

The impact of litigation issues on hepatitis B vaccination

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Centre for Infectious Disease Prevention and Control
Health Canada

Viral Hepatitis Prevention Board meeting
Geneva, March 13-14, 2003

Vaccination “acceptance” factors?

Positive

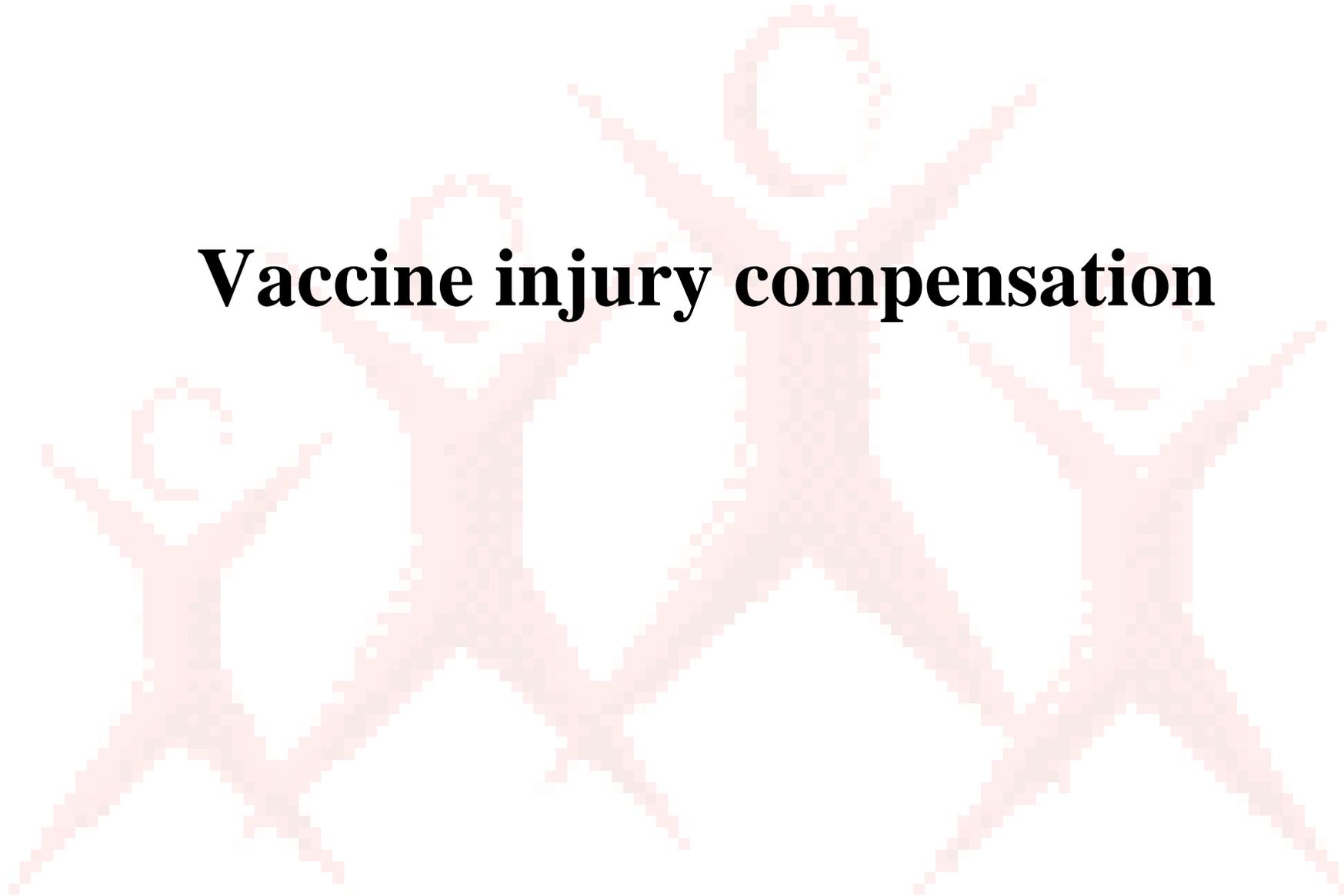
- Apathy: birth, well baby visit, school program...
- Fear of disease
- Safety of vaccines
- Media, Internet, journals
- Friends and family
- Injury compensation plans
- Recommendation of HCP

Negative

- Apathy: not offered, no school program
- No fear of disease
- Fear of vaccines
- Media, Internet, journals
- Friends and family
- Injury compensation plans
- Mandatory vaccination?
- Lawsuits?

Outline and Issues

- History and vaccine injury compensation
- Allegations, activism and lawsuits
 - HepatitisB/MS, MMR/Autism, Thimerosal
- Vaccination mandates (US, Canada)
 - Good, bad and ugly
- Information dissemination, hypothesis generation, publication
 - The use and abuse of information?

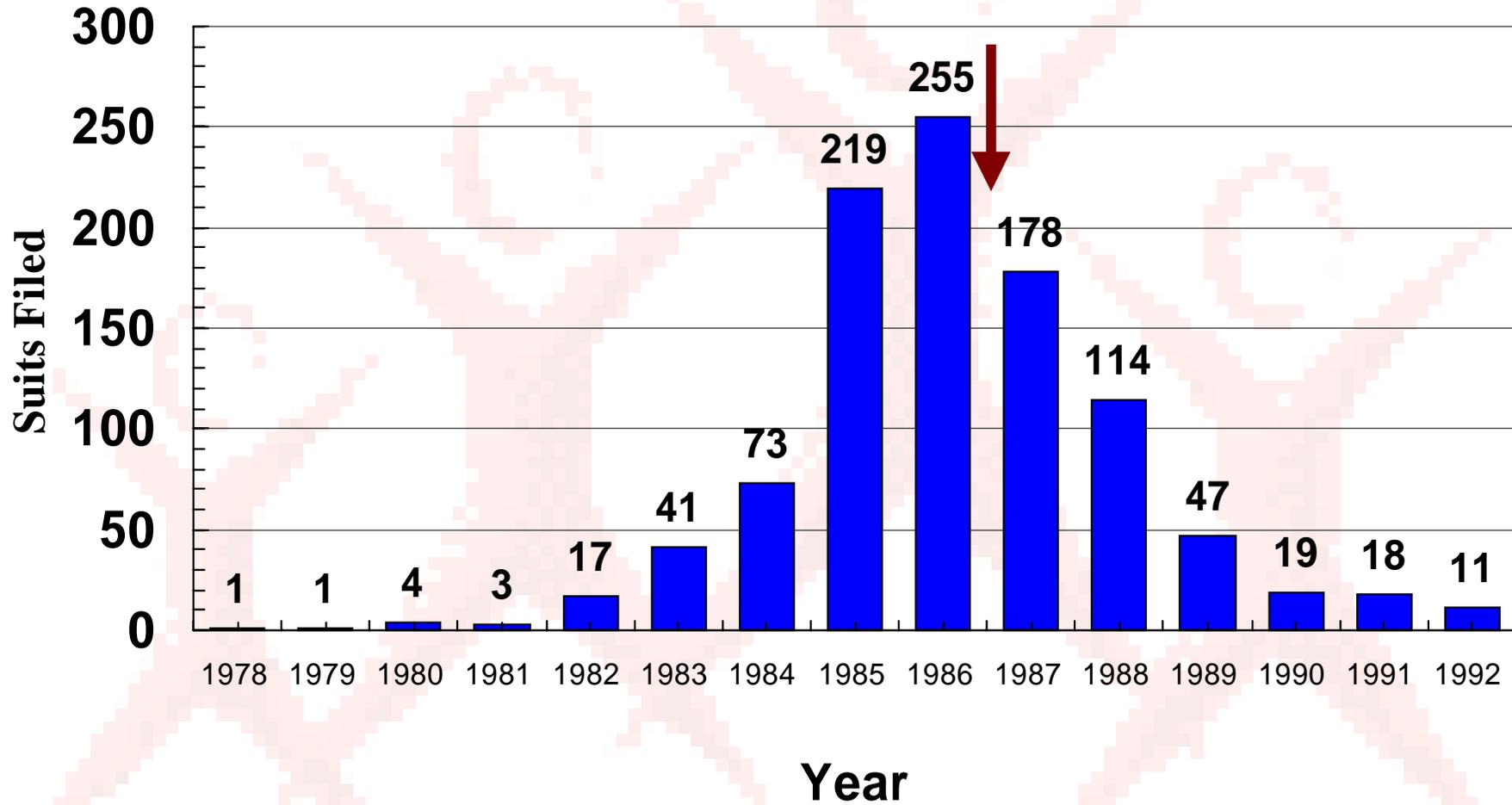


Vaccine injury compensation

Modern era of vaccine opposition: North America

- 1982- DPT: Vaccine Roulette
 - Emmy award winning documentary
 - Allegations of neurologic sequelae to DTwP
- Rebirth of "organized" vaccine activism
 - DPT: A Shot in the Dark
 - “Dissatisfied Parents Together”, later National Vaccine Information Center.
 - Vaccine litigation and fear of litigation by industry
- Outcomes largely positive
 - Creation of US vaccine injury compensation program
 - Vaccine safety studies and adverse event surveillance (VAERS)
 - Canada’s Vaccine Associated Adverse Events Surveillance system

