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# LEGAL SERVICES

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## MEMORANDUM

March 24, 1997

**SUBJECT:** Sectional Summary of SB 81. (Immunization records)

**TO:** Senator Lyda Green  
Attn: Shelton

**FROM:** Terri Lauterbach  
Legislative Counsel



You have requested a sectional summary of the above-described bill.

As a preliminary matter, please note that a sectional summary of a bill should not be considered an authoritative interpretation of the bill and the bill itself is the best statement of its contents. Since you have not asked any specific legal questions about the bill, this summary is brief. If you would like an interpretation of the bill as it may apply to a particular set of circumstances, let me know.

**Section 1.** Provides an exception to the confidentiality provision relating to medical review organizations so that the infant mortality review committee can disclose children's immunization records under the circumstances specified in sec. 2 of the bill.

**Section 2.** Requires immunization records to accompany the death certificate for a child who dies when under the age of seven. Specifies who should supply the information.

**Section 3.** Applicability section.

TML:glc  
97-208.glc

**BRIEFING PAPER:**  
**COLLECTION OF IMMUNIZATION RECORDS OF CHILDREN WHO HAVE DIED**  
**February 25, 1997**

Proposed legislation would establish new requirements for collection of immunization records on all children under the age of seven who die. The data required to be collected include all vaccines received by the child; the date(s), name, and type of each vaccine received; and the lot number, batch number, and manufacturer for each vaccine administered. The data are to be obtained by the funeral director and attached to the death certificate.

This legislation will require a considerable amount of new paperwork to collect information that will be difficult, if not impossible, to use in a meaningful way. Because almost all children are vaccinated, almost all children under the age of seven who die (approximately 150 children per year) will be covered.

The parents of a recently deceased child are under considerable stress, and many will not have readily available a copy of their child's immunization record. They may face considerable difficulty in trying to obtain the required information because much of the data (e.g., vaccine lot number and batch number) is not routinely recorded on the child's personal vaccination record.

In recent years, the recommended childhood immunization schedule has become increasingly complicated. By the time a child reaches the age of seven, he/she should have received at least 20 injections, and many will have received even more. Given the high degree of mobility of Alaska's citizens, particularly in those parts of the state with large proportions of military or fishing industry-related populations, the likelihood that a child will have received all of his/her immunizations in one location is small. Many vaccines will have been administered by different providers in different locations in Alaska, in other states, and even in foreign countries. Therefore, funeral directors will be faced with trying to determine both where a child's immunizations were received and how to obtain the required information from many different sources. Even if all of this information is known, a funeral director may not be in a position to obtain the information; a health record may not be available, or the facility may require the parent's written consent to release the immunization history. In spite of these difficulties, a death certificate must be filed within three days; it is hard to see how this information could be obtained in a timely fashion.

Finally, the data collected would not contribute to valid scientific research or understanding of vaccine-related side effects:

