDIATRICS 413, <http://www.aap.org/policy/01263.html>, (last visited Sept. 14, 2000). The amount of aluminum in those vaccines that contain it can be as high as .85 mg per 0.5mL dose. See, e.g., Acell-Imune manufactured by Lederle Laboratories. PDR51, *supra* note 14, at 1415.

88. See generally PDR 51, *supra* note 14.

89. "In the immunocompetent patient, [chickenpox] is usually a benign illness. . ." Richard J. Whitley, *Varicella-Zoster Virus Infections*, in, HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, *supra* note 64, pt. 7 § 185, at 1086.

per year in the United States,⁹⁰ and is no more than a sub-clinical infection⁹¹ in the overwhelming majority of America's 19 million children under the age of five.⁹² Those at risk for hepatitis B include adults who share intravenous needles, engage in promiscuous unprotected sex, and health care workers.⁹³ Yet, children who do not fit into these categories, receive three hepatitis B vaccinations before they are eighteen months old.⁹⁴ Concerned parents have asserted that the number of deaths and injuries caused by this vaccine may be more than the deaths and injuries caused by the illness that the vaccine is designed to prevent.⁹⁵ Some physicians and scientists have also challenged the risk-benefit equation for this particular vaccine.⁹⁶

90. *Conflicts of Interest and Vaccine Development* (oral testimony of Dixie E. Snider, MD, MPH, Associate Director of Science, Centers for Disease Control and Prevention), *supra* note 23, at transcript lines 2616 (“[There are approximately] only 20 deaths from rotavirus in the United States.”); Centers for Disease Control, *Rotavirus Vaccine for the Prevention of Rotavirus Gastroenteritis Among Children*, MMWR March 19, 1999, at 1-23, at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056669.htm>.

91. “The majority of rotavirus infections are subclinical or cause mild gastrointestinal illnesses that do not require hospitalization.” Greenberg, *Viral Gastroenteritis*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, *supra* note 64, pt. 7 § 194, at 1117. This statement from this well-respected medical treatise appears to be inconsistent with the claims of the CDC. According to the CDC, rotavirus “accounts for more than 500,000 physician visits and approximately 50,000 hospitalizations each year among children aged less than 5 years.” See Centers for Disease Control, *supra* note 90.

92. There are 18,987,000 children five years of age and under living in the United States according to U.S. Census Bureau Projections. See 1999 NEW YORK TIMES ALMANAC, 277 (John W. Wright ed. 1999).

93. See generally COMMITTEE ON INFECTIOUS DISEASES, AMERICAN ACADEMY OF PEDIATRICS, 1994 RED BOOK: REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES 225 (23rd ed. 1994).

94. See American Academy of Pediatrics, *supra* note 41.

95. See Press release, National Vaccine Information Center, Hepatitis B Vaccine Reaction Reports Outnumber Reported Disease Cases in Children According to Vaccine Safety Group, Jan. 27, 1999 at <http://www.909shot.com/prhepb.htm>; Michael Belkin, Testimony before the Advisory Committee on Immunization Practices—Centers for Disease Control and Prevention, February 17, 1999 at <http://www.909shot.com/acipmb.htm>.

96. Hepatitis B Vaccine: Helping or Hurting Public Health Hearing Before Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the House of Representatives, 106th Cong. (May 18, 1999) [hereinafter Hepatitis hearings] (statement of Burton A. Waisbren, Sr. M.D.) at <http://www.house.gov/reform/cj/hearings/99.05.18/waisbren.htm>. “Information regarding the risk/benefit ratio of this vaccine is not known and therefore cannot be given to parents in an informed consent.” *Id.*; Hepatitis hearings, *supra* (statement by Bonnie S. Dunbar, Ph.D.) at <http://www.house.gov/reform/cj/hearings/99.05.18/dunbar.htm>.

In view of this lack of scientific and medical information of neonatal immunology, it is remarkable to me that newborn infants, especially those not at risk for the Hepatitis B disease itself are being administered multiple injections of this vaccine and that there have been few, if any, clinical trials to adequately evaluate the potential long term effects of neonatal immunization especially as it relates to genetic diversity.

Id.

| Category | Number |
|---|--------------------|
| Approximate number of deaths from Hepatitis B for children 1-14 (annualized) | 11 ⁹⁷ |
| Approximate number of deaths from Hepatitis B Vaccine for all ages (annualized) | 53 ⁹⁸ |
| Approximate number of serious Injuries and/or Hospitalizations from Hepatitis B for children 1-10 (annualized) | 191 ⁹⁹ |
| Approximate number of serious Injuries and/or Hospitalizations from Hepatitis B Vaccine for all ages (annualized) | 828 ¹⁰⁰ |

The figures are a result of an analysis of data from the Vaccine Adverse Events Reporting System (VAERS), a federal database. They do suggest that the hepatitis B vaccine may be more dangerous to children than hepatitis B. In fact, the number of vaccine caused injuries and deaths may be even higher. According to Dr. David Kessler, former director of the FDA, the vaccine injury data from VAERS may only contain a "fraction" of all ad-

97. "In 1996, the number of deaths from viral hepatitis (of all types) reported in children under the age of 14 was 11, and in children under the age of 1 year was 1." *Vaccines: Public Safety and Personal Choice*, *supra* note 60 (statement by the Association of American Physicians and Surgeons on Vaccines submitted by Dr. Jane Orient) at <http://www.aapsonline.org/aaps/testimony/hepbstatement.htm> (citing tbl. 10, National Vital Statistics Report 1998;47(9):51.).

98. This figure is based on an analysis of raw VAERS data conducted by Michael Belkin, financial analyst at <http://www.new-atlantean.com/hepatiti.htm> (last visited Nov. 23, 2000) (Mr. Belkin's data has been annualized and normalized to subtract deaths caused by other vaccines). Injuries from the vaccine include: diabetes, partial blindness, lupus, polyneuropathy, seizures, neurological damage, multiple sclerosis, vasculitis, cerebral aneurysm, aseptic meningitis, cardiomyopathy, hepatitis, and other diagnosis requiring intubation. See VAERS database at <http://www.fedbuzz.com/vaccine/vac.html> (last visited Nov. 23, 2000).

99. This figure is based on the following extrapolation: In the age group 0-10, there were three reported cases of hepatitis B reported in New Hampshire from 1993 through 1997. This is equal to .75 annual cases of hepatitis B for that state. In 1997, New Hampshire had approximately 148,000 children under the age of ten. The rate of hepatitis B in this age group equals .75 per 148,000 or .000005. There are approximately 38,300,000 children under the age of ten in the United States. The above rate equals 191 children in the U.S. stricken with hepatitis B. For the number of reported cases of hepatitis B in New Hampshire see, Press release, Association of American Physicians and Surgeons, Physicians Oppose Mandatory Hepatitis B Vaccine for New Hampshire School Children. Parents, Not Government Should Decide, May 10, 1999, at <http://www.aapsonline.org/aaps/press/nrnhvac.htm>. For the population of New Hampshire see NEW YORK TIMES ALMANAC, *supra* note 92, at 278.

100. See *supra* note 98.

verse reactions.¹⁰¹ This suggests that the deaths and injuries caused by this vaccine and others are significantly underreported. Nonetheless, the Infectious Diseases Society of America strongly objects to these findings citing that "it is not possible to determine the number of adverse effects from a given vaccine simply by looking at the number of VAERS reports."¹⁰² However, according to the medical treatise *Vaccines*, co-edited by Dr. Walter Orenstein, Director of the CDC's National Immunization Program:

VAERS has successfully detected unrecognized potential reactions and obtained data to evaluate whether these events are causally linked to vaccines. . . VAERS is also currently the only surveillance system that covers the entire U.S. population with data available on a relatively timely basis. It is, therefore, the major means available currently to detect possible new, unusual, or extremely rare adverse events.¹⁰³

After undertaking their own analysis of the risks and benefits of the hepatitis B vaccine for infants and children, the Association of American Physicians and Surgeons¹⁰⁴ called for an immediate moratorium on mandatory hepatitis B vaccines.¹⁰⁵ Other physicians agree. Burton A. Waisbren, Sr., M.D. has stated, "the program of universal hepatitis B vaccination in the United States is an experiment being performed on our babies. A moratorium should be placed on this experiment until risk/benefit ratios are clearly defined."¹⁰⁶

In fact, after further study, the Association of American Physicians and Surgeons called for a moratorium on all mandatory vaccination.¹⁰⁷ In a press

101. See Kessler, *supra* note 57. This former commissioner of the FDA has written, "Although the FDA receives many adverse event reports, these probably represent only a fraction of the serious adverse events encountered by providers." *Id.* Of course, it should be noted that the number of injuries and deaths from hepatitis B itself may also be underreported.

102. Press release, Infectious Diseases Society of America, Recent Analysis of Hepatitis B Data Misrepresents Risk of Vaccination, Jan. 22, 2000, at <http://www.ama-assn.org/ama/pub/article/1809-2052.html> (American Medical Association website).

103. Chen, *supra* note 35, at 1151.

104.

The Association of American Physicians and Surgeons (AAPS) is a non-partisan professional association of physicians in all types of practices and specialties across the country. . . Since 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship and the practice of private medicine.

Association of American Physicians and Surgeons, at <http://www.aapsonline.org/> (last visited Feb. 1, 2001).

105. Press release, Association of American Physicians and Surgeons, Doctors Call for a Moratorium on Hepatitis B Vaccine for Schoolchildren Citing Potential Deadly Outcomes, (July 8, 1999) at <http://www.aapsonline.org/aaps/press/hepbroe.htm>.

106. Burton A. Waisbren, Sr., Universal Hepatitis B Vaccination: A Moratorium Should Be Placed On This Experiment, at <http://www.goodlight.net/nyvic/health/hep-b/moratori.htm> (last visited Nov. 24, 2000).

107. At their 57th Annual Meeting, the Association of American Physicians and Surgeons (AAPS) unanimously passed a resolution calling for an end to mandatory childhood

release Jane M. Orient, M.D., the executive director of the organization stated, "Our children face the possibility of death or serious long-term adverse effects from mandated vaccines that aren't necessary or that have very limited benefits."¹⁰⁸

Concerned physicians and parents have suggested that the reason children may be getting unneeded and potentially unsafe vaccines is due to the major conflict of interest that exists at the level of vaccine policymaking.¹⁰⁹ These critics cite the millions of dollars in sales manufacturers enjoy when their newest vaccine is approved for universal vaccination and they suggest a financial motive behind the ever-expanding vaccination schedule.¹¹⁰ They also challenge the wisdom of permitting doctors who play key roles in developing new vaccines to sit on the federal advisory panels that make policy decisions regarding their widespread use.¹¹¹ According to Dr. Orient, "It is

vaccines. See Press release, Association of American Physicians and Surgeons, Doctor's Group Votes to Oppose Vaccine Mandates, Nov. 2, 2000 at <http://www.aapsonline.org/aaps/press/nrvacres.htm>.

108. *Id.*

109. *Compensating Vaccine Injuries: Are Reforms Needed? Before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the House of Representatives*, 106th Cong. (June 14, 1999)[hereinafter *Vaccine Injury Hearings*] (statement of Jane Orient, M.D. Executive Director of the Association of American Physicians and Surgeons) ("Public policy regarding vaccines is fundamentally flawed. It is permeated by conflicts of interest.") at <http://www.aapsonline.org/aaps/testimony/hepbcom.htm>. See also Rock, *supra* note 22.

110. See ABC NEWS, Vaccine Gets Federal Approval, (Feb. 17, 2000), at <http://www.abcnews.go.com/sections/living/DailyNews/vaccine000217.html>. The newest vaccine approved for universal vaccination is a pneumococcal conjugate vaccine called Prevnar. *Id.* Four doses of Prevnar (the amount for each child starting at two months old) sells for \$232. *Id.* According to pharmaceutical industry-financial analysts interviewed by the news agency Reuters, Prevnar is expected to deliver sales of \$300 to \$500 million a year for its manufacturer Wyeth-Lederle Vaccines. *Id.*

In addition, once a vaccine is added to the CDC's childhood vaccination schedule, manufacturers will sell millions of units because most children are required to have the vaccine to enter school. See *Vaccine Controversies*, 10, No. 28, CQ RESEARCHER, 645 (2000). This also makes it much more likely that the vaccine will be recommended by the World Health Organization for distribution in third world countries, guaranteeing millions of additional units to be sold. *Id.* Furthermore, the rising prices of vaccines contributes to this multi-billion dollar industry. *Id.* "A key feature of Pasteur Merieux Connaught projections for a \$20 billion vaccine market by 2007 is the continuously rising prices of new vaccines." See *PMC/Oravax to Begin Phase I Studies for H. Pylori Vaccine in 1999*, 60 (No. 48) PINK SHEET 14 (1998).