DTP vaccine lawsuits



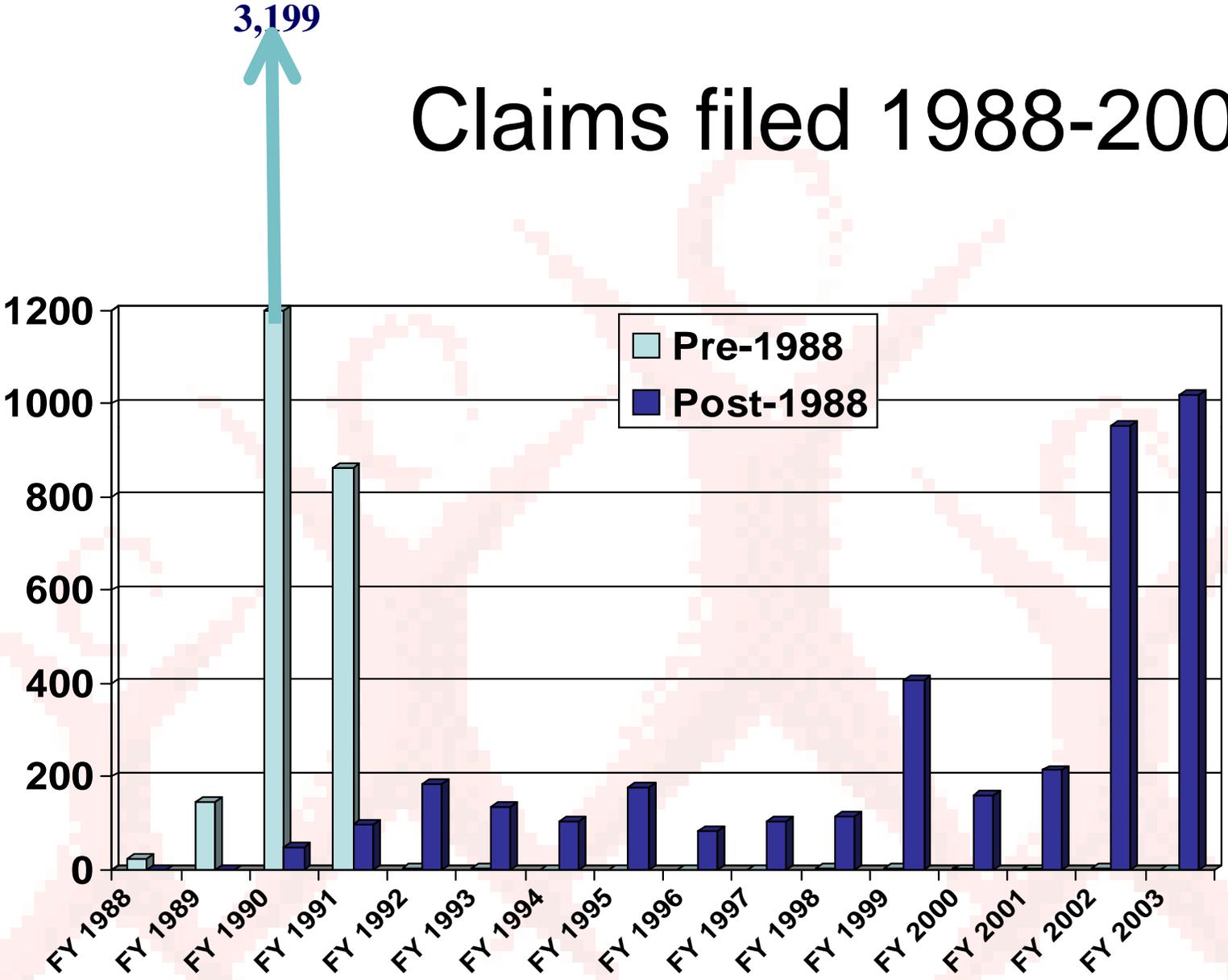
Source: CDC – Immunization Safety Branch

U.S. Vaccine Injury Compensation Program

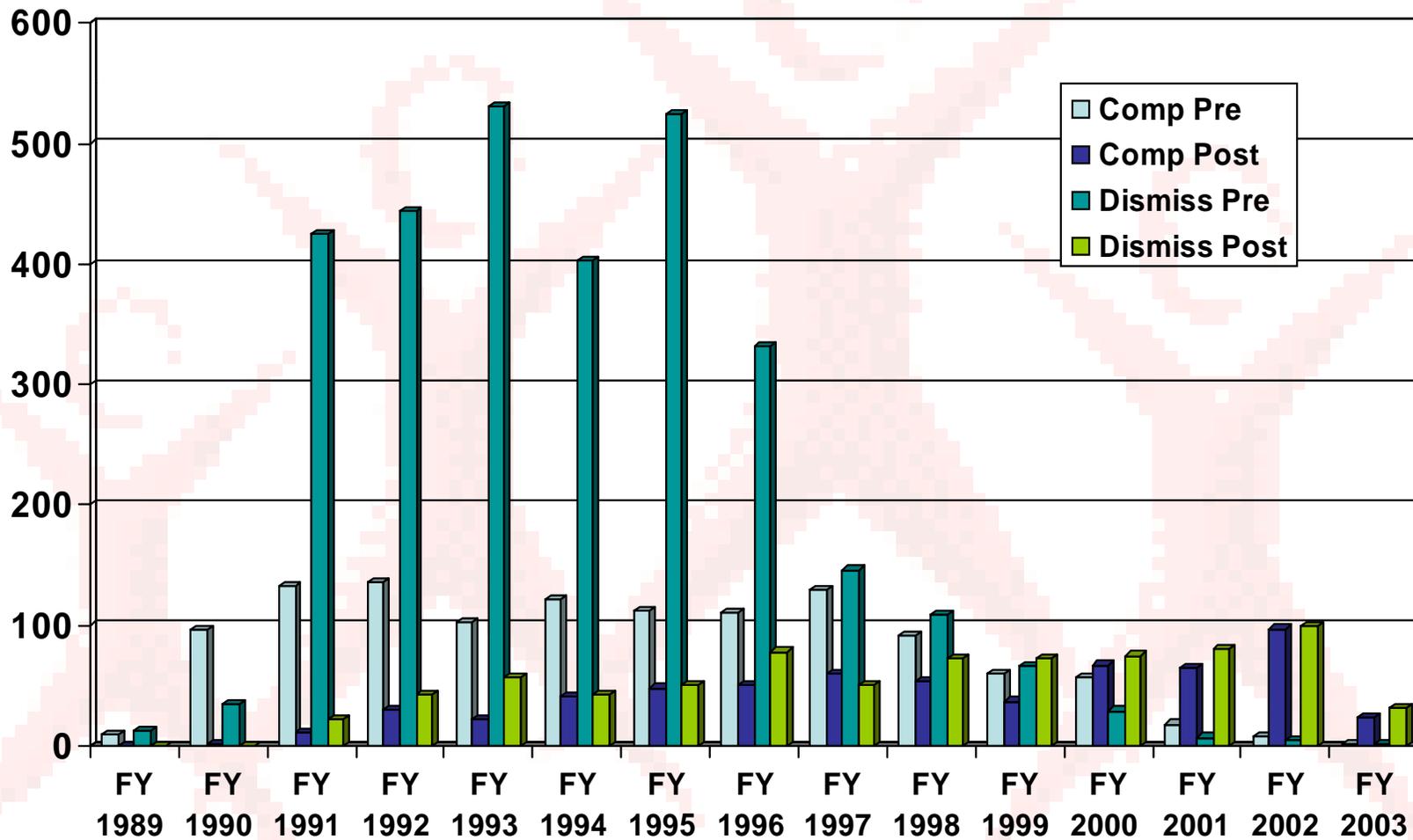
- Established under the National Childhood Vaccine Injury Act (1986)
 - No fault, less adversarial alternative to resolve injury claims
 - Designed by a coalition of parent groups, public health, industry, government
 - Stabilized the marketplace for vaccines
 - In effect October 1, 1988
- Administered by DHHS, DOJ and Court of Federal Claims – oversight by ACCV
- Covers all vaccines recommended for routine administration to children
 - By default, covers adult vaccines

