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LIMIT VACCINATION EXEMPTIONS

House Bill 4763 as introduced
First Analysis (9-15-93)

Sponsor: Rep. Lyn Bankes
Committee: Public Health

THE APPARENT PROBLEM:

Michigan, like other states, has mandatory vaccination requirements for children entering school (or daycare) for the first time. When the Public Health Code was rewritten in 1978, the Department of Public Health was given the authority to set requirements "for diseases and within an age period prescribed by the department." When parents apply to have a child registered for the first time in a school, they are required to present to school officials a certificate of immunization or exemption. The code prohibits teachers or principals from allowing a child to enter or attend school unless they are presented with a certificate (certified by a health professional or a local health department) indicating that the child has received a minimum of one dose of an immunizing agent against each of the diseases specified by the department. If a child is registered with a certificate indicating only minimum doses of the required immunizing agents, the child's parents are required to present to school officials an updated certificate of immunization, showing that the immunizations have been completed as prescribed by the Department of Public Health, within four months after the child's initial attendance at the school.

The health code currently allows parents to exempt their children from the code's immunization requirements for three reasons: (1) if a physician certifies that a specific immunization is (or may be) detrimental to the child's health or is not appropriate, (2) if a parent or guardian (or some other person in loco parentis) of the child objects, in writing, because of religious convictions, or (3) if a parent or guardian objects, in writing, for "other" reasons. This third, catch-all category of exemptions often is referred to as "philosophical" objections to immunizations, and Michigan reportedly is only one of twenty states allowing such an exemption. Some people believe that this "philosophical" exemption ought to be eliminated.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to:

- * delete exemptions to childhood vaccinations based on parental objections other than religious convictions; and

- * require that physician-certified exemptions:

- (a) be in writing, and

- (b) specify that a specific immunization be "medically" inappropriate (currently, the code specifies only that the physician certify that the immunization be "inappropriate").

MCL 333.9215

BACKGROUND INFORMATION

Childhood vaccinations: Existing and anticipated recommendations. As of August 1992, the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention (CDCP) and the American Academy of Pediatrics (AAP) recommended that children in the United States be vaccinated against nine diseases, but the medical community and public health officials expect these recommendations -- and the resulting required school immunizations -- to expand rapidly in the near future.

ACIP and AAP recommend a preschool and a school-age series of vaccinations against nine diseases: hepatitis B (HBV), diphtheria, tetanus, pertussis (whooping cough), polio, Haemophilus influenzae type b ("Hib," a major cause of meningitis), measles (rubeola), mumps, and rubella (German measles). The preschool series should begin at birth (with an HBV vaccination), and be completed when the child is 15 to 18 months old. A second set of vaccinations is recommended for children aged 4 to 6 years old, at or before entering school, with a measles-mumps-and-rubella (MMR)

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"booster" given to children between 11 and 12 years old, when they enter middle school or junior high school (unless the second MMR dose was previously given). A tetanus-diphtheria booster also is recommended for children between 14 and 16 years old.

However, rapid changes in vaccine recommendations are being anticipated because of the development of new vaccines, changes in the epidemiology of diseases, and other scientific findings. For example, a "conjugate" Haemophilus influenzae vaccine is now routinely recommended for the preschool vaccination series (where the "conjugate" refers to the fact that these forms of the vaccine have a "carrier" protein consisting of, or derived from, diphtheria or tetanus toxoids or an "outer-membrane-protein complex" of Neisseria meningitidis). In addition, a new generation of "acellular" pertussis vaccines have been licensed for use in the United States and efficacy trials of these vaccines during the 1990s on infants are expected to lead to approval of one or more of these acellular pertussis vaccines for routine use during the first year of life. (These kinds of vaccines reportedly already have been in use in Western Europe for some time. They are called "acellular" because, unlike the older pertussis vaccines prepared from inactivated whole Bordetella pertussis cells, they are instead prepared from parts of the cell.) Other new vaccinations under investigation include vaccines for varicella, the chicken pox that affects three million children each year; otitis media, or inflammation of the ear; respiratory syncytial virus, which can cause severe respiratory distress in young children; and rotavirus gastroenteritis, the chief cause of often lethal diarrheal disease. Recommendations for new combinations of existing vaccines currently in routine use also are anticipated (for example, a combination of DPT, HBV, the injectable killed polio virus [IPV], and Haemophilus influenzae vaccines). In addition, because virtually all of the eight cases of paralytic polio each year in this country result from the orally-administered live polio virus vaccine, sequential schedules of the killed injectable polio virus vaccine (IPV) followed by the oral, live polio virus vaccine (OPV) may be adopted.