111. See *Hepatitis Hearings*, *supra* note 96 (statement by Bonnie S. Dunbar, Ph.D.) at <http://www.house.gov/reform/cj/hearings/99.05.18/dunbar.htm>. "It is well documented, however, that committee members advising the CDC and members of organizations (such as the American Academy of Pediatrics, and the World Health Organization) obtain substantial funding from pharmaceutical companies. Furthermore it is well documented that investigators who have carried out clinical trials on this vaccine also benefit personally and obtain laboratory funding as consultants promoting the vaccine and as expert witnesses in legal conflicts. I leave it up to this distinguished committee to investigate and evaluate the seriousness of these apparent conflicts of interest" *Id.* See also Harold Buttram, M.D., Vaccine Scene 1999: Overview And Update at <http://www.whale.to/vaccines/buttram1.html> (last visited February 17, 2001).

Today we have a system in which vaccine production by the pharmaceutical companies is largely self-regulated. Of course these companies are interested in

apparent that critical medical decisions for an entire generation of American children are being made by small committees whose members have incestuous ties with agencies that stand to gain power, or manufacturers that stand to gain enormous profits, from the policy that is made."¹¹²

II. CONFLICTS OF INTEREST IN VACCINE TESTING AND POLICYMAKING

A. Congressional Investigation

To determine if a conflict of interest exists in federal vaccine policy-making, the House of Representatives Committee on Government Reform began an investigation in August 1999.¹¹³ Congressional hearings were held on June 14, 2000 and a committee report was published on August 21, 2000.¹¹⁴ This report focused on two influential committees: the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC's Advisory Committee on Immunization Practices (ACIP).¹¹⁵ Both committees help determine U.S. vaccine policy.¹¹⁶ The investigation examined the activities of these committees in reference to the approval of a vaccine called RotaShield.¹¹⁷

Manufactured by Wyeth-Lederle, RotaShield was designed to protect children against a virus that causes diarrhea.¹¹⁸ It was approved by the FDA on August 31, 1998.¹¹⁹ Distribution began on October 1, 1998.¹²⁰ By May 1999, life-threatening intussusception¹²¹ injuries were reported.¹²² The number of injuries continued to increase and there was at least one death.¹²³

panies is largely self-regulated. Of course these companies are interested in profits from their products which, in itself, is not wrong. However, when arbitrary decisions in the mandating of vaccines are made by the government bureaucracies, which are highly partisan to the pharmaceuticals, with no recourse open to parents, we have all the potential ingredients for a tragedy of historical proportions.

112. *Vaccine Injury Hearings*, *supra* note 109 (statement of Jane Orient).

113. MAJORITY STAFF REPORT, *supra* note 29, at 1.

114. *See generally Conflicts of Interest and Vaccine Development*, *supra* note 23; MAJORITY STAFF REPORT, *supra* note 29.

115. MAJORITY STAFF REPORT, *supra* note 29, at 1-2.

116. *Id.* at 1. "The VRBPAC advises the FDA on the licensing of new vaccines, while the ACIP advises the CDC on guidelines to be issued to doctors and the states for the appropriate use of vaccines." *Id.*

117. *Id.* at 2.

118. Centers for Disease Control, *supra* note 90.

119. MAJORITY STAFF REPORT, *supra* note 29, at 2, 8.

120. *Id.* at 8.

121. For a definition of intussusception, see *supra* note 30.

122. MAJORITY STAFF REPORT, *supra* note 29, at 10. "May 1999 there were ten cases of intussusception reported in the VAERS System." *Id.*

123. *Id.* (citing minutes of ACIP meeting, October 22, 1999, 56-57 - "As of October 15, 1999, 113 cases of intussusception had been received. Nine of these reported cases were determined not to be intussusception. Of the remaining 102 cases . . . 57 had received the vaccine . . . 29 required surgery, seven underwent bowel resection, and one five-month-old infant

Wyeth-Lederle suspended further distribution and administration of the vaccine on July 16, 1999, and withdrew it from the market on October 15, 1999.¹²⁴

According to a congressional investigation, the vaccine's clinical trials *prior to approval* demonstrated an intussusception rate of 5 in 10,054 children.¹²⁵ These figures are significant. Based on injecting 3,800,000 children¹²⁶, the anticipated number of injuries was approximately 1,865 per year.¹²⁷ Such a large number of injuries and potential deaths eclipse whatever benefit the vaccine might provide in preventing diarrhea.¹²⁸ The pre-market studies also demonstrated concerns about children "failing to thrive," developing high fevers which can lead to brain injury, and experiencing growth retardation.¹²⁹ Although the advisory committees were aware of this information, they voted unanimously to approve the vaccine.¹³⁰

1. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (VRBPAC)

The Committee on Government Reform investigated who the participants were on the FDA's vaccine advisory committee (VRBPAC). The investigation revealed that the same participants sat on the committee for many years despite term limits,¹³¹ four of the five permanent members who voted for RotaShield had conflicts of interest that necessitated waivers,¹³² and

died after developing intussusception five days after receipt of the vaccine.").

124. Press release, American Home Products Corporation, Wyeth Lederle Vaccines Voluntarily Withdraws from the Market its Rotavirus Vaccine Rotashield (Oct. 15, 1999) (on file with author).

125. MAJORITY STAFF REPORT, *supra* note 29, at 11 (citing RotaShield Package Insert, Wyeth-Ayerst, 13).

126. There are 18,987,000 children five years of age and under living in the United States according to U.S. Census Bureau Projections. Children under one year of age constitute 20% or approximately 3,800,000 individuals. *See* NEW YORK TIMES ALMANAC, *supra* note 92 at 277. RotaShield was targeted to children in this age group. *See* Centers for Disease Control, *supra* note 90.

127. According to the Congressional investigation, five children out of 10,054 suffered from intussusception during the pre-market study of RotaShield. MAJORITY STAFF REPORT, *supra* note 29, at 11. This rate is equivalent to 1,865 children out of 3,800,000, the size of the target population for this vaccine.

128. The vaccine had a predicted efficacy of 49% to 83%. *See id.* at 7-8. Number of deaths from Rotavirus was approximately 20 per year. *See supra* note 90.

129. MAJORITY STAFF REPORT, *supra* note 29 at 15. *See also* Wyeth RotaShield Viral Transmission Risk to Immunocompromised Family Members Should be in Labeling, 59 (No. 51) THE PINK SHEET 13 (1997). "Wyeth provided committee members with information that mentioned seven hospitalizations for febrile illness in RotaShield patients and two on placebo. . ." *Id.* Growth retardation was diagnosed in .7% of patients receiving RotaShield and failure to thrive in .5%. *Id.*

130. MAJORITY STAFF REPORT, *supra* note 29, at 15-17.

131. *Id.* at 20.

132. *Id.* at 16.

other conflicts of interest were permitted without even requiring a waiver.¹³³ The conflicts were varied. Committee members owned stock in vaccine companies, were involved in RotaShield development, had participated in licensing the vaccine to RotaShield's manufacturer, and had received tens or hundreds of thousands of dollars in grants from Wyeth-Lederle.¹³⁴ The congressional investigation concluded, "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."¹³⁵ Dr. Thomas Fleming, Chair of Biostatistics at the University of Washington, was a temporary voting member at the meeting. Speaking about the known side effects of the vaccine he stated:

[Therefore] I would ask the FDA to work with the sponsor to further quantify what these serious side effects are—specifically the adverse effects, driven in particular by febrile illness—is inducing hospitalizations and what is that level of excess. I still don't feel like I have a good grasp of that at this point.¹³⁶

133. *Id.* at 16-17.

134. *Id.* at 17-19. The report found that:

([Dr. Patricia Ferrieri chaired the discussion on the approval of RotaShield.] At the time of the proceedings, Dr. Ferrieri owned about \$20,000 of stock in Merck, an affected company and manufacturer of an upcoming rotavirus vaccine. [Dr. Caroline Hall's employer] the University of Rochester, had a \$9,586,000 contract with the National Institute for Allergy and Infectious Diseases (NIAID), the original developer of the rotavirus vaccine. [NIAID subsequently licensed RotaShield to Wyeth-Lederle.] [Dr. Kathryn Edwards] received a contract from Wyeth-Lederle for \$255,023 per year from 1996 to 1998 for the study of pneumococcal vaccines. She also had numerous grants and contracts with the NIAID, [the original developer of RotaShield], for research on other vaccines. [Dr. Mary Estes] employer, Baylor College of Medicine, was receiving a large amount of funds for the development of rotavirus vaccines, including a \$75,000 grant from American Home Products, the parent company of Wyeth-Lederle Vaccines, and a \$404,000 grant from National Institute for Allergy and Infectious Diseases from 8/93 to 7/98. . . . Dr. Estes was also listed as the principal investigator for a grant from Merck for the development of a rotavirus vaccine. [Ms. Rebecca Cole is] an advocate for vaccines and has received both travel expenses and honoraria from Merck. [Merck is also producing a Rotavirus vaccine.] [Dr. Neal Halsey, a consultant, has received] numerous grants from various vaccine manufacturers. [He has also received] frequent reimbursements for travel expenses and honoraria from . . . Merck . . . He has already received \$50,000 from Merck and was awaiting funds from Wyeth Lederle. Dr. Halsey also participated in the rotavirus working group of the ACIP. [Furthermore], Dr. Halsey was the Chair of the Committee on Infectious Diseases and representative of the American Academy of Pediatrics which, in conjunction with the CDC, sets and advertises the recommendations for schedules and dosages of immunizations. [Dr. John Modlin] owned approximately \$26,000 of stock in Merck, an affected company [and] has served on Merck's Immunization Advisory Board from 1996 to the present. [In addition] Dr. Modlin was at the time the Chairman of the ACIP and its rotavirus working group.

Id.

135. *Id.* at 19.

136. *Id.* at 16.

Even with these serious concerns Fleming voted to approve the vaccination for immediate use as did all the other members.¹³⁷

2. *The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP)*

The CDC's Advisory Committee on Immunization Practices (ACIP) held eight separate votes regarding RotaShield between February 11, 1998, and June 17, 1999.¹³⁸ The Congressional Investigation revealed that the ACIP, "recommended the RotaShield for universal use before it was even approved by the FDA."¹³⁹ The investigation also found that: every member was granted a blanket waiver regardless of conflicts of interest for up to a year; ACIP members vote on vaccine recommendations even when they have financial ties to drug companies developing related vaccines; some ACIP members sit on both the FDA and ACIP advisory committees contrary to the rules; and ACIP members do not fully disclose their conflicts of interest.¹⁴⁰

Some of the financial ties between these CDC advisory members and the vaccine manufacturers were just as dramatic as those found for the FDA committee members. These conflicts included: actually owning the patent on a similar rotavirus vaccine, receiving consulting fees and grants from the manufacturer, and owning thousands of dollars of stock in various vaccine companies.¹⁴¹

The Congressional Investigation also revealed that the actual recommendation was written by the ACIP "rotavirus working group." According to the investigation, "The working group has ten members, seven of whom have identifiable conflicts of interest with vaccine manufacturers or vaccine interest groups. The group's meetings were held in private with no minutes or records of the proceedings taken."¹⁴²

The investigation also detailed the conflicts of interest of the liaison rep-

137. *Id.*

138. *Id.* at 28.

139. *Id.* at 36.

140. *Id.* at 26-27.

141. *Id.* at 28-30 (In respect to financial ties to drug companies, the congressional report highlighted these ACIP members: Dr. John Modlin serves on Merck's Advisory Board, owns stock in the company and was chairman of the Rotavirus working group; Dr. Paul Offit shares the patent on the rotavirus vaccine being developed by Merck and voted yes three times to recommend RotaShield but abstained from voting to rescind the vaccine when RotaShield related injuries were reported; Dr. Fernando Guerra has contracts with most of the large vaccine producers including Merck, Pasteur Merieux Connaught, and Medimmune; Dr. Marie Griffin received consulting fees and expenses from Merck and her husband has consulted for American Cyanamid the parent company of Wyeth-Lederle; Dr. T. Chinh Le's employer Kaiser Permanente participates in vaccine studies with Wyeth-Lederle, Merck and SmithKline-Beecham; Dr. Richard Clover received educational grants from Merck and SmithKline-Beecham.).