- Qualifying for compensation
 - Showing that an injury listed on the Vaccine Injury Table occurred
 - Proving that a vaccine significantly aggravated a pre-existing condition.
 - Proving that the vaccine caused the condition
- Table is a “presumption of causation”
 - As long as injury not due to an alternate cause
- Injury must have lasted at least 6 months or resulted in hospitalization and surgical intervention
- Claim filing limits exist

Claims filed 1988-2003



Claims adjudicated 1988-2003



Hepatitis B Vaccine claims

- Table injury: Anaphylaxis and sequelae
 - No claims filed on this basis
- Several hundred claims for other injury (require proof of causation)
 - Grouped into ~10 categories
 - Demyelinating, Cardiac/Hematologic, Immunologic, Arthritis, etc...
 - Single cases: Death, Diabetes, CFS
- Most are on hold
- Arthritis and Neuro-demyelinating going forward

Quebec's compensation plan

- **1985: Viral encephalitis after measles vaccine with permanent sequelae**
- Lawsuit filed against the government,
 - Superior Court concluded there was a chain of causation
- Government / its employees / the manufacturer not at fault
 - Manufacture and production of vaccine adequate.
 - Informed consent of risk (1/1M) of encephalitis was obtained
- Moral pressure to get vaccinated = compulsory immunization
 - Not altered by consent to be vaccinated
 - Damage suffered for the good of society should be supported by society.
 - Government is liable
 - The courts suggested that an obligation to compensate independent of fault would be appropriate

- Quebec compensation program for victims of immunization was introduced in a new division of the *Public Health Protection Act*.
 - Administered by the Public Health Protection Branch of the Provincial Department of Health
 - Same organization that manages the Quebec Immunization Program
- Regulations governing the program were adopted in November 1987
 - The first applications for filed in 1988

Process

- A **claim must be made within three years** following date of immunization
- There is **no limitations on which vaccines are eligible** for compensation
- Application is studied by a **medical evaluation committee** (3 physicians):
- One each appointed by the Minister of Health, the claimant, and the first two.
- The committee's duties consist of:
 - **Evaluating the case** and the illness incurred ;
 - **Evaluate causation** between the illness and the immunization ;
 - **Evaluate compensation** based on the public auto insurance plan.
- The evaluation must deal with and consider the followings :
 - The clinical history, including a statement of relevant physical and mental ailments, intercurrent illness, medical history ;
 - A physical examination bearing particularly on the system affected by the immunization.

Results (1987-2000)

- A total of 117 claims were processed.
- 20 have been compensated (17%):
 - Oral polio vaccine : 13
 - Measles: 1
 - Rubella: 1
 - Hepatitis B: 1 (RSD without sequelae)
 - DTP: 1
 - Other (>1 vaccine): 2
- Other hepatitis B cases include chronic fatigue, not compensated.

Allegations, activism and lawsuits

Hepatitis B vaccine and MS

France / Manitoba

Vaccines and Autism

UK / US / Canada

The 1990's: storm after calm?

- Ongoing anti-vaccination activism
 - Freedom of choice in vaccination, perception of coercive public health authorities
 - Shift to ill-defined conditions, “chronic disease”, moving targets
- Mass immunization campaigns
 - Meningococcal vaccine was tolerated
 - Hepatitis B, yes and no
 - Measles: some questions
 - Provided a focus for opposition?
- Addition of vaccines to the schedule
 - Hepatitis B as adolescent program: school-based programs replacing traditional individual parent/child visit for vaccination?
 - Vaccines overload the immune system: not another shot!

France

Compte tenu de l'ensemble de ces éléments, il a été décidé de mettre en oeuvre les décisions suivantes :

- Une stratégie vaccinale mieux ciblée, selon des modalités plus propices à une bonne appréciation du risque individuel à l'égard de l'hépatite B comme de l'éventuel risque vaccinal ;

- pour les adultes : l'absence de notification d'atteinte démyélinisante du système nerveux central chez les enfants de moins de cinq ans et l'objectif d'améliorer la couverture vaccinale de la population conduisent à ne pas remettre en cause la vaccination recommandée chez les adultes ;

- pour les enfants et les adolescents : sans préjudice des actes de vaccination pour les individus, la vaccination contre l'hépatite B systématique en milieu scolaire au collège est suspendue. De nouvelles modalités de vaccination seront définies pour personnaliser l'acte vaccinal en prenant mieux en compte les bénéfices et les risques individuels ;

- pour les nourrissons : l'absence de notification d'atteinte démyélinisante du système nerveux central chez les enfants de moins de cinq ans et l'objectif d'améliorer la couverture vaccinale de la population conduisent à ne pas remettre en cause la vaccination recommandée chez les nourrissons.

Miscommunicated

W H O response (and VHPB !)

WHO Information

1998 Press Releases

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Press Release WHO/67
2 October 1998

NO SCIENTIFIC JUSTIFICATION TO SUSPEND HEPATITIS B IMMUNIZATION

On 1 October 1998, the French Ministry of Health announced a decision to suspend routine HB immunization of adolescents in French schools, while continuing the immunization of infants and high risk adults. This decision followed concerns, despite lack of scientific evidence establishing a causal relationship, that Hepatitis B immunization might be linked to the development or flare-up of demyelinating diseases such as multiple sclerosis (MS), and comes in the wake of enormous pressure from anti-vaccine groups.

WHO, with the assistance of external experts in neurology, epidemiology, immunology and public health, has carefully reviewed the scientific evidence on whether Hepatitis B vaccine can cause demyelinating diseases such as MS. WHO believes that available scientific data does not demonstrate a causal association between HB immunization and central nervous system diseases, including MS.

Argus de la presse

Copie journalière sans autorisation de C.F.C.

Hépatite B : le vaccin en procès

Pierre Morel

Francine Delgado a-t-elle contracté une sclérose en plaques après avoir été vaccinée contre l'hépatite B ? Telle est la délicate question à laquelle le tribunal de Paris devra répondre le 6 novembre. Première étape de la guerre judiciaire entre le mouvement antivaccin et les fabricants.

Le premier procès de l'hépatite B, qui s'est tenu en début de semaine à Paris, risque de s'avérer un redoutable casse-tête pour les médecins, mais aussi

pour la justice. La maladie s'était déclarée avant la vaccination, en 1989. Argument réfuté par les conseillers de Mme Delgado qui avait certes connu des problèmes de santé en 1989, mais à qui l'opinion

avait été prise sous le gouvernement Balladur, sur fond de guerre commerciale entre SmithKline Beecham et Pasteur Vaccins, de lancer une campagne d'urgence et de vacciner



Victime de la Direction est

Sclérose en plaques, accidents neurologiques divers, les chercheurs sont sur la piste des "effets indésirables" du vaccin contre l'hépatite B.

Après nos premières révélations, les soupçons sur les risques du vaccin s'accroissent

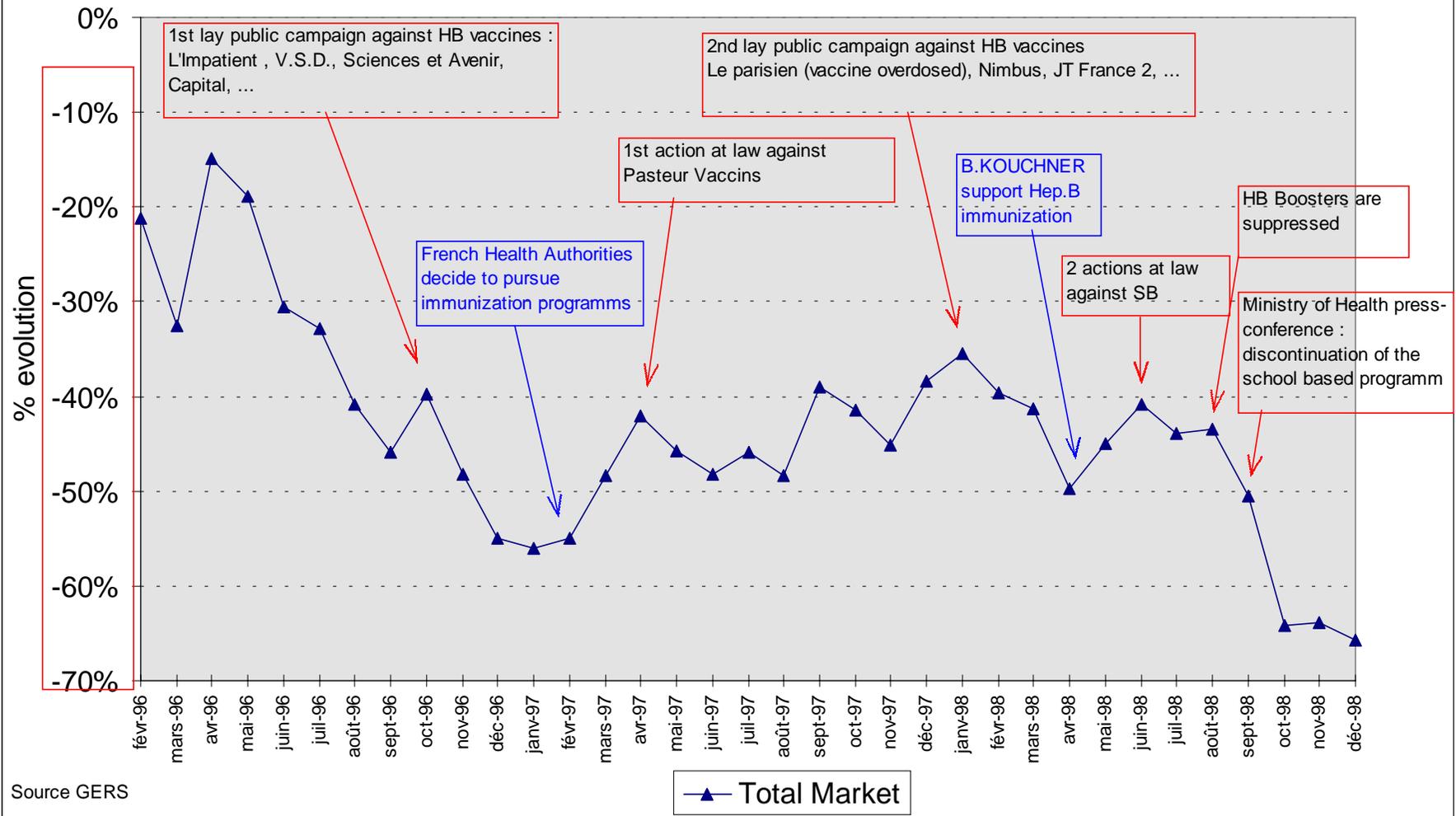
Notre article paru en novembre dernier a suscité un courrier...

