

January 24, 2007

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Vaccine Preventable Disease Program
Division of Epidemiology, Environmental, and Occupational Health
New Jersey Department of Health and Senior Services
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Dear Angela Sorrells-Washington:

The evidence-supported comments that follow this introductory letter suggest changes to the new rules and amendments published at:

http://www.state.nj.us/cgi-bin/dhss/njnewsline/view_article.pl?id=3013

that: a) the New Jersey Department of Health and Human Services is proposing and b) are to be discussed in a public hearing scheduled on the proposed amendments and new rules between 10:00 A.M. and 12:00 P.M. on Friday, January 26, 2007 at the New Jersey Department of Health and Senior Services, First Floor Auditorium, Health and Agriculture Building, 369 South Warren Street (at Market Street), Trenton, NJ 0860.

In general, to clearly differentiate between my assessment comments and those of the article, the article's printed statements are quoted in an *italicized "Times New Roman"* font followed by this reviewer's remarks in indented text written in a "**News Gothic MT**" font.

Quotes from other reference articles and documents will be presented in an "**Arial**" font.

For those who have a color printer, this reviewer's comments are made in a **dark blue** color.

Should anyone find any factual misrepresentations in this commenter's remarks, then this reviewer requests that you send the factual error along with the scientifically sound and appropriate documents that prove your point to this commenter so that this commenter can learn from you, incorporate that new knowledge into his understanding, and, where indicated, appropriately correct this document.

Respectfully,



Paul G. King, PhD,
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c: Jon S. Corzine, Governor of New Jersey (w/o enclosures)
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FORMAL COMMENTS

“PO Box 360
Trenton, NJ 08625-0360

Fred M. Jacobs, MD, JD
Commissioner

For Release:
December 18, 2006

For Further Information Contact:
(609) 984-7160

DHSS Proposes Amendments and New Rules at N.J.A.C. 8:57-4, Governing Immunization of Pupils in School

The Communicable Disease Service of the Division of Epidemiology, Environmental, and Occupational Health in the Public Health Services Branch of the Department of Health and Senior Services, in consultation with the Public Health Council, are proposing amendments and new rules at N.J.A.C. 8:57-4, Immunization of Pupils in School. The notice of proposal appears in the December 18, 2006 issue of the New Jersey Register.

N.J.A.C. 8:57-4, also known as Chapter 14 of the State Sanitary Code, establishes uniform immunization requirements applicable to children attending all schools, preschools, and child care facilities in New Jersey. The purpose of the subchapter is to ensure that those children have been immunized against specific vaccine-preventable diseases with recommended vaccines in order to prevent the transmission of vaccine-preventable diseases and to collect data on the immunization status of those children to identify areas of the State where immunization rates are not adequate in order to determine appropriate intervention.”

While this commenter supports the goal of preventing “*the transmission of vaccine-preventable diseases,*” he objects to the addition of vaccines to those required for attendance at school where the vaccines: **a)** have no “in use” proof of effectiveness in preventing the disease (e.g., the influenza vaccines that, based on published U.S. data covering two decades, is not effective in preventing those vaccinated from getting the flu), **b)** do not truly provide the degree of disease protection that the healthcare establishment claims they provide (e.g., the vaccines for certain strains of *Neisseria meningitidis* but not the strain, “B,” which causes about 50% of the clinical cases in the U.S.), **or c)** have questionable safety or effectiveness claims (e.g., so-called cervical-cancer vaccine, Merck’s Gardasil vaccine for four of the 100-plus strains of the human papilloma viruses [HPVs]) where the manufacturer was apparently allowed to use the vaccine formulation minus the active viral antigens as the placebo instead of sterile saline so that the manufacturer could minimize the high percentage of adverse reactions observed in the vaccine test arm of the clinical trial by noting that it was only slightly higher than the “artificial placebo” used to support a claim of “safety” and the “can prevent cervical cancer” claim is, at best, unproven hyperbole).