142. *Id.* at 32.

representatives who vote in the working groups and draft vaccine recommendations. According to the Congressional Report, liaison representatives are not required to disclose financial conflict of interest and the report noted that of the seven ACIP liaison representatives all seven “have ties to numerous vaccine manufacturers.”¹⁴³ One liaison represented the Pharmaceutical Research and Manufacturers of America which is a trade group consisting of 100 vaccine and drug manufacturers.¹⁴⁴

The Congressional Report concluded that in respect to the ACIP, the “automatic [conflict of interest] waivers given to every advisory committee member,” the use of working groups in which conflict of interest procedures are not even used, and the “absence of consumer representation” allows special interest groups with vested interests to unduly influence the government.¹⁴⁵

B. The Newest Vaccine for Children—Prevnar

Injuries related to Wyeth-Lederle’s vaccine RotaShield were reported in May 1999.¹⁴⁶ Two months prior, in March 1999, the FDA granted a “priority review” to another “novel” Wyeth-Lederle vaccine called Prevnar.¹⁴⁷ Prevnar is marketed to prevent pneumococcal infections that can cause earaches, meningitis, bacteremia and pneumonia.¹⁴⁸ Every year, approximately 42 children under the age of two years die of pneumococcal meningitis in the U.S.¹⁴⁹ People who are more likely to get pneumococcal infections usually have predisposing conditions such as immunoglobulin deficiency, Hodgkin’s disease, congenital or acquired immunodeficiency (including HIV), nephrotic syndrome, some viral upper respiratory tract infections, splenic dysfunction, splenectomy and organ transplantation.¹⁵⁰ Despite these known

143. *Id.* at 31.

144. *Id.* at 32. For the member vaccine and drug companies that are part of the Pharmaceutical Research and Manufacturers of America see <http://www.phrma.org/publications/publications/annual2000/members.phtml> (last visited on Oct. 29, 2000).

145. MAJORITY STAFF REPORT, *supra* note 29, at 34-35.

146. *Id.* at 10.

147. “In March 1999, Prevnar, a novel, seven-valent pneumococcal conjugate vaccine, was granted a ‘priority review’ by the FDA.” AMERICAN HOME PRODUCTS CORPORATION, 1999 ANNUAL REPORT 4 (2000).

148. Package Insert, *supra* note 82.

149. *Id.* The manufacturer states that “The annual incidence of pneumococcal meningitis in children between 1 to 23 months of age is approximately 7 cases per 100,000 persons” and that this disease “has been associated with 8% mortality.” *Id.* Seven cases per 100,000 = .00007%. Eight percent mortality = .0000056. .0000056 of 7,500,000 (the approximate number of children under two-years of age) = 42 children. For the approximate number of children in the U.S. under two years of age see NEW YORK TIMES ALMANAC, *supra* note 92, at 277. See also Centers for Disease Control, CDC’s Pneumococcal Conjugate Vaccine: What You Need to Know, at <http://www.cdc.gov/nip/publications/VIS/vis-pneumoConjugateInterim.pdf> (last visited on Mar. 7, 2001) According to the CDC, pneumococcal disease is responsible for about 200 deaths each year in children under five years of age. *Id.*

150. COMMITTEE ON INFECTIOUS DISEASES AMERICAN ACADEMY OF PEDIATRICS, *supra*

risk factors and the fact that 20 to 40 percent of healthy children have been found to already carry this micro-organism,¹⁵¹ the American Academy of Pediatrics Committee on Infectious Diseases has recommended universal vaccination for all children.¹⁵² Every child in America should receive four doses of the vaccine at 2, 4, 6, and 12-15 months of age.¹⁵³

The primary tests to determine the vaccine's safety and efficacy were undertaken by Drs. Black and Shinefield of Kaiser Permanente.¹⁵⁴ These studies were paid for by Wyeth-Lederle, the vaccine's manufacturer.¹⁵⁵ In fact, these doctors appear in a glossy photo in American Home Products' 1997 Annual Report.¹⁵⁶ The conferences these doctors attended to introduce

note 93, at 371; COMMITTEE ON INFECTIOUS DISEASES AMERICAN ACADEMY OF PEDIATRICS, 1997 RED BOOK: REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES 411 (1997).

151. Daniel M. Musher, *Pneumococcal Infections*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, *supra* note 64, pt. 7 § 5, at 870 ("S. pneumoniae colonizes the nasopharynx and can be isolated from 5 to 10 percent of healthy adults and from 20 to 40 percent of healthy children").

152. American Academy of Pediatrics, *Policy Statement: Recommendations for the Prevention of Pneumococcal Infections, Including the Use of Pneumococcal Conjugate Vaccine (Prevnar), Pneumococcal Polysaccharide Vaccine, and Antibiotic Prophylaxis (RE9960)* 106 PEDIATRICS 362-366 (2000), at <http://www.aap.org/policy/re9960.html>

153. *Id.* In addition to mortality, the morbidity associated with any disease must always be considered in any cost-benefit analysis of vaccination. In respect to bacteremia, a leading medical treatise states, "Almost all children with occult pneumococcal bacteremia recover uneventfully if they are treated with parenteral antibiotics when first seen. . ." David S. Fedson, et al., *Pneumococcal Vaccine*, in VACCINES, *supra* note 26, at 568. In respect to pneumonia, the same treatise states, "[i]n children 6 months of age and younger who live in developed countries, pneumococcal infection rarely causes serious lower respiratory tract disease requiring hospitalization." *Id.* at 567. Morbidity associated with meningitis can be severe and include mental retardation, deafness or seizure disorder. *Id.* at 568. However, it appears that there are only 525 cases per year in children under 23 months of age in the U.S. Musher, *supra*, note 151. Arguably many of these cases may be associated with the risk factors outlined by the American Academy of Pediatrics. See American Academy of Pediatrics, *supra* note 152.

154. See, e.g., Henry Shinefield & Steven Black, *Efficacy of Pneumococcal Conjugate Vaccines in Large Scale Field Trials*, 4 PEDIATR. INFECT. DISEASES J. 394-97 (2000); Steven Black et al., *Efficacy, Safety and Immunogenicity of Heptavalent Pneumococcal Conjugate Vaccine in Children. Northern California Kaiser Permanente Vaccine Study Center Group*, 3 PEDIATR. INFECT. DISEASES J. 187-95 (2000); T. A. Lieu et al., *Projected Cost-Effectiveness of Pneumococcal Conjugate Vaccination of Healthy Infants and Young Children*, 11 JAMA 1460-8 (2000); and Henry Shinefield et al., *Safety and Immunogenicity of Heptavalent Pneumococcal CRM197 Conjugate Vaccine in Infants and Toddlers*, 9 PEDIATR. INFECT. DISEASES J. 757-63 (1999).

155. Press Release, Harvard Medical School Office of Public Affairs, Researchers Find Use of Pneumococcal Conjugate Vaccine for Children Could Reduce Disease-Related Costs, March 14, 2000 at <http://www.hms.harvard.edu/news/releases/0300lieu.html> ("study was supported by a grant from Wyeth Lederle Vaccines & Pediatrics"). Associated Press, *New Vaccine Reduces Risk of Severe Pneumonia in Children*, (Oct. 1, 1999), available at http://www.idahonews.com/10011999/health_a/386.htm ("Wyeth-Lederle Laboratories "paid for the testing").

156. AMERICAN HOME PRODUCTS, 1997 ANNUAL REPORT (1997), available at <http://www.ahp.com/annrpt97/areport3.htm>.

the vaccine to other clinicians were also paid for by the manufacturer.¹⁵⁷

Another doctor who accompanied Drs. Black and Shinefield to a conference was Dr. Kathryn Edwards.¹⁵⁸ Wyeth-Lederle paid Dr. Edwards \$255,023 per year from 1996 to 1998 for the study of pneumococcal vaccines (i.e. Prevnar).¹⁵⁹ Edwards is also one of fifteen full-time members of FDA's vaccine advisory committee (VRBPAC) that recommended that the vaccine be approved.¹⁶⁰ In addition, she answers questions regarding Prevnar on a pro-Prevnar website called "pneumo.com" which is paid for by Wyeth-Lederle.¹⁶¹

Some of Dr. Edwards' answers to questions appear to be misleading. A mother named Susan wrote to Dr. Edwards on September 6, 2000 and said: "(I read) some disturbing comments from parents whose children have already received the vaccine. They said it has terrible side effects, such as poor appetite, difficulty breathing, sleeping problems, and can cause juvenile diabetes. . .of course this has me worried."¹⁶² Dr. Kathryn Edwards responded on September 12, 2000, "The vaccine was administered to nearly 20,000 children prior to licensure and the side effects seen in these children were carefully evaluated and not shown to increase the rate of diabetes, respiratory problems, or weight loss."¹⁶³ Contrary to Dr. Edwards' comments, one doctor has stated publicly that he is concerned that Prevnar may cause diabetes.¹⁶⁴ In addition, during the pre-market studies, cases of croup, pneumonia, asthma, bronchiolitis, and wheezing were diagnosed within three days of administration of Prevnar.¹⁶⁵

157. See MEDREGISTER, Preventing Pediatric Diseases—A Continuing Medical Education Course, at <http://www.mededregister.com/vaccine.html> (last visited May 26, 2000) (Conference to present Prevnar in Washington D.C. on October 8, 1999 was "supported by an unrestricted educational grant from Wyeth Lederle vaccines"); 9th International Congress on Infectious Diseases, April 10-13, 2000, Buenos Aires, Argentina, at http://isid.organize-it.com/9th_congress/sat_symposia.html (last visited May 26, 2000) (Conference was "sponsored by Wyeth Lederle vaccines"); Pediatric Academic Societies & American Academy of Pediatrics Joint Meeting - Haynes Convention Ctr. May 16, 2000, at <http://www.aps-spr.org/Meetings/2000/Monday.htm> (last visited May 27, 2000) (Conference was "supported in part by an educational grant from Wyeth-Lederle Vaccine and Merck Vaccine Division").

158. See <http://www.aps-spr.org/Meetings/2000/Monday.htm>.

159. MAJORITY STAFF REPORT, *supra* note 29, at 17.

160. *Id.*

161. Pneumo.com, Ask an Expert, at <http://pneumo.com/contact/contact2.html> (last visited on Sep 14, 2000) (The site is "supported by an unrestricted educational grant from Wyeth-Lederle Vaccines").

162. Pneumo.com, Online Forum at <http://www.pneumo.com/msgboard/messages/parent-messages.html> (last visited Sept. 13, 2000) (on file with author).

163. *Id.*

164. Dr. J. Bart Classen told the FDA that Prevnar "may be seven times as toxic as the hemophilus vaccine, possibly causing an estimated 400 to 700 children to develop insulin dependent diabetes per 100,000 children immunized. These cases of diabetes may not occur until 3.5 to 10 years following immunization." Press release, Classen Immunotherapies, New "Tuskegee-Like Experiment" Planned with Pneumococcal Pneumonia Vaccine, Reported by Classen Immunotherapies (Feb. 18, 2000), at <http://vaccines.net/pneumoco.htm>.

165. Package Insert, *supra* note 82.

Another doctor, Margaret Rennels, was involved in RotaShield and has participated in testing the safety of Prevnar.¹⁶⁶ The major vaccine and drug manufacturers (including Wyeth-Lederle) have donated a total of over \$2.5 million to the University of Maryland School of Medicine where Dr. Rennels works.¹⁶⁷ In addition, she is one of the twelve members of the Committee on Infectious Diseases, the committee that makes vaccine recommendations as part of the American Academy of Pediatrics.¹⁶⁸

Although it is FDA approved, it appears that Prevnar has not undergone thorough testing for either safety or efficacy. The manufacturer acknowledges that, "Prevnar has not been evaluated for any carcinogenic or mutagenic potential, or impairment of fertility."¹⁶⁹ The manufacturer also states that when Prevnar is administered simultaneously with other vaccines it may interfere with the effectiveness of at least two other vaccines.¹⁷⁰ Additional studies with Prevnar given in conjunction with other childhood vaccines used very small numbers of children of between 0-214.¹⁷¹ Finally the efficacy of Prevnar in respect to ear infections is only 7%¹⁷² and it reportedly reduces

166. Margaret Rennels et al., *Safety and Immunogenicity of Heptavalent Pneumococcal Vaccine Conjugated to CRM197 in United States Infants*, 101 PEDIATRICS 604-11 (1998).

167. University of Maryland School of Medicine Donors, and Medical System Donors, at <http://www.umm.edu/annualreport/9798ar/site/main.htm> (last visited Sept. 14, 2000). (Examples include: Warner-Lambert Company - 1,000,000-4,999,999; Parke-Davis - \$500,000-\$999,999; Hoffman LaRouche, Inc. - \$250,000-\$499,999; Merck & Company - \$250,000-\$499,999; Bristol-Myers Squibb - \$250,000-\$499,999; SmithKline-Beecham \$100,00-\$249,999; Abbott Laboratories - \$10,000-\$49,999; Pfizer Inc. - \$10,000-\$49,999; Wyeth-Ayerst Laboratories \$10,000-\$49,999 to Medical System and \$10,000-\$49,999 to Medical School; American Cyanamid - \$1,000-\$9,999).

168. See Gary D. Overturf & Committee on Infectious Diseases, *Technical Report: Prevention of Pneumococcal Infections, Including the Use of Pneumococcal Conjugate and Polysaccharide Vaccines and Antibiotic Prophylaxis (RE9960)*, 106 PEDIATRICS 367-76 (2000), at <http://www.aap.org/policy/re9960t.html>.