Hépatite B : l'enquête sur un vaccin très controversé

Le vaccin contre l'hépatite B peut-il avoir des conséquences dangereuses ? Certains médecins l'affirment, en dépit des assurances des laboratoires pharmaceutiques

HEPATITIS B VACCINES - PRIVATE MARKET

Evolution of monthly sales growth rate : 96 vs 95, 97 vs 96, 98vs97



Source – Dr. Benoit Soubeyrand

Manitoba

- Hepatitis B vaccine in provincial immunization schedules
 - 1992: British Columbia (urging of a parent)
 - 1994-1995: other provinces/territories except Manitoba
- Schedules
 - Grade 3x1, 4x6, 5x1, 6x2, 7x1 + (infantx3)
- Coverage
 - 85%-90%+

Very bad timing...

- Manitoba's hepatitis B immunization program to start November, 1998
- France suspends school immunization October 1, 1998
- Vaccine opposition in Manitoba
 - Parent association + Chiropractor group
- Consent forms had already been sent in

Winnipeg, November 7, 1998

Parents fight needles

Judge asked to halt hep B vaccination of province's Grade 4 students

By Leah Janzen
Staff Reporter

PARENTS CONCERNED about the safety of the hepatitis B vaccination are asking a judge to shut down a voluntary program to

lic health for Manitoba, said the vaccinations will go ahead on Monday despite a court proceeding on Tuesday at which Justice Marc Monnin will decide whether to halt the mass inoculations.

"I'm sure some shots will be given

"They are asking for an injunction on a voluntary program. For us to wait until after the hearing would be to deny access to an opportunity many parents wish to take advantage of. That would be improper."

improper for the province to proceed with the program in view of the court action.

"For them to go ahead before this can be heard represents bad faith," she said yesterday after filing the



Young students join their parents yesterday in a protest outside the Law Courts Building to demand the hepatitis B vaccination program be stopped.

Tuesday, November 10, 1998

Judge won't halt shots

Rules that stopping 'voluntary program' isn't fair to pro-vaccine majority

By Leah Janzen
Staff Reporter

AJUDGE ruled last night against a group of parents who had asked the court to stop a voluntary program immunizing children against hepatitis B.

Bench ruled.

"It is a voluntary program and parents who are concerned can seek out more information, as have the plaintiffs."

Monnin said halting the program — which will target up to 18,000 Grade 4 students across the province — would cause more headaches to the provin-

ents filed a motion to halt the program after a similar mass immunization was suspended in France last month amid concerns that the vaccination may be connected to auto-immune disorders like multiple sclerosis, lupus and diabetes.

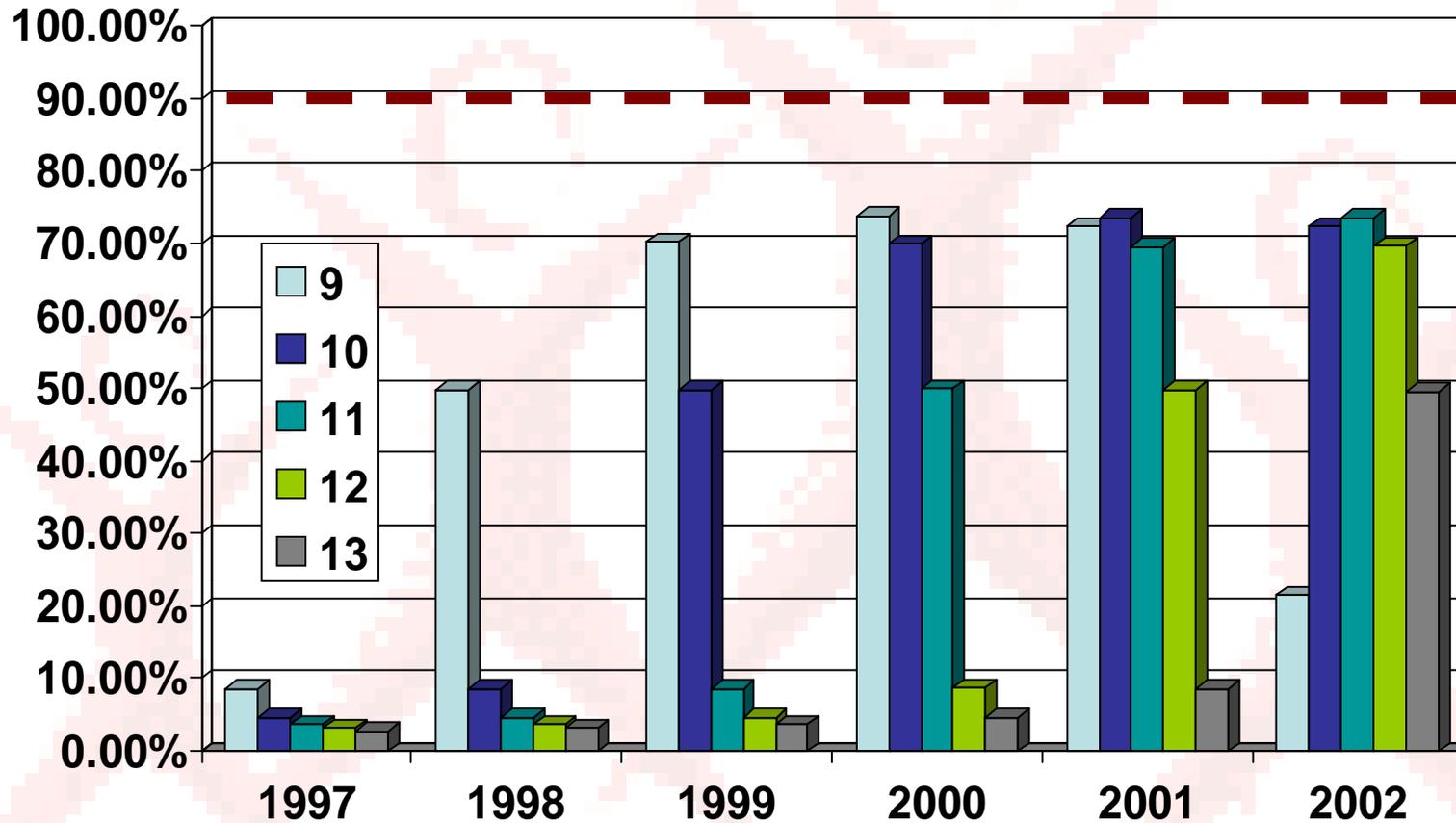
By the time the case made its way

cent of the 741 eligible students.

Cynthia Devine, lawyer for the parents, had argued the program should be temporarily put on hold because the information parents received with their consent forms was one-sided and didn't include enough information about the possible side-effects.