Currently required childhood vaccinations in Michigan. Under administrative rules published in April 1993, the Department of Public Health (DPH) basically adopted the ACIP recommendations as requirements for children in group settings (such as

daycare) or entering school. (The exception is the hepatitis B vaccine, which the DPH -- like ACIP -- recommends, but does not yet require.) Under the new rules, preschool children in group settings are required to have four sets of vaccinations. The first three sets in the series (at 2 to 4 months, 4 to 5 months, and 6 to 14 months of age) consist of vaccinations against diphtheria, pertussis, and tetanus (usually given in the form of a single "DPT" injection), polio (usually in the form of the Sabin oral polio vaccine, or "OPV"), and against Haemophilus influenzae type b ("Hib"). The fourth set of preschool vaccinations, given between 15 months to four years of age, adds a combined measles, mumps, and rubella ("MMR") vaccination to the five earlier vaccinations. The Hib vaccination is not required after the age of four, so the two sets of school-age entry vaccinations (one at 4 to 6 years old, when a child typically would enter kindergarten, and the other from 7 to 18 years, for children otherwise entering school in the state for the first time) consist of vaccinations against DPT, polio, and MMR. (Children 4 to 6 years old must have "booster" vaccinations against DPT and polio only if their last doses were given before their fourth birthday; they must have an MMR booster only if their last dose was administered before they were 15 months old.)

The required schedule of vaccinations can be summarized as follows:

2-4 months:	1 DPT, 1 polio, 1 Hib
4-5 months:	2 DPT, 2 polio, 2 Hib
6-14 months:	3 DPT, 3 polio, 3 Hib
15 months	
to four years:	4 DPT, 3 polio, Hib, 1 MMR
(Note: for this age group, one dose of Hib at 15 months or a complete series is required.)	
4-6 years:	4 DPT, 3 polio, 2 MMR
7-18 years:	4 DPT, 3 polio, 2 MMR
(Note: for MMR, either two doses or laboratory evidence of immunity is required.)	

The National Childhood Vaccine Injury Act (NCVIA). In 1986 Congress passed the National Childhood Vaccine Injury Act, followed by the Vaccine Compensation Amendments of 1987. The legislation contains several major provisions designed, among other things, to bring together information about vaccinations, to develop standard consent forms for use with administering vaccinations, and to promote the development of safer vaccines. The heart of the act, however, is the

establishment of a federal no-fault compensation system for those injured by vaccinations, funded at first by general appropriations and then by excise taxes imposed on manufacturers of vaccines. Congress reportedly hoped that this new system, which went into effect on October 1, 1988, would stabilize the vaccine market by responding to manufacturers' concerns about the increasing cost of liability associated with vaccine use. The new system, which largely replaces traditional tort remedies in the courts, sets forth a new and substantially streamlined system for addressing vaccine-related injuries, and limits both the liability of manufacturers (and the providers who administer the vaccines) and the potential recovery by claimants. Children injured before the effective date of the act (October 1, 1988) could pursue their remedies at state law, although some may elect to seek recompense under the federal scheme. Those harmed after this date, however, must follow the procedures set forth in the NCVIA.

The law was enacted basically to protect manufacturers of vaccines, who, in the preceding 15 years, had been sued increasingly successfully by families who believed that they or their children had been injured by childhood vaccinations. Not only did the manufacturers increase their prices to providers in order to pay for the millions of dollars the manufacturers had to pay to vaccine-injured individuals, many manufacturers stopped producing vaccines altogether. Thus, not only were there dramatic cost increases for vaccines, but also there were shortages in supplies of vaccines. For example, in the case of the DPT vaccine, in 1980 a single dose cost about nineteen cents; by 1989 a single dose cost nearly fifteen dollars. And during much of the middle 1980s, the DPT vaccine was in short supply.