169. Package Insert, *supra* note 82.

170. *Id.* Under "Simultaneous Administration with Other Vaccines," the package insert states:

Although some inconsistent differences in response to pertussis antigens were observed, the clinical relevance is unknown. The response to 2 doses of IPV given concomitantly with Prevnar assessed 3 months after the second dose, was equivalent to controls for poliovirus Types 2 and 3, but lower for Type 1. MMR and Varicella immunogenicity data from controlled clinical trials with concurrent administration of Prevnar are not available.

Id.

171. *Id.* According to the Wyeth-Lederle, for the study concerning DPT and Hib efficacy with Prevnar, the number of infants reviewed (who were given Prevnar) was a total of 214. *Id.* For toddlers the total number was forty-seven children. *Id.* For reviewing the efficacy of Hep B with Prevnar the number of infants studied (who were given Prevnar) was 156. *Id.* For toddlers the total number was zero. *Id.* The numbers of children tested (214, 47, 156, and 0) do not appear to be statistically valid in comparison to the over seven million infants and toddlers are scheduled to receive this vaccine.

172. Press Release, Kaiser Permanente, Investigational Vaccine is First to Show Effectiveness Against Childhood Ear Infections, (May 4, 1999), at <http://www.kaiserpermanente.org/newsroom/releases/vaccine1.html>. "In the primary analysis of all acute otitis media epi-

reduces the chances of a child under two years of age of getting pneumococcal disease from 0.15% (without Prevnar) to 0.02% (with Prevnar).¹⁷³

Even with the conflicts of interest, incomplete testing, questionable necessity, and lackluster efficacy, this vaccine was given a priority review by the FDA and approved for universal vaccination.¹⁷⁴ Injuries and reactions have already been reported.¹⁷⁵

III. PROTECTING CHILDREN THROUGH REESTABLISHING INTEGRITY IN VACCINE POLICYMAKING AND ALTERNATIVE LEGAL STRATEGIES

A. Parameters for Solutions

In order to protect children from potentially unsafe or unnecessary vaccines two parameters must be applied to any potential solution. The first parameter considers how well the approach provides for neutral, fair, and scientifically sound analysis regarding the vaccine's necessity, safety and efficacy. The second adjudges how well it provides parents with information and the opportunity to exercise informed consent. Any solution that fulfills both parameters will serve to protect children and optimize their health.

B. An Attempt to Eliminate Conflicts of Interest

The various rules concerning federal advisory committees allows the FDA and CDC to issue waivers and permits doctors with conflicts of interest to participate in their respective vaccine committees.¹⁷⁶ Without these waiv-

sodes [i.e. earaches] . . . children receiving the investigational 7-valent pneumococcal vaccine [i.e. Prevnar] had 7 percent fewer new episodes." *Id.*

173. Package Insert, *supra* note 82. Data derived from the text and figures in Table 1 of the package insert. Based on the intent to treat figures (children who received at least one dose of the vaccine), if you do not vaccinate with Prevnar the risk is approximately 20 in 100,000 (0.020%) for all persons, and 150 in 100,000 (0.15%) for children under two. If you do vaccinate with Prevnar, the risk decreases to 3 out of 18,906 (.016) rounded to .02%.

174. See AMERICAN HOME PRODUCTS, *supra* note 147.

175. See generally Pneumo.com Online Forum, at <http://www.pneumo.com/msgboard/messages/parent-messages.html> (last visited Sept. 13, 2000). This bulletin board contains anecdotal information - questions from parents whose children have been administered Prevnar and who have had adverse reactions such as: pneumonia, vomiting, rashes, inflammation, fevers, etc. *Id.* See also *News 8 Investigates: Prevnar-Part 1* (WFAA television broadcast (Dallas) Feb. 22, 2001) ("[A]s part of our investigation, News 8 reviewed nearly 800 adverse reaction reports filed with the FDA during past nine months. What we found is that one of out 10 children who had suspected side effects suffered some sort of seizure").

176. There are three groups of rules that regulate federal advisory committees. The first is the Federal Advisory Committee Act (FACA). 5 U.S.C.A. app. 2 § 1 et seq. (West, WESTLAW through P.L. 106-274, approved Sept. 22, 2000). FACA was enacted in 1972. *Id.* Its purpose is to better control spending on advisory committees and make the committees more accountable to the government. See *id.* To accomplish this, FACA provides recommendations on the scope of the committees, requires the meetings to be open to the public, and requires that committees contain balanced membership that is not "inappropriately influenced by special interests." 5 U.S.C.A. § 5. The second area of law that controls the advisory committees is 18 U.S.C. §§ 202-209 that address conflicts of interest. 18 U.S.C.A. §§ 202-209

ers, these physicians could be subject to fines or imprisonment.¹⁷⁷ Both agen-

mittees is 18 U.S.C. §§ 202-209 that address conflicts of interest. 18 U.S.C.A. §§ 202-209 (West, WESTLAW through P.L. 106-274, approved Sept. 22, 2000). This statute defines advisory committee members as Special Government Employees (SGE's). 18 U.S.C.A. § 202. The statute generally prohibits SGE's from participating in decision making when they have a conflict of interest. However, there are three waivers available: (b)(1) waivers are used when the appointing official decides the individuals conflict of interest is too insubstantial to effect the integrity of the policymaking; (b)(2) waivers are extended when the conflict of interest is too remote to have any effect at all; (b)(3) waivers are used when the appointing official determines that "the need for the employee's services outweigh the potential conflict of interest by the employee's financial interest." 18 U.S.C.A. § 208. The last group of rules that directly impacts federal advisory committees is the Code of Federal Regulations and Office of Government Ethics. 5 C.F.R. 2640 (West, WESTLAW through P.L. 106-274, approved Sept. 22, 2000). These rules interpret 18 U.S.C. §§ 201-219 and provide more specific regulations regarding what types of conflict of interest can exclude SGE's (absent a waiver). *Id.* The three waivers 18 U.S.C. §§ 208 (b)(1-3) and the construction of the various rules give the appointing officials in each agency tremendous latitude in appointing committee members and waiving or discounting conflicts of interest. *Id.* In fact, the FDA and CDC rely on the (b)(3) waivers to justify their allowing of committee members with significant conflicts of interest to participate in the meetings. See *Conflicts of Interest and Vaccine Development*, *supra* note 23 (June 15, 2000) (statement by Linda Suydam, D.P.A. Senior Associate Commissioner, FDA), at <http://www.house.gov/reform/hearings/healthcare/00.06.15/suydam.htm>.

Under section 18 U.S.C. 208(b)(3), an SGE, who may be a standing or temporary member, may participate in an advisory committee meeting despite a potential conflict of interest. After reviewing the SGE's financial disclosure statements, the Senior Associate Commissioner may determine that the need for the employee's services outweighs the potential conflict of interest created by the financial interest involved.

Id. "Congress has recognized the need for service on federal advisory committees by these experts and has provided for waivers of the conflict of interest prohibitions under 18 U.S.C. § 208 when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved." *Id.* (statement by Dixie Snider).

For a discussion of FACA see Kurtis A. Kemper, J.D., Annotation, *Construction and Application of Federal Advisory Committee Act* (5 U.S.C.A. app. 2 §§ 1-15), 160 A.L.R. FED. 483 (2000). For a discussion of 18 U.S.C. §§ 202-209 see Lewis J. Heisman, J.D., Annotation, *What Constitutes Acts Affecting Personal Financial Interest Within Meaning of 18 U.S.C.A. § 208(a), Penalizing Participation by Government Employees in Matters in Which They Have Personal Financial Interest*, 59 A.L.R. FED. 872 (1982). For a discussion of Code of Federal Regulations and Office of Government Ethics (5 C.F.R. 2640) see *FACA: Conflicts of Interest and Vaccine Development: Preserving the Integrity of the Process*, Before the Government Reform Committee of the House of Representatives, 106th Cong. (June 15, 2000) (statement of Marilyn L. Glynn, General Counsel, Office of Government Ethics). For an overview of all three rules in terms of federal vaccine advisory committees see MAJORITY STAFF REPORT, *supra* note 29, at 3-6.

177. 18 U.S.C. § 216(b):

The Attorney General may bring a civil action in the appropriate United States district court against any person who engages in conduct constituting an offense under section 203, 204, 205, 207, 208, or 209 of this title and, upon proof of such conduct by a preponderance of the evidence, such person shall be subject to a civil penalty of not more than \$50,000 for each violation or the amount of compensation which the person received or offered for the prohibited conduct, whichever amount is greater. The imposition of a civil penalty under this subsection does not preclude any other criminal or civil statutory, common law, or administrative remedy,

cies argue that they are liberal with waivers because they claim that they can not find vaccine experts without conflicts.¹⁷⁸ This reason appears dubious. Recently, when the Institute of Medicine formed a committee to examine the relationship between vaccines and autism they found expert doctors with fewer direct conflicts.¹⁷⁹ Some scientists see the FDA's and CDC's explanation as little more than an excuse. Dr. Gordon Stewart has studied the pertussis vaccine for decades and has stated, "[There's] something like one hundred people [who] are pretty well controlling what goes on in the entire world of vaccines. They are all in cahoots with each other and with the pharmaceutical companies."¹⁸⁰

The section that permits these liberalized waivers, 18 U.S.C. § 208 (b)(3), was enacted in 1989.¹⁸¹ Although the Supreme Court has not had an

which is available by law to the United States or any other person.

178. *Conflicts of Interest and Vaccine Development* (statement of Linda Suydam), *supra* note 176

(United States is increasingly supported by industry. For that reason, outside experts and research centers where they work, frequently have research grants from and contracts with regulated industry. Thus most active researchers in the private sector have some ongoing or past relationship with regulated industry. This, by itself, does not preclude them from serving as Special Government Employees. If this were the case, FDA would not get the top scientists in the field and recommendations of the advisory committees would not be of the highest scientific nature, with a likely impact on public health)

MAJORITY STAFF REPORT, *supra* note 29, at 3-6; *Conflicts of Interest and Vaccine Development* (statement of Dixie Snider), *supra* note 23.

(Federal advisory panels inherently have members who may have potential financial conflicts of interest because. . . the members are chosen for service based on their expertise in the areas in which advice is sought by the government. Experts in the vaccine field frequently have affiliations with, or may be engaged in research conducted by academic institutions or other institutions which may receive funding from vaccine manufacturers.)

During the hearing, Congress was told that it was theoretically possible for the CEO of a vaccine manufacturer to be invited to participate on a federal vaccine advisory panel. *Conflicts of Interest and Vaccine Development*, *supra* note 23, at transcript lines 1188-1192 (conversation between Congressman Dan Burton and Marilyn L. Glynn, General Counsel, Office of Government Ethics).

179. Representative Dan Burton, Address at the International Public Conference on Vaccination 2000, (Sept. 9, 2000).

180. COULTER & FISHER, *supra* note 22, at 181.

181. 18 U.S.C. § 208 was enacted in 1962, but the (b)(3) waiver was added by Congress in 1989 after the recommendation for the need of more liberalized waivers made by a commission appointed by President Bush during that same year. See *Conflicts of Interest and Vaccine Development supra* note 23, (statement of Marilyn L. Glynn, General Counsel, Office of Government Ethics), at <http://www.house.gov/reform/hearings/healthcare/00.06.15/glynn.pdf> This commission concluded that the government needed to be liberal with conflict of interest rules in order to obtain advice from individuals with expertise in the private sector. *Id.* It recommended that federal agencies be given broad discretion to grant individual waivers if the need for the individual's services outweighed the perceived conflict of interest. *Id.* The commission's report is entitled *Report of the President's Commission on*

opportunity to interpret the application of this section, it has interpreted the meaning of 18 U.S.C. § 434, the predecessor of 18 U.S.C. § 208.¹⁸² In *United States v. Mississippi Valley Generating Co.*,¹⁸³ the Supreme Court noted:

The statute is directed at an evil which endangers the very fabric of a democratic society, for a democracy is effective only if the people have faith in those who govern, and that faith is bound to be shattered when high officials and their appointees engage in activities which arouse suspicions of malfeasance and corruption.¹⁸⁴

The majority cited a Biblical admonition in which “no man can serve two masters”¹⁸⁵ and stated that the statute’s purpose is to insure “honesty in the Government’s business dealings” by preventing federal employees from “advancing their own interests at the expense of the public.”¹⁸⁶ The Court recognized that an “impairment of impartial judgment can occur in even the most well-meaning men when their personal economic interests are affected by the business they transact on behalf of the Government.”¹⁸⁷ The Supreme Court asserted that the statute is designed to “prevent honest government agents from succumbing to temptation by making it illegal for them to enter into relationships which are fraught with temptation.”¹⁸⁸ In this way, the Court explained, the statute is “directed not only at dishonor, but also at conduct that tempts dishonor.”¹⁸⁹

On July 11, 2000, the chairman of the Committee on Government Reform, Congressman Dan Burton, offered an amendment that would halt funding to the FDA advisory committee if it abused its discretion when granting waivers on conflict of interest.¹⁹⁰ A brief debate ensued on the floor

Federal Ethics Law Reform (March 1989). *Id.*

182. Heisman, *supra* note 176. “Subsection (a) was modeled on former 18 U.S.C.A. § 434, which disqualified a Federal Government employee who had an interest in the profits or contracts of a business entity from the transaction of business with such entity. However, subsection (a) improved upon the former law by abandoning the limiting concept of the ‘transaction of business.’” *Id.*

183. 364 U.S. 520 (1961).