~15% of parents reversed consent

Hepatitis B vaccine coverage Manitoba, 1997-2002 (Sep1-Aug31)



Source: MIMS registry data, Dr. Digby Horne

UK

THE SUNDAY POST JANUARY 4TH 1998

Vaccine victims' parents set to sue

A SCOTTISH dad who claims his daughter contracted an incurable disease after a routine jab is one of a growing band of parents planning to take legal action for compensation. At least a dozen Scots parents - and more than 1200 others across the UK have sent details of ailments experienced by their children after the vaccination for measles, mumps and rubella (MMR) to a firm of solicitors which is collecting evidence for a court hearing. David Symington, of North Queensferry, had his daughter Rebecca (14) vaccinated for MMR following Government advice in 1994.

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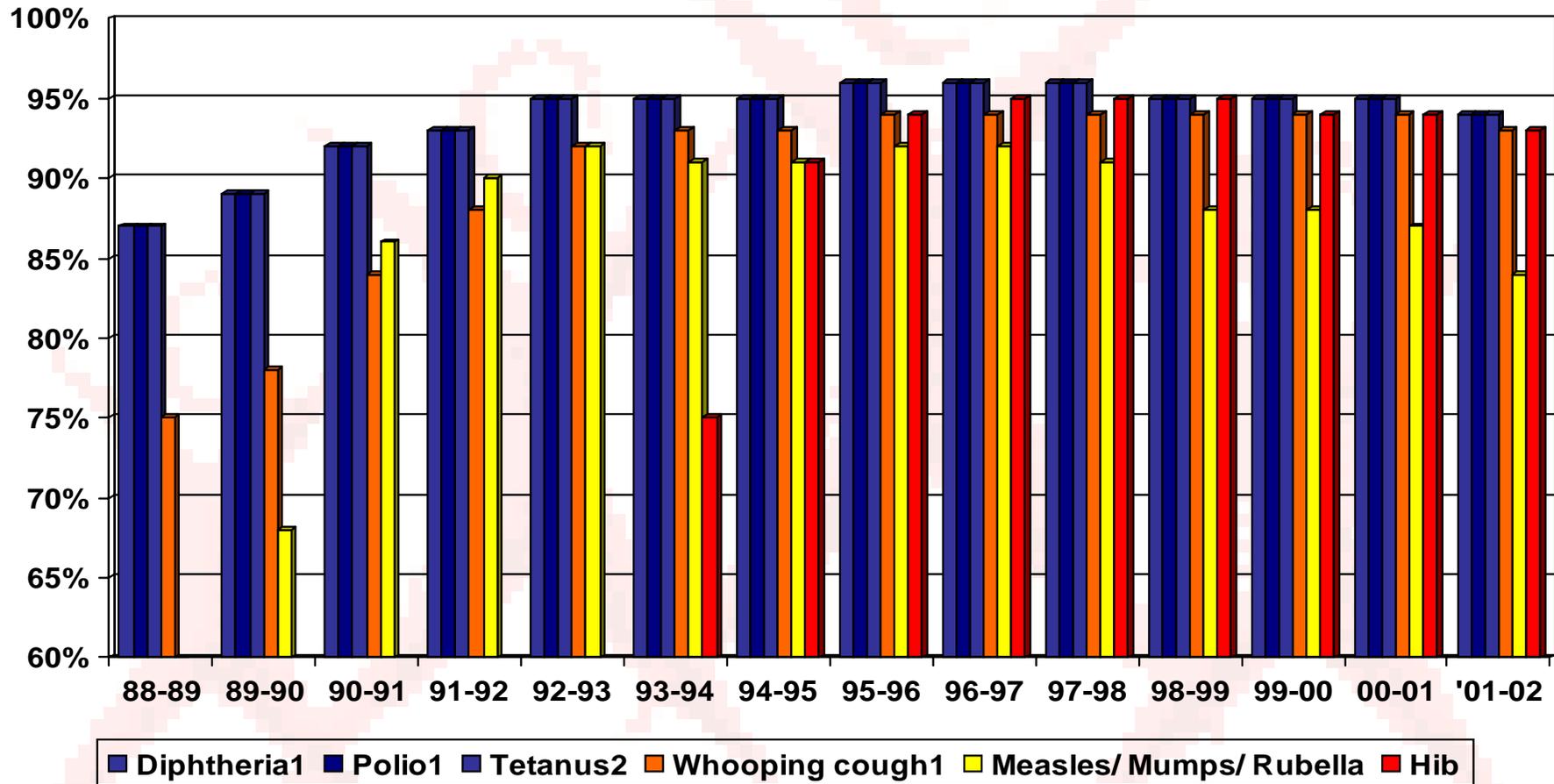
MMR Cases News

Please click items below.

MMR Latest News	
October 2001	Newsletter
February 2001	Newsletter
February 2002	Newsletter
October 2002	Newsletter
October 2002	Judgement of Mr Justice Keith of 24th October 2002
November 2002	MMR: Manufacturers product information leaflet

[Mumps, Measles and Rubella \(MMR\) Vaccines and Measles Rubella \(MR\) Vaccines Factsheet](#)
[MMR & MR Vaccines Factsheet](#)

Vaccination coverage by 24mo, England and Wales 1988-89 to 2001-02



Source: PHLS web site

More measles cases confirmed



Health officials recommend the MMR jab

Another eight children have been confirmed as having the measles virus in a south London outbreak.

Measles cases soar

This means a total of 18 cases in Lambeth have now tested positive.

A further 18 children in a separate investigation and investigation are also negative.

There have also been 18 cases in the north east of England.

The results come from a "media hysteria" campaign against the triple vaccine - a

The number of confirmed cases of measles in England and Wales rose significantly last year.

Provisional figures seen by the BBC indicate there were 310 cases, the highest number seen since the triple measles, mumps and rubella vaccine was introduced in 1988.

It is around three times the number of cases seen in previous years.

Experts say it is a "significant rise" in cases, despite the relatively small numbers.

First measles case for seven years

The illness of a six-month old baby has been confirmed as the first case of measles in Hull for seven years.

Health officials are now expressing concern over the low uptake of the MMR vaccine, which protects children against mumps, measles and rubella.



Doctors are urging parents to get their child the MMR jab

Successful it requires an uptake of

was discovered, 82% of children

as a whole the uptake is 86%.

about links with the MMR jab



MMR vaccination rates have fallen

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Hepatitis B Vaccine

Studies show that an estimated 1.25 million people in the United States carry the hepatitis B virus. It is also estimated that an additional 200,000 Americans are infected with hepatitis B each year. 11,000 of those people are hospitalized and 20,000 remain chronically infected. In addition, between 4,000 and 5,000 hepatitis B sufferers die each year due to hepatitis B-related chronic liver disease or liver cancer.

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A person may become infected if other bodily fluids infect more at risk to contract hepatitis B.

The hepatitis B vaccine has been effective in preventing hepatitis B. However, some studies suggest a link between the hepatitis B vaccine and serious neurological diseases or chronic illnesses, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, or optic neuritis.

See your doctor if you are concerned about the safety of the hepatitis B vaccine. In addition, it may be important to contact an attorney who can help you protect your legal rights. Please keep in mind that there may be time limits within which you must commence suit.

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United States

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See your doctor if you are concerned about the safety of the hepatitis B vaccine. In addition, it may be important to contact an attorney who can help you protect your legal rights. Please keep in mind that there may be time limits within which you must commence suit.

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Have you been *injured by a thimerosal vaccine?*

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On April 3, 2002 a class action lawsuit was filed in the United States District Court for the Eastern District of New York on behalf of three groups against the manufacturer of Thimerosal, a preservative containing mercury, and against the vaccine manufacturers that use or used Thimerosal in the manufacture and/or distribution of childhood vaccines.

Thimerosal is a preservative that was used in childhood vaccines that is approximately 50 percent mercury by weight. Mercury is one of the most toxic elements on earth and its exposure by humans has been linked to neurological, motor, sensory and autoimmune disorders, as well as behavioral dysfunction. Before the FDA recommended that



Special provisions in the Homeland Security Act

- A protective order sealing all information produced by the Department of Health and Human Services (HHS) in the Omnibus Autism Proceeding before the U.S. Court of Federal Claims Office of Special Masters, or “vaccine court.”
 - Claims involving thimerosal not bypass the compensation plan.
 - Pending and future civil suits transferred to the vaccine court.
- Scope of the protective order: all oral, e-mails, transcripts, graphic matter or other written or electronically stored information provided by HHS, *either in the past or in the future*, in connection with the Omnibus Autism Proceeding.
- Covers information that may otherwise be subject to release pursuant to the Freedom of Information Act (FOIA).
- Limit access to government information, to the lawyers and experts in the case
- HHS “will not voluntarily produce discovery material” unless the protective order is entered.