Under the act, vaccine manufacturers have a clearer picture of their potential liability and clearer incentives for future behavior (including incentives for developing safer and more effective vaccines). They know that they will have to pay an excise tax for each dose of vaccine sold (for example, in 1989, \$4.56 for each DPT vaccine dose) and that the rules governing their civil liability are now much more favorable for manufacturer-defendants. Manufacturers can still be liable if they fail to use due care in making vaccines or if they fail to comply with their own specifications, but Congress severely limited the availability of punitive damages. These changes in the law are seen as particularly

significant because they are national in effect. In general, the legal rules governing medical malpractice and products liability -- the rules most often involved in vaccine cases -- vary from one state to another, which means that damages awarded in different states in otherwise similar cases could vary greatly. The primary impact of the NCVIA is to greatly limit the two predominant theories on which manufacturers' liability had been based -- misdesign and inadequate warning. In the area of misdesign, Congress said that there can be no liability for vaccine-related injuries if the vaccine could not have been made more safely with the state of knowledge at the time of manufacture. This rule eliminates a series of cases in which, for example, plaintiffs tried to impose liability on the manufacturers of whole cell pertussis (whooping cough) vaccines on the ground that split cell and acellular vaccines were safer and so should have been developed by the producers. Similarly, Congress passed two laws that effectively eviscerated cases permitting liability to be imposed on manufacturers for failure to warn physicians and their patients sufficiently about the risks of vaccines. Not only did Congress say that producers have no obligation to inform children and their families directly about the risks of immunizations, but it also made compliance with federal labeling requirements almost conclusive proof of adequate warning. The final reform benefiting manufacturers was that Congress severely limited the availability of punitive damages. Finally, despite its avowed desire not to preempt state law totally, Congress, as the final step in its tort reform, largely prohibited states from going any further than Congress had already gone in limiting manufactures' liability under tort law.

Although vaccine manufacturers are the primary beneficiaries of Congress' tort reforms, the NCVIA also benefits vaccine-injured children and their families because they have a much easier time qualifying for compensation under the act than they would under the old tort system (though the damages they receive under the act likely will be lower than they would be under the old tort system). Under the act, the fact of injury itself is enough (and is established by whether it appears on a Vaccine Injury Table). This simplified requirement for making a claim benefits claimants not only because it makes it much more likely that they will qualify for compensation but also because it streamlines the proceeding, requiring less legal involvement and permitting more rapid recovery of damages. In addition, the act has a provision that

allows claimants to reject an award made under the federal scheme and to pursue their remedies at tort law.

FISCAL IMPLICATIONS:

Fiscal information is not available. (9-14-93)

ARGUMENTS:

For:

There is virtually unanimous agreement within the medical community and among public health officials that one of the most important medical developments in the 20th century has been the control of once common childhood infectious diseases by the administration of highly effective vaccines. In the United States, for example, reductions of 90 percent or greater from peak reported occurrence have been achieved for diphtheria, measles, mumps, pertussis, polio, rubella, congenital rubella syndrome, and tetanus. The introduction in the United States of vaccines against Haemophilus influenzae type b (a major cause of meningitis) also has had a substantial impact on such infections. Even with the recent resurgence of measles (in the measles epidemic of 1989 to 1991, in which there were a reported 55,000 cases of measles with 150 deaths) resulting in the highest morbidity in more than a decade, reported cases are still only a fraction of the cases reported in the prevaccine era. The marked decline in the incidence of vaccine-preventable diseases in the United States has correlated with the high levels of vaccination achieved before and at the time of school entry through the enactment and enforcement of school vaccination laws, with vaccination levels for all routinely used vaccine being 95 percent or greater among children entering school since the 1981-82 school year.

Unfortunately, however, among children in the first two years of life rates of vaccination in the United States are substantially below the national goal of 90 percent for completion of the recommended vaccinations by the second birthday, with poor or delayed vaccination being a problem especially for poor and minority children (where rates can range as low as 12 percent). The principal cause of the measles epidemic of 1989 through 1991 -- which disproportionately affected preschool children, particularly in the inner-cities -- was failure to vaccinate children at the recommended age. Preschool children, moreover, account for a

disproportionate share of all complications reported from measles. Although preschool children accounted for an average of 35 percent of the measles cases between 1985 and 1989, they accounted for substantially greater proportions of measles-induced ear infections (80 percent), diarrhea (62 percent), pneumonia (64 percent), hospitalization (55 percent), and death (61 percent). What is more, the measles outbreak indicates the potential for outbreaks of other vaccine-preventable diseases.