184. *Id.* at 562.

185. *Id.* at 549 (citing Matt. 6:24).

186. *Id.* at 548-49 (citing *United States v. Chemical Foundation* 272 U.S. 1, 18, 47 (1926)).

187. *Id.* at 550 (citing *Rankin v. United States*, 98 Ct. Cl. 357 (1943)).

188. *Id.* at 549.

189. *Id.* It does not appear that the liberalized waiver provisions enacted in 1989, (18 U.S.C. § 208(b)(3)), were designed to overrule the purpose of the statute as interpreted by the Supreme Court. *Conflicts of Interest and Vaccine Development* (statement of Marilyn L. Glynn) *supra* note 176. Rather, the Report of the President’s Commission on Federal Ethics Law Reform suggests that they were designed to provide the Government with the opportunity to better utilize expertise from the private sector. *Id.*

190. The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, H.R. 68 106th Leg., (2000).

None of the funds made available in this Act may be expended for a vaccine-related Federal advisory committee (Vaccines and Related Biological Products

of the House of Representatives and the amendment was not passed.¹⁹¹

C. Controlling the Abuse of Discretion

Congress has decided that it is not prepared to use its authority over funding to control conflicts of interest in the vaccine advisory committees. Nonetheless, other options exist to control the discretion exercised by these committees in allowing conflicted members to participate in vaccine policymaking. These approaches include tightening the current law, implementing a more stringent code, changing the composition of the committees, and employing an ombudsmen or oversight council at the state level.

1. Tightening the Current Law

On August 10, 2000, Congressman Dan Burton, chairman of the Com-

Advisory Committee) that grants a waiver on applicable conflicts of interest rules pursuant to the Federal Advisory Committee Act and sections 202 through 209 of title 18, United States Code, and regulations issued thereunder.

Id.

191. H.R. 106th Cong. (July 11, 2000), at <http://thomas.loc.gov/cgi-bin/query/D?r106:1:./temp/~r106DtiLUP:e98972> (last visited Oct. 26, 2000). Some excerpts of the debate might prove helpful:

Mr. Burton of Indiana: Mr. Chairman, the health of every American child is affected by decisions made at the Department of Health and Human Services about vaccines. Those decisions have to be made free of conflicts of interest, and right now that just is not the case. Health and Human Services relies on two advisory committees to give scientific advice on vaccine policy. Unfortunately, those advisory committees are dominated by the pharmaceutical industry. HHS routinely gives doctors with serious conflicts of interest waivers to vote on vaccine policies. My amendment stands for a simple proposition. We should be getting the best scientific advice possible and it should not be tainted by possible conflicts of interest.

Mr. Skeen: [The] top scientists are few in number and very specialized. Most of them have worked in research sponsored by industry at some point in their careers.

Mr. Burton: If we grant waivers to those people, we are going to continue the process which endangers kids in this country.

Mr. Waxman: We have got to have the people who have the knowledge and expertise to be on these advisory committees. . . The conflicts of interest. . . were quite remote, had nothing to do with vaccine approval. In some cases they involved people who because of their knowledge and expertise in this area had worked for pharmaceutical companies because they were the best experts in the country to advise on those vaccines.

Curiously, this debate has shifted the burden to the Committee on Government Reform to prove that the advisory committees can operate without conflict of interest, rather than on the vaccine committees to demonstrate that they cannot operate without these conflicted individuals. There are over 700,000 doctors in the United States in various specialties. The FDA and CDC have never explained why none of these 700,000 physicians cannot replace some or all of the current physicians who have worked for the vaccine manufacturers.

mittee for Government Reform, sent a letter to Donna Shalala, Secretary of Health and Human Services.¹⁹² The letter stated:

It has become clear over the course of this investigation that the VRBPAC and the ACIP are dominated by individuals with close working relationships with the vaccine producers. This was never the intent of the Federal Advisory Committee Act. . . [The] Committee found a flawed process that placed expediency before vigilance. . . [V]accines that have not been subjected to rigorous scientific review can be dangerous. . . Please act now to implement these straightforward recommendations.¹⁹³

The congressman offered nine recommendations¹⁹⁴ designed to tighten the current law. They included:

stopping the issuing of annual conflict of interest waivers by the CDC; adopting stricter standards for determining conflicts of interest in areas such as stock ownership: disallowing recused individuals from participating in the approval meetings; disallowing members with conflicts of interest from participating in working groups which draft the recommendations; and holding working group meetings in public.¹⁹⁵

On November 16, 2000, Ms. Melinda K. Plaisier, Associate Commissioner for Legislation for the Department of Health and Human Services responded.¹⁹⁶ She stated that conflicted individuals are often used on vaccine committees because they are the “most active researchers” and the need “for their expertise outweighs the conflict of interest.”¹⁹⁷ She also reiterated that the FDA has the authority to allow conflicted members to participate.¹⁹⁸ In defending the participation of one conflicted member, Dr. John Modlin, Ms. Plaisier concluded that his participation was not extensive because “[I]n a transcript of over 6,000 lines, Dr. Modlin speaks [only] 12 times in open session for a total of 94 lines.”¹⁹⁹

2. Implementing a More Stringent Code

Dr. Erdem Cantekin²⁰⁰ has suggested that advisory committee members should be required to adopt more stringent conflict of interest regulations

192. Letter from Dan Burton, Chairman of the Committee on Government Reform, House of Representatives (August 10, 2000), *available at* <http://www.house.gov/reform>.

193. *Id.*

194. *Id.*

195. *Id.*

196. Letter from Melinda K. Plaisier, Associate Commissioner for Legislation, Department of Health and Human Services, to the Honorable Dan Burton, Chairman, Committee on Government Reform (Nov. 16, 2000) (on file with the author).

197. *Id.* at 1 (letter) and at 4 (attachment).

198. *Id.* at 2 (letter).

199. *Id.* at 5 (attachment).

200. Erdem Cantekin, Ph.D. is Professor of Otolaryngology at the University of Pittsburgh.

such as the guidelines mandated in the Judicial Code of Conduct.²⁰¹ Judges must abide by the six canons articulated in the code.²⁰² Canon two states, "A judge should avoid impropriety and the appearance of impropriety in all activities. . . . A judge must . . . accept restrictions that might be viewed as burdensome by the ordinary citizen. . . ."²⁰³ Canon three states, "A judge shall disqualify himself or herself in a proceeding in which the judge's impartiality might reasonably be questioned. . . ."²⁰⁴ In addition to the code of conduct, under 28 U.S.C. § 455, federal judges must disqualify themselves when they know their impartiality might reasonably be questioned²⁰⁵ or when they have a financial interest in the subject matter in controversy.²⁰⁶ The U.S. Supreme Court has interpreted 28 U.S.C. § 455(a) to mean that even an appearance of partiality should be avoided.²⁰⁷

Although this code applies to all federal judges, its requirements may be viewed as most significant in respect to district court judges. The decisions of these judges generally have a direct effect on a limited number of actors—the plaintiffs (or prosecution) and the defendants. Nonetheless, these judges must abide by these strict codes of conduct. Conversely, the decisions made by the members of the vaccine advisory committees effect millions of children a year. Considering the numbers of people affected by their decisions, advisory committee members should abide by codes of conduct at least as stringent as those of judges.

One way the code is implemented is by requiring judges to submit a record of financial disclosure when their impartiality may be questioned.²⁰⁸ Requiring vaccine advisory committee members to also make public any financial ties to drug companies would also provide for a heightened level of public scrutiny and oversight.

201. E-mail from Dr. Erdem Cantekin (Sept. 27, 2000) (on file with the author).

202. Judicial Conference of the United States, Judicial Code of Conduct. Quotations are from the canons themselves and excerpts of the official commentary from the Judicial Conference at <http://cSept.iit.edu/codes/coe/judicial-coc.htm> (last visited on Oct. 18, 2000).

203. *Id.*

204. *Id.*

205. 28 U.S.C. § 455(a) cited in Kurtis A. Kemper, J.D., Annotation, *Disqualification of Judge Under 28 USCA § 455(b), Providing for Disqualification Where Judge Has Financial or Other Interest in the Proceeding*, 163 A.L.R. FED. 575 (2000).

206. 28 U.S.C. § 455(b) cited in Kemper, *supra* at 575.

207. *Liljeberg v. Health Services Acquisition Corp.*, 486 U.S. 847, 860 (1980) ((citing *Hall v. Small Business Administration*, 695 F. 2d 175, 179 (5th Cir. 1983)) "The goal of § 455(a) is to avoid even the appearance of partiality. If it would appear to a reasonable person that a judge has knowledge of facts that would give him an interest in the litigation then an appearance of partiality is created. . . .").

208. 28 U.S.C.A. § 455(e). "Where the ground for disqualification arises only under subsection (a), waiver may be accepted provided it is preceded by a full disclosure on the record of the basis for disqualification."

3. *Changing the Composition of the Committees*

Another approach has been suggested by Barbara Loe Fisher. Ms. Fisher is the only consumer voting member of the FDA's Vaccines and Related Biological Products Advisory Committee (VRBAPC).²⁰⁹ She considers bias to be the major obstacle towards equitable vaccine policymaking and financial conflict of interest as only one example of bias.²¹⁰ She views the shared, almost militant, ideology amongst the members of the committee as the major challenge.²¹¹

A pervasive problem that can cause as much bias as financial conflict of interest is ideology. The federal vaccine advisory committees . . . are dominated by infectious disease specialists and public health doctors who not only have significant financial relationships with vaccine makers but also embrace a common vision. They see their mission as eradicating most, if not all, infectious microorganisms from the earth. So when drug companies produce a new vaccine that is, in effect, a new weapon in their war on infectious microorganisms, they want everyone to use it. In their minds, the benefits of using this new weapon to achieve their mission always outweighs the risks associated with its use. They are conditioned to believe that casualties are acceptable in order to achieve the mission, which they define as the 'greater good.' Human nature leads them to want to dismiss or minimize the risks in order to persuade everyone to cooperate and fight the war.²¹²

Ms. Fisher believes that the advisory committees should include, "members with expertise in different subspecialties and those with and without varying degrees of financial ties to pharmaceutical firms."²¹³ She stresses the importance of including researchers from the subspecialties of molecular and cell biology, microbiology, genetics, neuroimmunology, and toxicology.²¹⁴ Currently, these experts do not have a significant opportunity to participate in vaccine policymaking.²¹⁵ It is these subspecialties, Fisher points out, who have the scientific expertise to address the links between vaccination and learning disabilities, ADHD, autism, asthma, diabetes, arthritis, epilepsy, multiple sclerosis and cancer.²¹⁶ Today, the vast majority of scientists

209. In addition to her position on the FDA's VRBPAC to which she was appointed in 1999, Barbara Loe Fisher is president of the National Vaccine Information Center, a non-profit, educational organization she co-founded with parents of vaccine injured children in 1982. She is the co-author of *DPT: A Shot in the Dark* (1985), author of *The Consumer's Guide to Childhood Vaccines* (1997) and editor of *The Vaccine Reaction*. Additionally, Ms. Fisher has served on the National Vaccine Advisory Committee (1988-1991) and Institute of Medicine Vaccine Safety Forum (1995-1998).

210. E-mail from Barbara Loe Fisher (Oct. 9, 2000) (on file with the author).

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*

216. *Id.*

on the vaccine advisory committees are infectious disease specialists who have no expertise in these areas.²¹⁷

Ms. Fisher's approach of considering who should be included in vaccine policymaking as opposed to focusing strictly on who should be excluded, is an important insight and consideration. Both the integrity and scientific validity of the vaccine approval process would be greatly improved by replacing some of the current conflicted members with non-conflicted scientists from these various sub-specialties.