- Unfortunately, infants die for many reasons unrelated to vaccination, such as infectious diseases, congenital defects and metabolic disorders. Chance alone dictates that infant deaths will occur from these, and for other reasons, after vaccination. Almost all infants are vaccinated during the first year of life. Therefore, **any infant with a medical illness or who dies is likely to have been vaccinated earlier in life.** Since vaccinations are usually administered at ages 2, 4, and 6 months, a statistically measurable chance of any event, death or otherwise, can occur within 24 hours of vaccination by coincidence alone.
- The vast majority of vaccine adverse events are minor and temporary, like a sore arm or mild fever. More serious adverse events occur rarely; some are so rare that risk cannot be accurately assessed. As to vaccines causing death, there are **so few deaths that could plausibly be attributed to vaccines that it is hard to assess the risk statistically.**
- The concept that DTP causes Sudden Infant Death Syndrome (SIDS) is a myth which developed because a moderate proportion of SIDS deaths occur in children who have recently been vaccinated with DTP; on the surface, this seems to point toward a causal connection. But this logic is faulty; **one might as well say that eating bread causes car crashes, since most drivers who crash their cars could probably be shown to have eaten bread within the past 24 hours.** If you consider that most SIDS deaths occur during the same range of ages when 3 shots of DTP are given, you would expect DTP shots to precede a fair number of SIDS deaths simply by chance. In fact, a number of well-controlled studies have indicated that the SIDS deaths (within the study populations) would have occurred even if no vaccinations had been given. In fact, **in several of the studies children who had recently gotten a DTP shot were *less* likely to get SIDS.**
- **No deaths caused by anaphylaxis following DTP vaccination** have been reported to CDC since the inception of vaccine-adverse-events reporting began in 1978, a period during which more than 80 million doses of publicly purchased DTP vaccine were administered.
- All deaths reported to the national Vaccine Adverse Events Reporting System (VAERS) are evaluated and additional information is sought by the FDA. The deaths have been found to be related to a wide variety of causes; most importantly, **no specific, clinical syndrome has been identified as one might expect if these deaths had the same cause, i.e., a vaccine reaction.** In consideration of this, a 1994 Institute of Medicine report indicated that the "vast majority of deaths reported to VAERS are temporally but not causally related to vaccination."
- Although no one can guarantee that the vaccines (or any medications) are totally without risk, it is important to look at both the risks and the benefits of vaccine use. **The risks of NOT being vaccinated are much greater than the reverse.** If there were no vaccines, there would be many more cases of disease, and along with them, more serious side effects, including death.

- A child is far more likely to be seriously injured by a vaccine preventable disease than by any vaccine. While any serious injury or death caused by vaccines is too many, it is also clear that the benefits of vaccination greatly outweigh the slight risk, and that many, many more injuries and deaths would occur without them. The following comparison of the risk from disease with the risk from the vaccines that protect against them can give us an idea of the benefits we get from vaccinating our children.

Risk from Disease vs. Risk from Vaccines	
Disease	Vaccines
<b>Measles</b> Pneumonia = 1 in 20 Encephalitis = 1 in 2,000 Death = 1 in 3,000  <b>Mumps</b> Encephalitis = 1 in 300  <b>Rubella</b> Congenital Rubella Syndrome = 1 in 4	<b>MMR</b> Encephalitis or severe allergic reaction = 1 in 1,000,000
<b>Diphtheria</b> Death = 1 in 20  <b>Tetanus</b> Death = 3 in 100  <b>Pertussis</b> Pneumonia = 1 in 8 Encephalitis = 1 in 20 Death = 1 in 200	<b>DTP</b> Continuous crying, then full recovery = 1 in 100 Convulsions or shock, the full recovery = 1 in 1,750 Acute encephalopathy = 0-10.5 in 1,000,000 Death = None proven  <div style="border: 1px solid black; padding: 2px;">             Information compiled by the Centers for Disease Control &amp; Prevention (CDC, Atlanta)           </div>

- Even one serious adverse effect in a million doses of vaccine cannot be justified if there is no benefit from the vaccination. But an analysis of the benefit and risk of DTP immunization, for example, has shown that **without an immunization program there could be a 71-fold increase in cases of pertussis and a nearly 4-fold increase in deaths due to pertussis in the United States.**
- A **risk-benefit analysis** has been performed for the U.S. to compare the outcomes with or without a vaccination program using a hypothetical cohort of 1 million children from birth to 6 years of age who received and did not receive pertussis vaccination. Without a program, the estimated annual number of residual defects from encephalitis (both vaccine and disease induced) would decrease from 54 to 29 cases. However, **the estimated annual deaths from pertussis would increase more than 10-fold, from 44 to 457.**

- The experiences of other countries are useful in evaluating the value of vaccination.

In the mid-70s, the use of pertussis vaccine was greatly reduced in **Great Britain** because of fear about the vaccine. The effect was dramatic and immediate. A drop in pertussis vaccination in 1974 was followed by an epidemic of more than 100,000 cases of pertussis and 36 deaths by 1978.