Parents who object to vaccinations on "philosophical" grounds often do so from fear of adverse reactions from the vaccines. While no vaccine is perfectly safe or perfectly effective, most side effects are mild and temporary. Rare serious effects following vaccinations have been reported, but in many cases it isn't possible to determine whether a vaccine actually caused the illness or was simply coincidental to an illness that would have occurred anyway. In any case, all comprehensive assessments of the risks and benefits of vaccines indicate that the benefits of vaccines for almost all children far outweigh the risks.

By allowing parents to exempt their children from vaccinations for "philosophical" or personal reasons, these parents put many children at risk: their own children, children who have been exempted for medical or religious reasons, children who have been vaccinated but for whom the vaccination did not "take" (reportedly, about 75 percent of measles victims in one recent year in Michigan were children who had been vaccinated, though the one child who died had not been vaccinated for "philosophical" reasons), and poor and minority children who tend to have poor or delayed vaccination coverage. The bill is needed in order to prevent needless outbreaks of -- and possible tragic deaths from -- vaccine-preventable diseases.

Against:

The bill doesn't go far enough. Rather than just eliminating the exemption for "other" objections to immunizations, the bill also should eliminate exemptions based on religious objections. In the first place, since no criteria must be met for "religious" objections, people could exempt their children from vaccinations simply by lying, saying that their opposition was based on religious grounds even if that were not true. But even where parents do object for religious reasons, the health and welfare of people who do believe in the safety and

efficacy of vaccinations can be jeopardized by the non-vaccinated status of religiously-exempted people. While the United States has a long history of respecting freedom of religion, the rights of individuals to practice their religion traditionally has ended when those rights threaten the health or wellbeing of other people. Only medically-indicated exemptions should be allowed for childhood immunizations.

Against:

The bill would fundamentally violate the rights of parents to make decisions which they consider to be in the best interests of their children. What is more, at a time when medical care users are becoming much more sophisticated about the benefits and risks of orthodox scientific medicine and beginning to make informed decisions on whether and how to use mainstream medicine, the bill would close off a very important avenue by which parents could make health and medical choices for their children. The bill not only would lessen parental rights and strengthen the right of the state to make highly personal medical decisions, it also would punish those who hold minority or alternative views on health and medical care. And people who use alternative therapies are not rare. As a study conducted by Harvard Medical School researchers (and published in the January 1993 issue of The New England Journal of Medicine) pointed out, one-third of health care consumers use unconventional therapies, spending an astonishing \$13.7 billion on such therapies in 1990 alone, 75 percent of which was paid for out of pocket. Moreover, only 28 percent of those who saw alternative health care practitioners admitted as much to their regular physicians (probably with good reason: in commentary accompanying the study, Dr. Edward Campion scoffed at alternative medicine as "patently unscientific" and, perhaps more to the point, "in direct competition with conventional medicine.") With regard to vaccinations, minority opinions need to be respected as much out of respect for the rights of people to question conventional medical "wisdom" as out of respect for parents rights.

It is not unusual to see claims that because of vaccinations smallpox has been eradicated from the face of the earth and polio has virtually been eradicated from the Western Hemisphere. Yet anyone familiar with historical epidemiology knows that the smallpox epidemic was in decline before the discovery and widespread use of vaccinations

against the disease, and the same apparently is true of the polio epidemic in the United States in mid-century. While the widespread availability of vaccinations may have helped to drastically reduce the incidence of serious infectious diseases in childhood, so, too, have improved nutrition and better public sanitation. What is more, the use of vaccinations has not been free of side effects, some of which are minor but some of which also can be catastrophic. For example, even conventional medicine recognizes that children frequently are fretful, drowsy, or have local reactions after receiving the DPT vaccine, while at the same time, according to the most widely quoted figures, one in 750 children will have a seizure or a "hypotonic-hyporesponsive episode," and one in 330,000 will sustain permanent neurologic injury. In a Public Broadcasting Service episode of the Nova program, titled "Can You Still Get Polio?" the answer, of course, was yes -- from the orally-administered live polio vaccine. In fact, in recognition of the fact that virtually all of the eight or so cases of paralytic polio in this country are caused by the oral polio vaccine itself, there is speculation that instead of requiring a series of oral polio vaccinations, in the future public health officials will move to recommending beginning with an injection of the Salk, killed polio virus vaccine (which reportedly has not been associated with causing paralytic polio), to be followed only later by the oral polio vaccine. Other common childhood vaccines also have well-reported, if relatively infrequent, side effects. For example, the rubella (German measles) vaccine reportedly has been followed in some cases by transient and not-so-transient arthritis.