4. Utilizing an Ombudsman or Oversight Council

Although the states are permitted to adopt or reject the federal vaccine recommendations, they typically adopt every vaccine endorsed by the CDC.²¹⁸ One reason for this is that states can receive federal funds for each child who is vaccinated through various federal programs such as the Childhood Immunization Initiative.²¹⁹ Such financial incentives can curtail independent decision making among the respective state departments of health. By acting independently they may risk losing millions of dollars for their state. In contrast, by adopting the federal vaccine recommendations they can bring in these needed funds. One solution to this problem is to create a vaccine ombudsman program in every state.²²⁰

A vaccine ombudsman program could have four roles in respect to vaccines. First, the ombudsman could undertake or facilitate independent research on childhood vaccination including studying the necessity, efficacy and safety of federally recommended vaccines. It might be helpful if the program had the power to subpoena documents such as the raw data involved in vaccine testing. Many of the studies are undertaken by the manufacturers and the data is considered proprietary²²¹ so an independent review of the data would be valuable. The program's independent research would permit it to focus on the issues motivating state health departments to adopt federal vaccine policies.

217. *Id.* "The expertise and ideology reflected in the membership of these federal vaccine advisory committees must be diverse and balanced in order to achieve a more enlightened vaccine licensing and policymaking process." *Id.*

218. *Vaccines: Public Safety and Personal Choice* (statement by the Association of American Physicians and Surgeons on Vaccines submitted by Dr. Jane Orient), *supra* note 97. ("Recommendations' by the Advisory Committee on Immunization Practices are often transformed into mandates by state health departments, with or without specific agreement by the legislature. . .").

219. The CDC's Childhood Immunization Initiative provides performance-based funding to state and local health agencies that meet or exceed immunization targets. <http://www.theglassceiling.com/health2/heimmuni.htm> (last visited Nov. 25, 2000) The FY 1997 budget includes was more than \$88 million. *Id.*

220. The term "ombudsman" comes from the Swedish word that means an investigator of citizen complaints. See Howard A. Davidson, *Applying an International Innovation to Help U.S. Children: The Child Welfare Ombudsman*, 28 FAM. L.Q. 117, 117-18 (1994).

221. See Package Insert, *supra* note 82.

Second, the children's vaccine ombudsman office could play a role influencing legislation and public policies based on its studies and findings. Third, information regarding the results of the independent studies should be disseminated. If, for example, the ombudsman finds that the reason behind the adoption of a particular vaccine is the federal financial incentives then that information can be disseminated to the public and used to influence public policy. Fourth, the vaccine ombudsman program must be careful not to be seduced into becoming an instrument of the pharmaceutical industry, but instead continually promote children's rights. To accomplish these goals, the program should be established by legislation so it has the authority to carry out its purpose.²²²

An ombudsman approach would add a layer of objectivity and expertise between the conflicts of interest present at the federal and possibly the state levels and the children who will be injected in each state. In addition, it can decentralize decision making by opening up vaccine policy decisions to more experts, and allow states to exercise more discretion in determining whether they need a particular vaccine based on their own distinctive health demographics.

There are reputable vaccine awareness organizations in most states that are run by concerned parents. Many of these groups are affiliated with independent physicians and scientists. An ombudsman program could align with these organizations and would, therefore, not need to be created from square one.

5. *The Optimum Strategy to Control Discretion*

Each of the four ideas discussed above, have strengths and weaknesses in respect to meeting the goal of protecting children's health.

Tightening the current law addresses much of the conflict of interest in vaccine approval, but may be less effective in policing potential abuses involved in vaccine testing. Allowing parents to exercise informed consent is not addressed.

Implementing a more stringent code of ethics also concerns conflicts in vaccine policymaking, but does little to address potential conflicts in vaccine

222. The concept of a children's ombudsman is not new. See Malfrid Grude Flekkoy, *The Children's Ombudsman as an Implementor of Children's Rights*, 6 *TRANSNAT'L L. & CONTEMP. PROBS.* 353, 354 (1996). Children's ombudsman programs have been used throughout various countries of the world including the United States to improve government accountability in various areas affecting children's lives. See Davidson, *supra* note 220, at 118

(It coincides with the broader role of the ombudsman for children in other nations, and encompasses not only improvement of government accountability in the area of child protective service agencies, foster care, and adoption programs, but also in the activities of juvenile justice, youth services, and youth corrections agencies, including all agencies responsible for the institutional care of children, both during the day and in residential settings).

testing unless the code is extended to all scientists involved in vaccine testing, which is not practicable. Besides giving parents the theoretical opportunity to act as a watchdog by scrutinizing the financial records of committee members, this approach does little to address the need for parental involvement in decision making.

Changing the composition of the advisory committees by providing for more balanced membership may not eliminate conflicts of interest but will compensate for it with a rich diversity of scientific viewpoints. In addition, if membership in the committee is opened to more parents, this approach will provide for greater parental involvement in vaccine policymaking.

The idea of using an ombudsman does not have a direct impact on either vaccine testing or approval. By acting in a mediation fashion, however, a team of medical experts and parents with diverse viewpoints can provide a valuable service to their state's children. An objective body whose purpose it is to look out for children, challenge assumptions and share information with parents would help neutralize any fraud that was part of the original federal recommendation.

None of these four approaches should be thought of as mutually exclusive. Valuable synergies may develop from implementing more than a single approach.

The CDC and FDA are likely to reject every one of these ideas. They will argue that the best experts are already making vaccine decisions and that the conflicts of interest that exist do not interfere with the quality of their policymaking. When faced with this explanation during the congressional hearing, Congressman Burton replied, "Can the FDA and CDC really believe that scientists are more immune to self-interest than other people?"²²³ Another reason for inaction will likely be that the advisory committees are not the last word, but actual recommendation and approval is made by FDA and CDC officials.²²⁴ While this is may true in theory, in fact every recommendation made by the federal advisory panels in the last 10 years has been endorsed by federal public health officials.²²⁵

D. Protecting Children in an Inadequate System

In addition to what has already been discussed, the legal system pro-

223. *Conflicts of Interest and Vaccine Development*, *supra* note 23 (opening statement by Congressman Dan Burton), at http://www.house.gov/reform/hearings/healthcare/00.06.15/opening_statement.htm.

224. *Id.* (statement by Dixie E. Snider).

225. *See id.* at 90 (conversation between Congressman Burton and Linda Suydon):

Congressman Burton: "So for the past 10 years, the recommendations of the advisory panels have pretty much been followed 100 percent?"

Linda Suydam, D.P.A. Senior Associate Commissioner, FDA: "With some delay in some cases."

vides a number of other potential remedies to protect children from unsafe or unnecessary vaccines. One strategy is tort liability, but federal officials who grant waivers to conflicted doctors and scientists are free from this liability because they are acting within their discretion.²²⁶ Nonetheless, there are at least two creative approaches that can send a not so subtle message to the federal government and the manufacturers that people are watching for fraud and poor fiscal decision making in respect to unnecessary or unsafe vaccines. These approaches are taxpayer derivative suits and Qui Tam claims under the false claim act and they are available to concerned physicians or parents who wish to use the law to exercise oversight over the vaccine policymakers, albeit, indirectly.

1. *Taxpayer Derivative Suit*

Public officials are empowered to make decisions regarding how government's limited resources may be distributed for the purchase of goods and services. Because taxes are the major source of these resources, taxpayers have an interest in how well this function is performed. If, for example, too much money is spent on a good of low priority, this will leave insufficient funds for more pressing priorities. Taxpayer suits are one legal mechanism to hold public officials accountable.²²⁷ Generally, taxpayers' suits are defined as:

Proceedings brought by one or more taxpayers on behalf of themselves as representatives of a class similarly situated within a taxing district or area, upon a ground which is common to all members of the class, and for the purpose of seeking relief from illegal or unauthorized acts of public bodies or public officials which acts are injurious to their common interests as such taxpayers.²²⁸

Both the states and the federal government permit taxpayer suits. But the federal government requires the suit to relate to a constitutional violation.²²⁹ In contrast, some states allow a suit when the taxpayer can make a

226. See, e.g., *Berkovitz by Berkovitz v. U.S.* 484 U.S. 1003 (1988).

227. Susan L. Parsons, *Taxpayers' Suits: Standing Barriers and Pecuniary Restraints*, 59 *TEMP. L.Q.* 951 (1986).

228. *Id.* at 951-52 (quoting 74 *AM. JUR. 2D Taxpayers' Actions* § 1 (1974)).

229. In *Flast v. Cohen*, the Supreme Court created a two-prong test for federal taxpayer suits. *Flast v. Cohen*, 392 U.S. 83 (1968). The first prong requires that the expenditure is pursuant to a Congressional taxing and spending decision. *Id.* at 102. An incidental expenditure related to a regulatory statute will not meet this prong. *Id.* The second prong, requires that the cause of action relates to a constitutional violation. *Id.* See, e.g., Parsons, *supra* note 227. The few suits that have had standing have alleged that the federal government acted illegally within the meaning of the 1st Amendment when it purchased goods for religious organizations such as church-related schools or universities or denominational stamps. See, e.g., *Lemon v. Kurtzman*, 403 U.S. 602, (1971), *Flast v. Cohen*, 392 U.S. 83 (1968), *Tilton v. Finch* 312 F. Supp. 1191 (D.C. Conn. 1970) (books for church-related schools); *Protestants and Other Americans, etc. v. Watson*, 407 F.2d 1264 (D.C. Cir. 1968) (Christmas stamps).

prima facie case that the government used funds to purchase unnecessary goods or services.²³⁰

Both federal and state funds are expended for the purchase of vaccines²³¹ and the dollars expended are significant. For example, Prevnar may cost the federal government approximately \$448.5 million a year.²³² If the product works, it is expected to save the lives of approximately 42 children.²³³ In addition to Prevnar, there are eight other vaccines paid for by federal or state funds.²³⁴

230. See *Parsons*, *supra* note 227, at 955. Each state has different requirements. *Id.* Some states (i.e. Texas) requires that a bureaucrat violates the law or the state constitution, but in general there are four hurdles: 1) Some jurisdictions require that taxes must have increased to pay for the disputed good or service; 2) Eight states require a bond to be posted to cover the defendant' litigation costs; 3) Some jurisdictions will not pay attorneys fees even if the taxpayer is the prevailing party; 4) Most jurisdictions require that the taxpayer demonstrate that the state's purchase is illegal or at least unnecessary and not merely within the discretion of an acting official. *Id.* There is also a pecuniary interest required but this is usually satisfied whenever there's a waste or unlawful expenditure of public monies. *Id.* at 953. The remedies of a taxpayer action are at equity and a prevailing plaintiff can seek to enjoin the expenditure or obtain a writ of mandamus to compel an official to perform a specific duty. See, e.g., *City of Stuttgart v. McCuing*, 234 S.W.2d 209, 211-13 (Ark. 1950); *Bernstein v. Krom*, 111 N.J. Super. 559, 561-63 (1976), cited in *Parsons*, *supra* note 227, n.102.

In New York and Pennsylvania, taxpayers have standing to bring suits based on misapplication of state funds. This suggests, a cause of action can be brought for vaccines purchased with state dollars. "[T]axpayer has course of action to enjoin wrongful expenditure, misappropriation, misapplication, or any other illegal or unconstitutional disbursement of state funds or state property." N.Y. State Fin. Law § 123(b) (McKinney 1974 & Supp. 1986) cited in *Parsons*, *supra* note 227, n.88. See also *New York State Builders Ass'n v. State*, 98 Misc. 2d 1045 (N.Y. 1979) cited in *Parsons*, *supra* note 170, at 951, n.112. ("[in this case] a taxpayer suit had standing for "misapplication of state funds"). See also *Price v. Philadelphia Parking Auth.*, 422 Pa. 317, 326 (Pa. 1966) cited in 74 AM. JUR. 2D *Taxpayer's Actions* § 16, n.26 (1974).

231. There are a variety of sources of government funds for the purchase of vaccines, including: the Vaccines for Children Program (VFC), § 317 of the Public Health Service Act, and various state revenues. INSTITUTE OF MEDICINE, CALLING THE SHOTS: IMMUNIZATION FINANCE POLICIES AND PRACTICES § 3, 49-50 (2000) at <http://www.books.nap.edu/0309071291/html/69/html>. Federal entitlements subsidize VFC and "Section 317" vaccine purchases. *Id.* Approximately 12% of all state-supplied vaccines are purchased with state funds, VFC accounts for 65%, and "Section 317" accounts for 22%. *Id.*

232. The CDC price for Prevnar for one child is approximately \$184 (\$45.99 per dose * 4 doses). CDC Vaccine Price List, at http://www.cdc.gov/nip/vfc/cdc_vaccine_price_list.htm (last visited on Oct. 27, 2000). There are approximately 7.5 million children under two years of age. THE NEW YORK TIMES ALMANAC, *supra* note 92, at 277. Sixty-five to seventy percent of those children will have their vaccines purchased by the VFC. See Henry Grabowski and John Vernon, The Search for New Vaccines: The Effects of the Vaccines for Children Program, presented by the American Enterprise Institute for Public Policy Research, <http://www.aei.org/bs/bs8117.htm> (last visited on Oct. 27, 2000).
 $(\$184) (7.5 \text{ million}) (.65) = \$897,000,000$. The doses are spread over two years so the annual cost is $\$862,875,000/2 = \$448,500,000$.