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Vaccines News

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Canada

February 25, 2003	Class Action Lawsuits Filed in British Columbia Against Merck Frosst Canada and Glaxosmithkline and Aventis Pasteur for Injuries Caused by Thimerosal ...read the details
November 10, 2002	The Not-So-Crackpot Autism Theory By ARTHUR ALLEN ...read the details
October 7, 2002	Mcleans Article - TO VACCINATE OR NOT - Has a mercury-based preservative caused autism? ...read the details (pdf 445 KB)
October 7, 2002	Gregory Article - Lawyer files class action lawsuit saying vaccinations harmed kids ...read the details (pdf 336 KB)



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Attention News Editors:

Class-action suit seeks justice for thousands of children left autistic by mercury-laced vaccines

TORONTO, May 9 /CNW/ - A class action lawsuit was filed in Ontario Superior Court yesterday on behalf of children who developed autism after receiving vaccines preserved with thimerosal, a mercury derivative.

Vancouver law firm Klein Lyons filed a Statement of Claim seeking damages from Aventis Pasteur, a pharmaceutical manufacturer whose widely used DPT (Diphtheria/Pertussis/Tuberculosis) vaccine contained thimerosal until 1994. Thimerosal is a compound of 50% mercury, a highly toxic metal known to cause severe neurological and behavioural damage. Infants are particularly vulnerable to mercury poisoning due to their incomplete brain development.

Canadian victims represented in the Klein Lyons suit include nine-year-old Kean East, who began life as a healthy, happy, alert and developmentally normal infant. Soon after receiving a series of three DPT vaccines containing thimerosal, he became withdrawn and unresponsive, failing to develop normal language, social, and motor skills. He has since been diagnosed with autism.

Although the medical and pharmaceutical communities knew of mercury's dangers for almost a century, they did not advocate removal of thimerosal from pediatric vaccines until the late 1990s. In July 1999, the American Academy of Pediatrics issued a statement calling for thimerosal-free vaccines. That same year, a U.S. Food and Drug Administration report noted that infants injected

NEEDLE TIPS

Volume 1 - Number 1

September - December 1994

Hospitals & Doctors Sued for Failing to Immunize

Three lawsuits against physicians and hospitals who failed to immunize came to the attention of the Coalition in the December 27, 1993, issue of CDC's Immunization Action News. Since the publication of that article, the Coalition has sought further information about these cases. To date, four additional lawsuits were discovered and descriptions of all seven cases follow.

- **Case #1: Hepatitis B** - In 1989 on the West Coast, a woman was identified as a hepatitis B carrier during her prenatal care. However, this information was not transmitted to the newborn nursery at the time of delivery. Her baby received neither HBIG nor hepatitis B vaccine and the infant subsequently became a chronic carrier. The mother sued the hospital, the obstetrician, and the pediatrician. A substantial settlement was awarded.

- **Case #2: Hepatitis B** - In a large Midwestern city in approximately 1988, a woman was screened in pregnancy and was found to be HBsAg positive. Her baby was born and appropriately immunized both with HBIG and hepatitis B vaccine. The baby returned for well child care with a nurse practitioner who was at the hospital-based clinic. The parents asked if the baby needed a second dose of hepatitis B vaccine. The provider reviewed the birth record and told the parents that the vaccine was not necessary and did not give the follow-up dose. The nurse practitioner did not understand the indications for hepatitis B vaccine. At 12 months of age, the child was found to have chronic persistent hepatitis B by the hospital's follow-up clinic that tracks the infants born to HBsAg positive mothers. The hospital was sued and the case was settled out of court.

- **Case #3: Measles** - A 25-year-old woman who worked in a private clinic as a nurse's aide in California contracted measles and died in February of 1988. The clinic in which she worked had seen patients with measles and this was her only known exposure. This woman had received one dose of MMR as a child. In late 1989, the ACP recommended a second dose of measles vaccine for new employees in medical facilities, since they are at higher risk for measles than the general population. The ACP also recommended "catch-up" programs for employees already working at these sites when resources were available. This nurse's aide never received a second dose of measles vaccine. The

family has sued the physician's practice. The case is pending.

- **Case #4: TB meningitis** - In 1991, a California infant developed TB meningitis and the family has sued the private clinic for failure to immunize. The case occurred in early 1991, shortly after the new TB vaccine became available (November 1990) and shortly after the ACP approved TB vaccine for infants at 2 months of age. The clinic had provided some doses of both DTP and polio vaccines to the infant. The mother asked for TB vaccine for her infant in January 1991 but was told that it was only recommended for children 15 months and older. She returned in March of 1991 with her infant and was again told that the vaccine was not indicated. (The provider was not aware of the new recommendation.) In spring 1991, the infant developed TB meningitis. The child remains developmentally delayed three years later. The case is pending.

- **Case #5: Invasive TB disease** - The information on this case is sketchy. At the time of this occurrence, the child was between ages of 2 and 5 and eligible to receive TB vaccine. The case occurred between 1985 and 1990 at some point after TB vaccine became recommended for children at 15 months of age. The child required hospitalization and today has some residual effects of the disease. This West Coast family has sued their child's physician for failing to provide the vaccine.

- **Cases #6 and #7: Hepatitis B** - Both of these cases occurred at a large teaching hospital affiliated with a medical school in a state where a law exists mandating prenatal hepatitis B screening. In this hospital, mothers were not routinely screened at delivery, but the neonatologist tested every infant for HBsAg as part of a panel of tests that were routinely done on cord blood. If this test was negative, no hepatitis B vaccination was given. If the test was positive, sometimes vaccine and HBIG were given and sometimes they were not. ("too late - baby already infected.") Both of the infants at the centers of these lawsuits were born in 1991 when this policy was in effect.

In one case, the mother had been tested during her pregnancy but the test results were not communicated to her or to the hospital. The infant's cord blood test was negative. In a subsequent pregnancy she was discovered to be

HBsAg positive and was referred to the prenatal program. Her other children tested as a part of this program and the child was discovered to be a carrier.

In the other case, the mother had not tested during the pregnancy. The cord blood test was positive for HBsAg. Her report was received after the discharge of infant and the report was filed without act.

In both cases, the infants were not in for prenatal exposure because the hospital relying on cord blood testing to determine need for hepatitis B prophylaxis. The law policy has since been changed and all are screened on admission to labor and delivery. Lawsuits are pending in both cases.

By contrast, according to Dr. S. Ma Marcy, president of the Los Angeles Ped Society, there have been no recent immunization-related lawsuits against physicians giving required vaccines and following standard practices since 1977.

CDC has published the *Standards for Accreditation of Immunization Practices* which is cited by the National Vaccine Advisory Council, the American Academy of Family Physicians and the American Academy of Pediatrics. For copy, call CDC's Immunization Hotk 800/232-2522.

Do you know of additional situations similar to the cases described above? If so, please contact the Immunization Action Coalition.

Hospitals & Doctors Sued for Failing to Protect Newborns from Hepatitis B Virus Transmission

Case #1

In 1989 on the West Coast, a woman was identified as a hepatitis B carrier during her prenatal care. However, this information was not transmitted to the newborn nursery at the time of delivery. Her baby received neither hepatitis B immune globulin (HBIG) nor hepatitis B vaccine and the infant subsequently became a chronic carrier. The mother sued the hospital, the obstetrician, and the pediatrician. A substantial settlement was awarded.

Case #2

In a large Midwestern city in approximately 1988, a woman was screened in pregnancy and was found to be hepatitis B surface antigen (HBsAg) positive. Her baby was born and appropriately immunized at birth with HBIG and hepatitis B vaccine. The baby returned for well child care with a nurse practitioner who was at the hospital-based clinic. The parents asked if the baby needed a second dose of hepatitis B vaccine. The provider reviewed the birth record and told the parents that the vaccine was not necessary and did not give the follow-up dose. The nurse practitioner did not understand the indications for hepatitis B vaccine. At 12 months of age, the child was found to have chronic persistent hepatitis B by the hospital's follow-up clinic that tracks the infants born to HBsAg positive mothers. The hospital was sued and the case was settled out of court.