In addition to recognized mild or catastrophic side effects, there have been some well-publicized and unanticipated vaccine disasters. In the so-called "Cutter incident" of 1955, 260 paralytic poliomyelitis cases were caused by the use of lots of Cutter polio vaccine that contained active polio virus, while the 1976 mass campaign of "swine flu" vaccination (which lasted from October 1 to December 16) was followed by more than 500 cases of Guillain-Barre paralysis, 23 of whom died.

In addition to recognizing that existing vaccines have known adverse "side" effects (recognition attested to, in part, by the passage of the National Childhood Vaccine Injury Act in 1986), and, in some cases, are outright disasters, many opponents of mandatory vaccinations also raise a series of questions about the possible unrecognized and long-

term adverse effects of routine childhood vaccinations. For example, questions have been raised about the possibility of damage to immature immune systems by introducing foreign and toxic substances; about the possible decrease in the percentage of reserve immune capacity (and subsequent immune malfunction) by early and intentional introduction of such substances; and about the possibility that one long-term result of early vaccinations may be immunologic disorders later in life, including chronic degenerative diseases (such as multiple sclerosis) and autoimmune diseases (such as rheumatoid arthritis and systemic lupus erythematosus). Although the standard response to such concerns has been that there are no scientific studies establishing such connections between early vaccinations and later diseases, it is also the case that the medical community's research priorities (and articles published in peer-reviewed journals) are set from within the community, so that such connections are not likely to be pursued. (This, however, may begin to change with the establishment of the federal Office of Alternative Medicine under the National Institutes of Health's 1992 budget.)

Many people do have serious, thoughtful reservations about the questionable effectiveness of vaccines, the risks of serious long- and short-term side effects, and the appropriateness of depending on vaccines for disease prevention instead of working to strengthen the immune system through healthy living (good diet and sanitation, for example). These people may not necessarily object to vaccinations on religious grounds, but should, nevertheless, be allowed to continue to exercise their best judgment concerning what is best for their children's health.

Against:

Even if serious adverse effects from vaccinations are rare, families should have the option of deciding whether or not to incur these risks -- especially since people receive vaccinations not only to prevent or cure their own illness but also are encouraged (or required) to be vaccinated because vaccinations help others. Sometimes the benefit is even directed toward specific third parties: public health policy seeks to prevent rubella (German measles) not because it is a bad disease in toddlers -- it usually is not -- but because it is a disaster for the first-trimester fetus whose mother catches it from her own or other toddlers. Benefits to others, in fact, are among the primary justification for the

enactment of mandatory vaccination laws (for example, the concept of "herd immunity" teaches that epidemics are prevented if a high proportion of the population is immune to an infecting agent), but it still is possible to question putting one's child at risk in order to benefit others. And, in fact, the law generally has recognized that parents at least have the right to delay immunizations, and many states have statutes expressly giving parents the right to opt out of vaccinations for religious or other reasons. What is more, fears about vaccine safety have not been cited as major reasons for low vaccination levels in most studies of the more vulnerable inner-city children, while high vaccination levels at school entry attest to the fact that safety is not the major reason for low preschool coverage, so both religious and "other" vaccine exemptions should be preserved in law.

POSITIONS:

The Department of Public Health supports the bill. (6-30-93)

The Department of Education supports the bill. (6-29-93)

The Michigan Association of Osteopathic Physicians and Surgeons supports the bill. (9-14-93)

The Michigan Chapter of the American Academy of Pediatrics supports the bill. (9-14-93)

The Michigan Advisory Committee on Immunizations supports the bill. (9-14-93)

The Michigan Parent-Teacher Association supports the bill. (9-14-93)

The Michigan Council for Maternal and Child Health supports the bill. (9-14-93)

The Michigan Chiropractic Council opposes the bill. (9-14-93)