233. See *supra* note 149 and accompanying text.

234. These vaccines are 1) Varicella, 2) Polio, 3) MMR, 4) Influenza, 5) DPT, 6) Hib, 7) Hep A, 8) Hep B. See VFC ACIP Resolutions, at <http://www.cdc.gov/nip/vfc/acip.htm> (last visited Oct. 27, 2000).

Theoretically, it can be argued that the procurement of unnecessary, poorly tested, or dangerous vaccines is a misapplication of state and federal funds. Such an argument, if successful, would keep these products away from children, and also allow these monies to be expended on more essential public health and welfare needs.²³⁵

2. *Qui Tam Litigation Under the False Claims Act*

The Qui Tam provision of the False Claims Act (FCA) allows whistleblowers to sue parties who fraudulently bill the government.²³⁶ This law has been used successfully in cases where defense contractors and subcontractors

235. For example, can the millions of dollars spent on Prevnar be better expended to protect not only those few who will be stricken by invasive pneumococcal disease, but others as well? Can this disease be prevented through a wiser expenditure of funds? One risk factor for this disease is being HIV positive. 1997 REDBOOK: REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES 411 (1997). Can some portion of the money be utilized to address this factor? What about using the funds to address those issues that have the biggest impact on children? Can the money be used to improve living conditions, nutrition or housing? Accidents around the home kill approximately 7,000 children every year and seriously injure 50,000 more. *See Home Safety*, at <http://www.opfer.com/homeasafenotsorry/> (last visited Oct. 28, 2000). In addition, reports of child abuse totaled 2.9 million cases between 1985 and 1992. *See Davidson*, *supra* note 220, at 120 (quoting WILLIAM J. BENNETT, THE INDEX OF LEADING CULTURAL INDICATORS 11 (Heritage Foundation Mar. 1993) (citing statistics from American Humane Association and the National Committee for Prevention of Child Abuse)). Millions of dollars will be expended from federal and state treasuries for, Prevnar, a vaccine that may save the lives of about 42 children. *See supra* notes 148-50 and accompanying text. Can some of this money be better spent in these areas? These are some of the questions taxpayer plaintiffs may ask if they allege a cause of action for misuse of funds.

236. Congress enacted the Federal False Claims Act (FCA) in 1863 to protect the Union from unscrupulous suppliers of war materials. *See* 31 U.S.C. §§ 3729-3731 (West, WESTLAW, through P.L. 106-274, approved Sept. 22, 2000). In 1863, the United States was in the middle of the Civil War. To provide the weapons and materials for war, the Union contracted with various manufacturers. Some of these manufacturers proved themselves to be corrupt. According to an article written in 1864, "For sugar [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors, or the refuse of shops and foreign armories." Tomes, *Fortunes of War*, 29 HARPER'S MONTHLY MAG. 228 (1864). F. SHANNON, THE ORGANIZATION AND ADMINISTRATION OF THE UNION ARMY, 1861-1865, at 54-56 (1965) (Quoted in U.S. ex rel. Newsham v. Lockheed Missiles and Space Co., Inc. 722 F. Supp. 607, 609 (N.D. Cal. 1989)). The Act was subsequently amended in 1943 and 1986 and provides that anyone who presents a false financial claim to the federal government shall be liable for double or treble damages and civil penalties of up to \$10,000 per false claim. *See* 31 U.S.C.A. § 3729. Under the qui tam provisions of the Act, any person with the appropriate knowledge may bring a civil action to recover damages and penalties. *See* 31 U.S.C.A. § 3730(b)(1). Qui tam is short for the Latin phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur," which means "who pursues this action on our Lord the King's behalf as well as his own." Vermont Agency of Natural Resources v. U.S. ex rel. Stevens 529 U.S. 765, 769 (2000). To bring a qui tam action a parent will need access to some "inside information" on fraudulent practices. AMERICAN BAR ASSOCIATION, QUI TAM LITIGATION UNDER THE FALSE CLAIMS ACT 37 (Howard W. Cox & Peter B. Hutt II eds., 2d ed. 1999) [hereinafter QUI TAM LITIGATION] ("Public disclosures are barred unless asserted by an original source of the information").

tors perpetrate fraud on the government.²³⁷

The plain language of the act, its legislative history, and a recent Supreme Court decision suggest that the FCA could also be used to penalize vaccine and drug manufacturers who falsify their studies or sell an unsafe or defective product to the government.²³⁸

The statute states that any person is liable who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government."²³⁹ Actual intent does not have to be proved.²⁴⁰ Congress recognized that it is very difficult to detect fraud without the assistance of private citizens "who are either close observers or otherwise involved in the fraudulent activity."²⁴¹ And recently, the Supreme Court concluded that, "the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government."²⁴²

When the government subsidizes the testing of vaccines and the evaluation is carried out in a knowingly fraudulent way, a Qui Tam action would be theoretically possible against the manufacturer. This is no different than a defense contractor who makes knowing misrepresentations regarding the testing and development of a missile system. In addition, the action could theoretically be brought when the federal government does not finance the testing, but rather purchases the vaccines. As discussed *supra*, the state and federal governments are the largest purchasers of vaccines.²⁴³ If the federal government spends millions of dollars on a vaccine that is unsafe or ineffective it is not getting what it paid for.²⁴⁴ This is no different than the unscrupu-

237. See, e.g., U.S. ex rel. Madden v. General Dynamics Corp. 4 F.3d 827, 829 (9th Cir. 1993) (relator alleged that the defendant, a large defense contractor, "made misrepresentations to the United States Navy concerning the testing and development of the Phalanx close-in missile system"). See U.S. ex rel. Kelly v. Boeing Co. 9 F.3d 743 (9th Cir. 1993) (relator claimed that Boeing improperly charged to the government certain facilities lease costs).

238. "The starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." U.S. ex rel. Precision Co. v. Koch Industries, Inc. 971 F.2d 548, 552 (10th Cir. 1992) (quoting Consumer Products Safety Comm v. GTE Sylvania, Inc., 447 U.S. 102 (1980)).

239. Knowingly can mean either: (1) having actual knowledge of the information; (2) acting in deliberate ignorance of the truth or falsity of the information; or (3) acting in reckless disregard of the truth or falsity of the information. See 31 U.S.C.A. § 3729(b).

240. See *id.*

241. "The legislative history indicates that Congress sought to encourage more private enforcement of the FCA because [d]etecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity. Yet in the area of Government fraud, there appears to be a great unwillingness to expose illegalities." S. Rep. No. 345 at 4, reprinted in 1986 U.S.C.C.A.N. at 5269, quoted in U.S. ex rel. Kelly v. Boeing Co., 9 F.3d 743, 745 (9th Cir. 1993).

242. "The Senatorial sponsor of this bill broadly asserted that its object was to provide protection against those who would 'cheat the United States'." 317 U.S. 537, 544 (1943) (quoting Congressional Globe, 37th Cong., 3rd Sess., 952).

243. INSTITUTE OF MEDICINE, *supra* note 231.

244. Because the False Claims Act is a federal statute it would only apply to fraud that

lous defense contractors of 1863 selling the government donkeys when horses were ordered.²⁴⁵

Any parent or group of parents would theoretically have a right to bring such an action if they are aware of “inside” information pertaining to the vaccine’s fraudulent testing or manufacturing.²⁴⁶ After the suit is filed, the government would have an opportunity to intervene and take over the lawsuit. Alternatively, if the federal government opts out of such a suit, the individual or individuals would still have the opportunity to bring the suit forward. Moreover, the Act provides a generous incentive for private citizens to pursue such actions. Citizens are entitled to up to 30% of the damages and damages can run into the millions of dollars.²⁴⁷ Such an approach, if successful, would serve to protect children from fraudulent or dangerous vaccines and also punish manufacturers for acting capriciously.

3. *The Optimum Alternative Strategy*

Taxpayer derivative suits and Qui Tam actions are available to concerned physicians, parents and drug company employees who wish to use the law to exercise limited and indirect oversight over the vaccine policy-makers. In some states a successful taxpayer derivative suit will require sufficient evidence to prove that the decision to purchase a vaccine violated a state law or constitution. Other states have a lower burden requiring the plaintiff to prove that the purchase was an irresponsible one and a waste of taxpayer money. The success of any Qui Tam action will be dependent on the degree to which the “inside” information is capable of proving fraud. Theoretically, any such information related to the vaccine testing (if the government subsidized it) or related to the vaccine’s safety, efficacy and necessity (if the government purchased it) would be fair game.

impacts the federal treasury.

245. U.S. government purchase of dangerous or unnecessary vaccines is arguably indistinguishable from recent cases in health care fraud where health care services were medically unnecessary or because the quality of the healthcare was substandard. See QUI TAM LITIGATION, *supra* note 236, at 93-94 (citing United States ex rel Dorsey v. Dr. Warren E. Smith Comm. Mental Health/Mental Retardation and Substance Abuse Ctrs., 1997 U.S. Dist. LEXIS 9424 (E.D. Pa. 1997)).

246. “Riley has not offered any binding or persuasive authority that the Supreme Court has either implicitly or explicitly closed the door on arguments that qui tam relators under the FCA lack standing.” Riley v. St. Luke’s Episcopal Hosp., 196 F.3d 514, 535 (5th Cir. 1999).

247. If the government intervenes, a qui tam plaintiff is now guaranteed 15% and may recover up to 25% of any amount recovered by the government. QUI TAM LITIGATION *supra* note 236, at 93-94. If the government does not intervene, a qui tam plaintiff is guaranteed 25% and may recover up to 30% of any amount recovered for the government. *Id.* A qui tam plaintiff also now has a right to recover reasonable attorney’s fees. *Id.*

IV. REDEFINING THE PROBLEM

A. *Defining A Preventive Law Approach*

The Preventive Law model is founded on the principle that preventing a problem from occurring is generally easier, cheaper and better than reacting after the problem has already happened.²⁴⁸ In respect to the conflicts of interest in vaccine policymaking there are two assumptions: 1) we need vaccines; 2) we need vaccines that are produced and approved without conflicts of interest. A preventive law approach challenges both of these assumptions.

B. *Do Children Need More Vaccines?*

Do children need twenty injections and thirty individual vaccines in their first eighteen months of life? Should healthy children be targeted for the seventy-five new vaccines in the pipeline?²⁴⁹ Pediatricians, scientists and parents are asking these questions. In fact, a small but growing number of doctors believe that “with some immunizations, the danger of taking the shot may outweigh that of not taking it.”²⁵⁰

A sincere and open-minded examination of the need for vaccines by non-conflicted scientists, physicians and public health experts would be the first step. Another step would be to apply the “gold standard” of scientific testing. No large-scale study has ever been undertaken to compare the rates of any disease among vaccinated and unvaccinated children to determine the ultimate impact of vaccination.

C. *Do Children Need Vaccines Devoid of Conflicts of Interest?*

If, after objective scientific studies, the question of do children need all of these vaccines is answered affirmatively, then preventive law can still offer a strategy to address the conflict of interest. Vaccine policymaking is

248. Thomas D. Barton, Presentation to Health Law: Selected Problems (Sept. 19, 2000).

249. “Big Pharma now views vaccines as a great opportunity for growth. . . [there are more] than 75 different vaccines now in various stages of clinical trials.” See Bruce Goldman, *Why Vaccines Are Hot*, Signals, Jan. 18, 1999 at <http://www.signalsmag.com/signalsmag.nsf>.