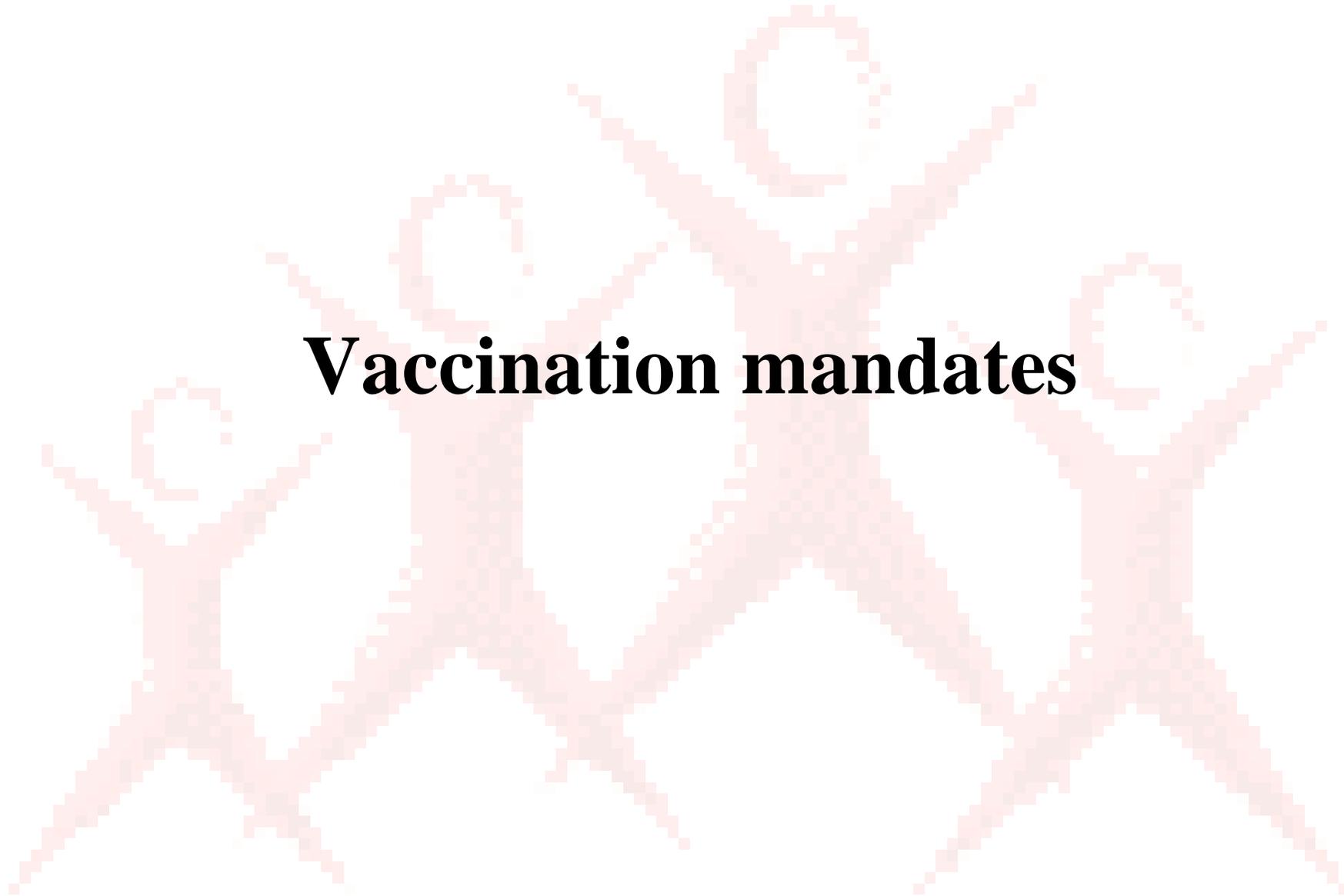
Cases #3 and #4

These cases occurred at a large teaching hospital affiliated with a medical school in a state where a law exists mandating prenatal hepatitis B screening. In this hospital, mothers were not routinely screened at delivery, but the neonatologist tested every infant for HBsAg as part of a panel of tests that were routinely done on cord blood. If this test was negative, no hepatitis B vaccination was given. If the test was positive, sometimes vaccine and HBIG were given and sometimes they were not ("too late—baby already infected"). Both of the infants at the centers of these lawsuits were born in 1991 when this policy was in

effect. In one case, the mother had been tested during her pregnancy but the test results were not communicated to her or to the hospital. The infant's cord blood test was negative. In a subsequent pregnancy she was discovered to be HBsAg positive and was referred to the state's perinatal program. Her other children were tested as a part of this program and the one child was discovered to be a carrier. In the other case, the mother had not been tested during the pregnancy. The cord blood of this infant was positive for HBsAg, but the report was received after the discharge of the infant and the report was filed without action. In both cases, the infants were not treated for perinatal exposure because the hospital was relying on cord blood testing to determine the need for hepatitis B prophylaxis. The hospital policy has since been changed and all mothers are screened on admission to labor and delivery. Lawsuits are pending in both cases [1994].

Case #5

On December 13, 1990, a previously healthy 3-month-old infant of Southeast Asian descent was brought to a hospital emergency department and was admitted following a 5-day history of fever, diarrhea, and jaundice. Upon admission to the hospital, hepatitis B serology was obtained along with liver function tests and liver enzymes. Laboratory results revealed that the infant was HBsAg positive and IgM core antibody (IgM anti-HBc) positive. The infant's mother was tested at the same time and was found to be HBsAg positive and anti-HBc positive. A diagnosis of hepatic failure due to hepatitis B virus infection was made; sadly, the infant died on December 17 of fulminant hepatitis B. Investigation revealed that the infant's mother had tested positive for HBsAg during her pregnancy but that the test result was communicated incorrectly as "hepatitis negative" to the hospital where the baby was born. Neither the laboratory nor the prenatal care provider reported the HBsAg-positive test results to the local health department as required by state law. The infant received no hepatitis B vaccine and no HBIG at the time of birth. There has been no litigation to date, but the physician lost his license to practice medicine.



Vaccination mandates

- US model
 - Medical, Religious, Philosophical exemptions vary by state
 - Antigens covered vary by state, includes pertussis.
 - Hepatitis B, Varicella, being added.
- Canadian model
 - In place in 3 provinces
 - Full exemptions
 - Antigens covered vary by province (D, T, Polio, M)
 - To date no new vaccines added to requirements

Incidence of measles^a in states with and without school entry laws
1973–74^b

	Laws	No laws	% difference
1973	26.5	53.9	–51%
1974	33.1	55.4	–40%

^a Per 100,000 < 18 yr.

^b MMWR 1977; 26: 109–11.

Measles in 6 states strictly enforcing school laws vs other states^a

	Measles incidence ^b		
	1975–76	1977	1978 ^c
6 states	47.0	40.6	2.7
Other states	50.4	90.3	35.2

^a MMWR 1978; 27: 303–4.

^b Per 100,000 < 18 yr.

^c 1st 31 weeks.

The immunization system in the United States — the role of
school immunization laws