In **Japan**, pertussis vaccination was used nationwide by 1950. By 1974, pertussis incidence had dropped from 100 cases to 1 case per 100,000 population. However, in the last half of the 1970s, vaccine utilization in Japan markedly decreased after two deaths occurred following pertussis immunization. A major epidemic of pertussis ensued, with an increase in incidence rate to 11.5 per 100,000 in 1977, and an increase in the annual number of deaths from an average of less than 5 for the years 1970-1974 to an average of 32 during 1977-1979.

## Vaccine Adverse Events Reporting System (VAERS)

- VAERS was created as part of the National Childhood Injury Act of 1986. The system is one method used to monitor vaccine safety.
- Since 1990, VAERS report forms and information have been mailed annually to all U.S. physicians who are likely to administer vaccines. The Alaska Immunization Program has required the use of VAERS reports by all providers participating in the state's Universal Vaccine Distribution System.
- **Strengths of VAERS:**
  - ◊ provides information on the number of adverse events reported nationwide
  - ◊ permits collection and analysis of vaccine-specific and lot-specific information
  - ◊ potentially identifies risk factors for adverse events that may be contraindications to additional doses
  - ◊ serves as a sentinel for the detection of either previously unreported vaccine adverse events or unusual increases in reported events
- **Limitations of VAERS:**
  - ◊ describes only the number of events reported, without placing in context of number of vaccines given
  - ◊ cannot track the rate of similar events occurring in individuals who were not recently vaccinated
  - ◊ cannot in itself establish causation
- **A VAERS report does NOT mean that the vaccine caused the adverse event.**
  - (a) The reporting system is "open" to all reports that an individual/provider wishes to make.
  - (b) The report indicates simply that an event was temporally associated with receipt of a vaccine -- NOT that the vaccine necessarily caused the event.
- The small number of VAERS reports should be taken into context within the number of doses of vaccine delivered to Alaska's children. Each year 50-60,000 doses of vaccine are given to Alaska children <9 years of age.

**Number of Reports to the Vaccine Adverse Event Reporting System (VAERS)  
for Children <age 7, Alaska, 1994-96**

	Minor or Transient Reaction	Serious* or >1 month Duration
1994	20	3
1995	12	2
1996	10	6

\* Serious event = requires hospitalization or medical follow-up

**Review of "Serious" Adverse Events**

	Age of Child	Vaccines Received	Event	Outcome
1994	8 weeks	OPV Hib DTP	9 hours after vaccination - became limp and cyanotic; hospitalized for observation	Fully recovered
	2 months	OPV Hib DTP	6 hours after vaccination - continuous crying, 102° fever; observed overnight	Fully recovered
1995	18 months	OPV DTP	18.5 hours after vaccination - 1 seizure, fever > 100°; not hospitalized	Fully recovered
	16 months	MMR DTP	9 days after vaccination - seizures for 2 hours; hospitalized	Fully recovered
	2 months	OPV Hib DTP	27 hours after vaccination - afebrile seizures, 5-6/day; hospitalized	Not resolved
1996	17 months	MMR DTP	8 days after vaccination - fever of 104°; unresponsive; diagnosed with pneumonia	Fully recovered
	4.5 months	Tetramune OPV Hep B	5 minutes after vaccination - high pitched screaming; vomiting; fever; diarrhea; swelling at site	Fully recovered
	19 months	Tetramune OPV/MMR Hep B	6 days after vaccination - fever, vomiting, rash	Fully recovered
	5 years	DTaP MMR OPV	30 minutes after vaccination - fainted	Fully recovered
	2 months	DPT OPV Hib	4 hours after vaccination - high pitched, inconsolable crying	Fully recovered
	5 months	DTP OPV Hib	48 hours after vaccination - 104° fever; pneumococcal meningitis; (VERY unlikely related to shots)	Fully recovered

**CONCLUSION:**

Logistic problems make it unlikely that accurate and valid information will be collected through this approach. Little benefit in understanding or preventing side effects from vaccination would be gained. The burden on funeral directors and health facilities to obtain these data would be great. Bereaved parents would be stressed with an additional burden at one of the most difficult times in their lives.

For more information, the following individuals may be reached at (907) 269-8000:

**John Middaugh, MD, MPH**  
State Epidemiologist

**Laurel Wood, MPA**  
Immunization Program Manager