250. See ROBERT S. MENDELSON, MD, CONFESSIONS OF A MEDICAL HERETIC 144 (1979). For example, Dr. Robert Mendelsohn, a pediatrician and past chairman of the Medical Licensure Committee for Illinois, calls the value of diphtheria vaccine “questionable” and cites studies in which the rare outbreaks of diphtheria occurred among people who were vaccinated. *Id.* He has also challenged the need for the pertussis vaccine stating, “Only about half of its recipients benefit, and the possibility of high fevers, convulsions, and brain damage is too high to ignore.” *Id.* In respect to the measles vaccine he has said, “Any doctor who has decades of experience with measles knows that . . . among well nourished . . . children the incidence [may be] one in 100,000. Meanwhile the vaccine is associated with encephalopathy. . . [and] retardation, hyperactivity, aseptic meningitis, seizures, and hemiparesis (paralysis of one side of the body).” *Id.* In respect to the rubella vaccine he has said, “[it] may do more harm than good.” *Id.*

centralized²⁵¹ and therefore any conflicts of interest effect millions of children. Must vaccine decision-making rest with a handful of men and women who are unfamiliar with the health history of a particular child?²⁵² The two groups who know the health status of a child best are the child's parents and pediatricians.²⁵³ Yet, the decision whether a child needs three hepatitis B vaccines or a chicken pox vaccine or four doses of Hib are made hundreds or thousands of miles away by complete strangers.²⁵⁴

We assume that parents love their children and, when properly informed, will make decisions in their child's best interest. If parents and physicians are provided with full disclosure regarding the risks and benefits of vaccination then they can make intelligent decisions for their children. In addition, if the decision making power is shifted from the government to parents, then parents can exercise informed consent.²⁵⁵ Currently, parents are handed a brief checklist that offers a very incomplete description regarding each vaccine.²⁵⁶ If the parent objects, and the child is not vaccinated, at worst

251. See generally Majority Staff Report, *supra* note 29.

252. There is growing scientific evidence that children's immune systems and immune responses are not identical. See, e.g., T. Shirakawa, et al., *The Inverse Association Between Tuberculin Responses and Atopic Disorder*, 275 SCIENCE 77-79 (1997) ("Human immune responses are heterogeneous..."); IMMUNE DEFICIENCY FOUNDATION, *THE CLINICAL PRESENTATION OF THE PRIMARY IMMUNODEFICIENCY DISEASES: A PRIMER FOR PHYSICIANS* (1992).

253. "We cannot continue a policy of 'treat every child the same' for vaccines because every immune system is different." E-mail from Mary N. Megson, M.D., F.A.A.P (Oct. 9, 2000) (on file with the author).

254. See generally *Vaccines: Public Safety and Personal Choice* (statement by the Association of American Physicians and Surgeons on Vaccines submitted by Dr. Jane Orient) *supra* note 97.

(Public policy regarding vaccines is fundamentally flawed. It is permeated by conflicts of interest. It is based on poor scientific methodology (including studies that are too small, too short, and too limited in populations represented), which is, moreover, insulated from independent criticism. The evidence is far too poor to warrant overriding the independent judgments of patients, parents, and attending physicians, even if this were ethically or legally acceptable. Indeed, evidence is accumulating that serious adverse reactions are being ignored.)

255. "The remote but real risk of serious disease that attends vaccinations must be scrupulously and comprehensively disclosed to the parents of the children that await vaccination." *Vaccines: Public Safety and Personal Choice* (statement of Marcel Kinsbourne, M.D.), *supra* note 60. See also Karin Schumacher, *Informed Consent: Should it be Extended to Vaccinations*, 22 TJLR 89 (1999).

256. The CDC publishes a vaccine information sheet for each major childhood vaccine and this sheet must be provided to the parent or legal guardian of the child. See 42 U.S.C.A. § 300aa-26(a) (West, WESTLAW through P.L. 106-274, approved Sept. 22, 2000). These sheets typically exclude the overwhelming majority of the information provided in the manufacturer's inserts. For example, the sheet for Pneumococcal Conjugate Vaccine (i.e. Prevnar) states that "In clinical trials, pneumococcal conjugate vaccine was associated with only mild reactions." Centers for Disease Control, Vaccine Information Statement (Interim) Pneumococcal Conjugate Vaccine, July 18, 2000 (on file with author). This statement neglects to mention the more serious reactions associated with the vaccine and reported in the insert. See Package Insert, *supra* note 82. For information on the CDC's Instructions for Use of Vaccine

the parent will be prosecuted, and at best the child may not be allowed to attend school.²⁵⁷ However, a very different approach would result if parents had autonomy and full disclosure in respect to vaccine decision making for their children. Below is a hypothetical example of how an excerpt from a “full disclosure” vaccine information sheet might appear for Prevnar.

- Prevnar is marketed to prevent pneumococcal infections that can cause earaches, meningitis, bacteremia and pneumonia.²⁶¹
- Invasive pneumococcal disease can be a life-threatening disease to some children.
- Each year, approximately 42 children (under the age of two) die from pneumococcal meningitis.²⁶²
- Children who are at risk for this disease are those who have pre-existing conditions such as: Hodgkin’s disease, congenital or acquired immunodeficiency (including HIV), nephrotic syndrome, some viral upper respiratory tract infections, splenic dysfunction, splenectomy and organ transplantation.²⁶³
- The vaccine was tested for safety and efficacy by the manufacturer.²⁶⁴
- No long-term tests were done looking at potential associations between the vaccine and chronic autoimmune diseases.²⁶⁵
- The vaccine was not tested to determine if it was carcinogenic.²⁶⁶
- The vaccine does interfere slightly with the efficacy of two other vac-

Information Materials see <http://www.cdc.gov/nip/publications/VIS/vis-Instructions.pdf> (last visited Mar. 7, 2001). For information on the requirement to provide these materials see 42 U.S.C. § 300aa-26. For information on the Pneumococcal Vaccine Conjugate Sheet see CDC website (last visited on 3/7/2001), at <http://www.cdc.gov/nip/publications/VIS/vis-pneumoConjugateInterim.pdf>.

According to Jane Orient, M.D.:

Information given to parents about [the hepatitis B vaccine] often does not meet the requirement for full disclosure. For example, it may state that ‘getting the disease is far more likely to cause serious illness than getting the vaccine.’ This may be literally true, but it is seriously misleading if the risk of getting the disease is nearly zero (as is true for most American newborns). It may also be legalistically true that ‘no serious reactions have been known to occur due to the hepatitis B recombinant vaccine.’ However, relevant studies have not been done to investigate whether the temporal association of vaccine with serious side effects is purely coincidental or not.

Vaccines: Public Safety and Personal Choice (statement by the Association of American Physicians and Surgeons on Vaccines submitted by Dr. Jane Orient), *supra* note 97.

257. Kitch, *supra* note 26, at 1175 and Orenstein et al., *Public Health Considerations-United States*, in *VACCINES*, *supra* note 26, at 1022.

258. Package Insert, *supra* note 82.

259. *Supra* note 149.

260. COMMITTEE ON INFECTIOUS DISEASES AMERICAN ACADEMY OF PEDIATRICS 1997 RED BOOK: REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES 411 (1997).

261. Package Insert, *supra* note 82.

262. *Id.*

263. *Id.*

cines.²⁶⁷

- One doctor believes it could lead to diabetes.²⁶⁸
- The federal recommendation and approval of the vaccine were undertaken by committees of whom some of the members had financial ties to the manufacturer.²⁶⁹
- The American Academy of Pediatricians calls Prevnar the most reactogenic of all childhood vaccines.²⁷⁰

On its face this kind of full disclosure may appear preposterous but providing the truth is critical where children's health is at stake even if it reflects poorly on the manufacturer and on current vaccine policymaking. By making all the issues visible and allowing for parental autonomy, parents would be able to factor this information into their decision making. Granted, it would still be a benefit to have vaccines devoid of conflict of interest, but it would no longer be a necessity upon which parents are totally dependent. In this sense, full disclosure compensates for conflict of interest.

D. The Feasibility of a Preventive Law Approach

Taking a preventive law approach addresses conflicts of interest in vaccine testing and policymaking and the importance of parental informed consent. If a vaccine is not needed, all the issues in respect to this single vaccine become moot. If parents are given full disclosure, than any fraud loses its power to do harm by becoming fully exposed. Approaches like these challenge the status quo and ask people to confront their preconceptions. It is for that reason, that these ideas would most likely enjoy a very hostile reception. The CDC and FDA would likely argue that parents should not have the right to full autonomy in respect to vaccines because the public health is different than an individual's health. While they are different, this argument presupposes that vaccinating one child protects another. Many of the new vaccines have not been tested to prove whether such an assumption is true.

V. CONCLUSION

Children once had to be protected from disease. Today, they must be protected from a system that "shoots first and asks questions later."²⁶⁸ Integrity must be injected back into the sphere of vaccine policymaking. Children have a right to get shots that are both necessary and safe, and not tainted with conflicts of interest. Pneumococcal meningitis disease takes the lives of

264. *Id.*

265. Classen *supra* note 164.

266. *See supra* notes 154-168 and discussion.

267. Overturf & Committee on Infectious Diseases, *supra* note 168.

268. Michael Belkin Address at the International Public Conference on Vaccination 2000, (Sept. 10, 2000), at http://mercola.com/2000/oct/22/shoot_first.htm. Mr. Belkin's healthy daughter died after being administered a hepatitis B vaccine. *Id.*

approximately 42 children a year.²⁶⁹ Rotavirus claims the lives of twenty children.²⁷⁰ Hepatitis B kills fewer than 15 children.²⁷¹ There is data to suggest that at least one vaccine may be causing more death and injury than the illnesses that the vaccine was designed to prevent. Yet, billions of dollars are paid to pharmaceutical manufacturers on poorly tested and potentially dangerous vaccines to prevent diseases that are hardly epidemics.²⁷² During the congressional hearing on Vaccine Conflict of Interest, Congressman Gilman summed up these concerns:

[The] apparent ties between the pharmaceutical industry and the Federal Drug Administration and Centers for Disease Control advisory committee members results in more than an ethical question. . . . The breach of integrity in vaccine development has culminated in the serious need for reform. . . . Human life should not be undermined or compromised for personal or financial ties that advisory members may have to the pharmaceutical industry.²⁷³

With at least seventy-five more vaccines in the pipeline, vaccines are big business.²⁷⁴ Manufacturers and their representatives in government will not surrender their authority without being confronted. For this reason, a variety of solutions should be pursued. The loopholes that permit these conflicts should be closed. Higher standards of accountability should be enforced. The advisory committees should be opened to representatives from all the medical and scientific subspecialties that can offer a valuable perspec-

269. See *supra* note 149.

270. See *supra* note 90.

271. See *supra* notes 92-100.

272. Miguel A. Faria, Jr., MD, Vaccines (Part II): Hygiene, Sanitation, Immunization, and Pestilential Diseases, at <http://www.haciendapub.com/article36.htm> (last visited Nov. 1, 2000).

Before 1960, there were only a few vaccines that were administered for rampant diseases that were known to have posed a clear and present danger, an immediate and imminent epidemiologic threat. Today, it seems that the public health establishment is obsessed with developing vaccines against every conceivable microorganism, and these government programs are bent to include everyone, every child, every infant in the immunization loop.

Id. See also telephone interview with F. Edward Yazbak, M.D., F.A.A.P. (Oct. 9, 2000) (on file with author). Vaccines are not necessary for every single disease without a thorough risk-benefit analysis by independent doctors and scientists. *Id.* Dr. Yazbak practiced pediatrics for 35 years. *Id.* He was the Assistant Clinical Director, Charles V. Chaplin Hospital in Providence, past President of the Medical Staff and Director of Pediatrics at Woonsocket Hospital, Deputy Director for Pediatrics, Child Development Study, Brown University with the National Institutes of Neurological Diseases and Blindness. *Id.*

273. *Conflicts of Interest and Vaccine Development*, *supra* note 23, at 106-07 (oral testimony of Congressman Gilman (see transcript at lines 2521-2563)).

274. See Goldman, *supra* note 249. "Wyeth has been touting the growth potential of its vaccine line. At an analysts meeting in September, the company predicted an annual global growth rate for the business of 34% from 1997 to 2001.: *Smithkline, AHP Vaccine Businesses are Logical Merger Candidate*, 60 (No. 4) PINK SHEET 8 (1998).

tive in respect to vaccine safety. Vaccine ombudsmen programs whose only focus is the health of children should be implemented in every state to act as mediator between the federal decision-makers and the state's population of children. Taxpayer derivative actions and Qui Tam litigation should be filed where appropriate to put the federal government and manufacturers on notice that they are being watched for malfeasance. Full disclosure should be practiced and autonomy should be provided so that parents have the information they need to make informed decisions before the shots are administered. In the final analysis, no less than the health of our nation's children is dependent on our efforts.

*“ . . . Man, proud man!
Dress'd in a little brief authority,—
Most ignorant of what he's most assured,
His glassy essence,—like an angry ape,
Plays such fantastic tricks before high heaven
As makes the angels weep.”*

—WILLIAM SHAKESPEARE, MEASURE FOR MEASURE act 2, sc. 2.

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* J.D. Candidate, December 2001, California Western School of Law; M.A., International Business, Webster University, St. Louis 1990; B.A., Cultural Anthropology, University of California, Santa Barbara 1984. Dedicated to the children who have been injured or killed by a system that puts profits before children's lives. My thanks to the courageous physicians, scientists, and parents who continue to fight for objective science and who have assisted me in this article. Special appreciation to: Michael Belkin, Erdem Cantekin, Ph.D., Beth Clay of the House of Representatives Government Reform Committee, Barbara Loe Fisher Co-founder and President of the National Vaccine Information Center, Mary Megson, M.D., Jane Orient, M.D., and F. Edward Yazbak, M.D. I would also like to acknowledge Dean Smith for his counsel in formulating this article, and Professors Hargrove and DeKoven for instructing me in the fundamentals of legal writing.