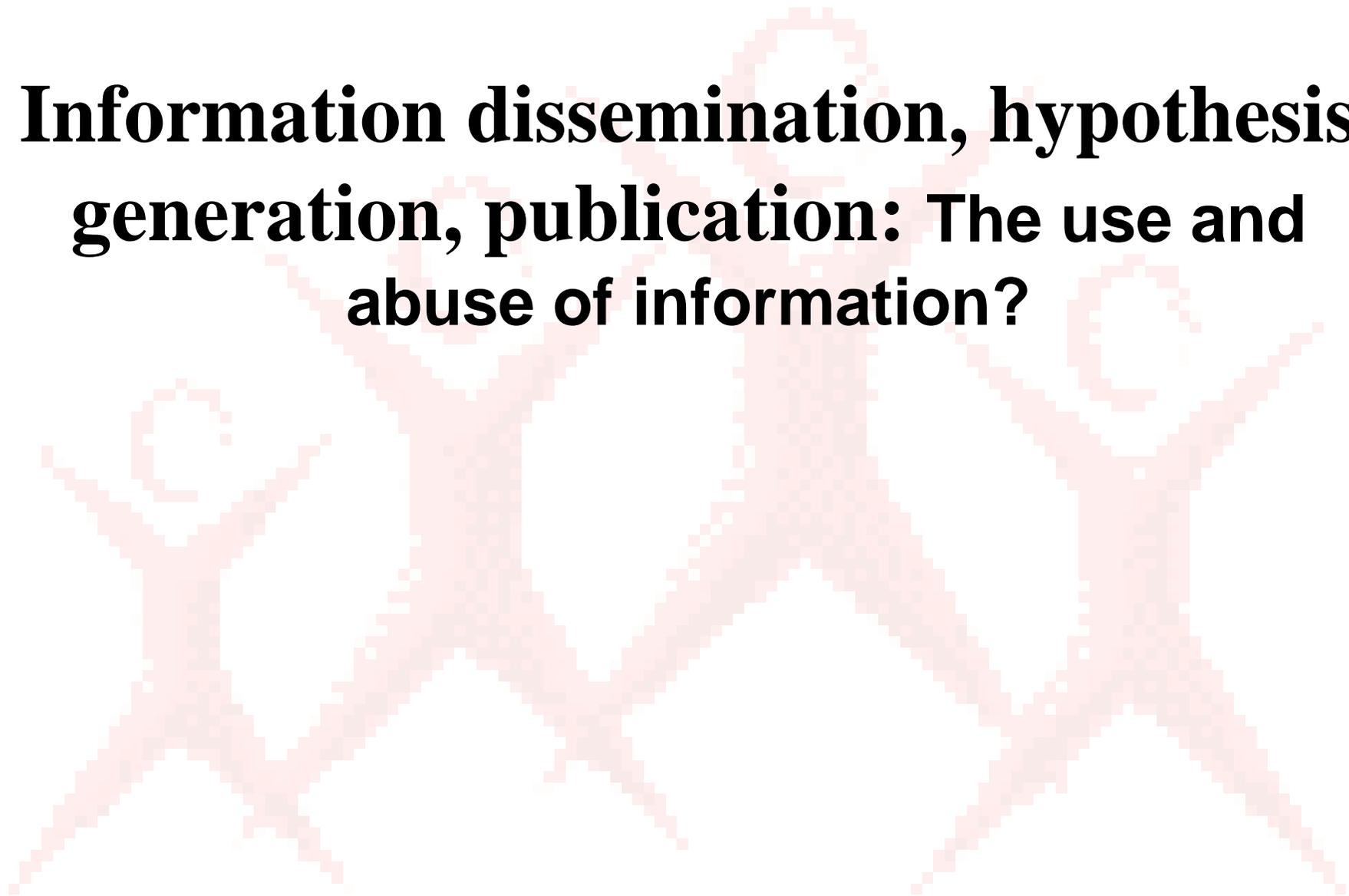
Vaccine 17 (1999) S19–S24

Walter A. Orenstein^{a,*}, Alan R. Hinman^b

Critical factors

- Positive
 - Ensures vaccination of children entering school and/or daycare
 - Even with full exemptions – ensure that someone is checking
- Negative
 - Perception of coercion: provides a rallying point for opposition
 - Misrepresentation in Canada: Forced vaccination
- Model state exemption – new concept
 - Written request by parent explaining why
 - Counseling session related to decision
 - Annually renewed
 - Final decision rests with medical health officer (can be refused if coverage rates threaten resurgence of disease)

**Information dissemination, hypothesis
generation, publication: The use and
abuse of information?**



Selective presentation: Japan and SIDS

- “When Japan moved its pertussis immunization program to age 2, the incidence of SIDS dropped”
- Did vaccines really cause SIDS?
 - Not the whole truth...

Failure in fact checking...

- "600 patients atteints d'effets secondaires graves, juste à l'Hotel Dieu de Montreal!..."

➔ L'Hotel Dieu de Montreal soigne à lui seul plus de 600 patients atteints d'effets secondaires graves à la suite d'une vaccination contre l'hépatite B.

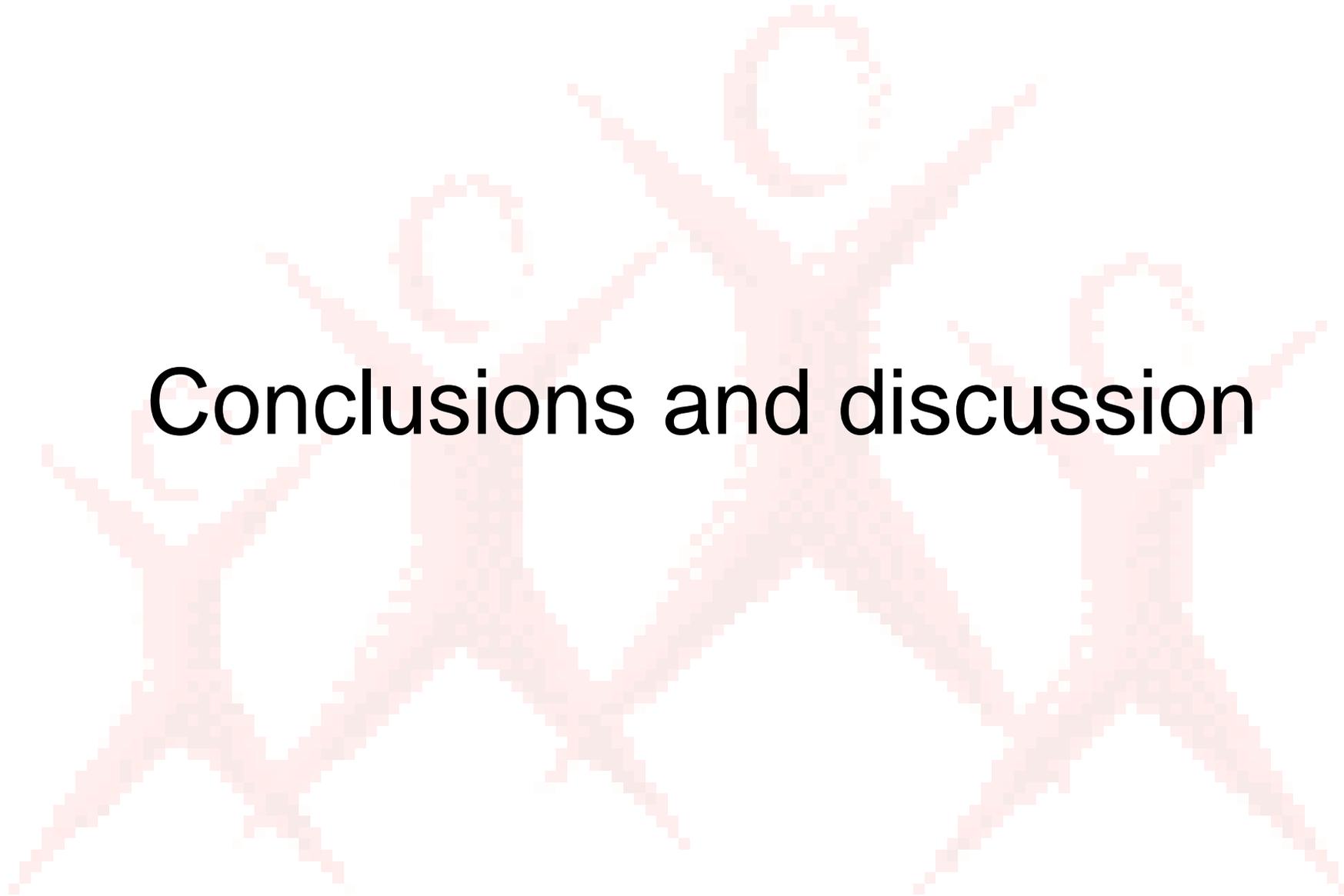
The correction

- "Hepatite B : moins d'effets secondaires qu'annoncés"

- 600 consultations, 80 with history of HepB vaccination and adverse events, 2 serious.

Examples of misinterpretations of VAERS data in the published literature

- All suspected adverse events are reported to VAERS as mandated by law
- The VAERS database is a reliable source of information concerning the potential ability of a vaccine to cause an adverse reaction.
- All serious reactions to VAERS require telephonic and written confirmation by the CDC.
- The Biologics Surveillance Summaries provide estimates of vaccine doses administered for the calculation of incidence rates of adverse reactions.
- Any limitations of VAERS data apply equally to all vaccines and therefore the incidence rate of a specific adverse reaction to one vaccine would be expected to be similar to the incidence rate following another vaccine administered to a similarly aged population.
 - The use of a “control” vaccine provides an estimate of the background rate of the adverse event under consideration
- The incidence of the adverse event for the vaccine under study, divided by the incidence rate of the same adverse event following the control vaccine, provides the relative risk (RR) of the adverse reaction compared to the control vaccine.



Conclusions and discussion

Compensation

- Provide a safety net for vaccination
- Must be evidence-based, otherwise
 - Conclusions misrepresented
 - Inherently unfair (?lucky vaccination)...
- Can they be used as an educational tool regarding real vs. false safety issues?

Lawsuits

- Regression back to the 1980's
- Visible blow to confidence in vaccination
 - Outcome may not be related to causality
- Current thimerosal-related cases are a real threat to vaccine supply...
- IF rational verdicts and outcomes, provides an educational opportunity
 - Missed in Manitoba

Mandates

- Vocal minority perceive them as coercive
- May create anti-vaccine activists from those who otherwise would vaccinate...
- Movement towards allowing full philosophic exemptions
- Must be as difficult to get exemption as vaccination
- Provides an opportunity to check immunization status
- Opportunity to educate about the importance of vaccination

Information and publication

- Misconceptions about vaccination still persist despite efforts to educate
- Peer review process can be incredibly poor
- Conflicts of interest arise from both sides, only “our side” has to avoid it
- Activists not sued for failure to vaccinate, but health care providers are...
- Missing potentially strong opportunities to demonstrate that the “emperor has no clothes”

Anti Anti-Vaccination Anyone?

- Evidenced-based compensation
- If vaccine mandates in place, allow exemptions (properly managed)
- More aggressive countering of misconceptions
- More diligence in responding to bad science
 - Letters to the editor or “Review articles” in prominent journals