With respect to “*collect data on the immunization status of those children to identify areas of the State where immunization rates are not adequate in order to determine appropriate intervention,*” this reviewer agrees with the statement up to the point it states “*in order to determine appropriate intervention*” because the current rules are already coercive enough and, for a democratic republic, perhaps too coercive because Japan and Canada, democratic nations, do not coerce vaccination by tying it to school attendance or job prerequisites as we do, but they have equally low or lower disease rates.

Moreover, since Japan has an infant mortality rate that is about half that of the United States,¹ perhaps New Jersey should adopt the delayed flexible schedule

¹ <http://www.cia.gov/cia/publications/factbook/rankorder/2091rank.html>, Japan: 3.24 infants per 1000 live births; United States: 6.43 infant deaths per 1000 live births (when web site visited)

used by the Japanese for their recommended vaccination program since, based on the VAERS adverse event reports, it is clear that the more intensive and much less flexible United States vaccination program is a clear contributor to the 3+ extra infant deaths that we have.

“The Department is proposing substantive and technical amendments and new rules throughout the subchapter. Noteworthy substantive amendments and new rules include the following:

- An amendment at N.J.A.C. 8:57-4.5 to establish the requirement that a school, preschool, and child care center provide provisional admission if there is evidence that the child has completed at least one dose of each required vaccine and is in the process of completing the rest of the doses and to establish that a 30-day grace period is required for pupils from out-of-State or out-of-country to obtain their immunization documentation.”

This commenter is fundamentally opposed to the current proposed rules because they fail to explicitly provide language for children who, for whatever reason, are exempt from vaccination.

The current proposed rule with changes reads:

“8:57-4.5 Provisional admission

- (a) A child [may] shall be admitted to a school, preschool, or child care center on a provisional basis if a physician, an advanced practice nurse (certified registered nurse practitioner or clinical nurse specialist) or health department can document that at least one dose of each required age-appropriate vaccine(s) or antigen(s) has been administered and that the pupil is in the process of receiving the remaining immunization(s).
- (b) Provisional admission for children under age five shall be granted in compliance with the specific requirements set forth in N.J.A.C. 8:57-4.10 through 4.15 and 4.18 for a period of time consistent with the current Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service or the American Academy of Pediatrics (AAP) immunization schedule, but shall not exceed 17 months for completion of all immunization requirements.
- (c)-(d) (No change.)
- (e) Those children transferring into a New Jersey school, preschool, or child care center from out-of-State or out-of-country [may] shall be allowed a 30-day grace period in order to obtain past immunization documentation before provisional status shall begin.
- (f)-(g) (No change.)”

This commenter suggests changing these provisions to read (proposed changes underlined for emphasis):

“8:57-4.5 Provisional admission

- (a) A child [may] shall be admitted to a school, preschool, or child care center on a provisional basis if a parent or guardian states that the child is exempt from being vaccinated for medical or religious reasons and agrees to provide a copy of the appropriate certifying document to the admitting agent within 30 days of admission. or a physician, an advanced practice nurse (certified registered nurse practitioner or clinical nurse specialist) or health department can document that at least one dose of each required age-appropriate vaccine(s) or antigen(s) has been administered and that the pupil is in the process of receiving the remaining immunization(s).
- (b) For children not exempted from further vaccination, provisional admission for children under age five shall be granted in compliance with the specific requirements set forth in N.J.A.C. 8:57-4.10 through 4.15 and 4.18 for a period of time consistent with the current Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service or the American

Academy of Pediatrics (AAP) immunization schedule, but shall not exceed 17 months for completion of all immunization requirements.

(c)-(d) (No change.)

(e) Those children not exempted from further vaccination and transferring into a New Jersey school, preschool, or child care center from out-of-State or out-of-country [may] shall be allowed a 30-day grace period in order to obtain past immunization documentation before provisional status shall begin.

(f)-(g) (No change.)”

In this commenter’s view, it is critical that exemption and alternative means be explicitly incorporated into any regulation for vaccination.

- An amendment at N.J.A.C. 8:57-4.10(e) to change the age requirement from seven years of age and older to seven through nine years of age for that particular completion of the primary Diphtheria, Tetanus, Pertussis and DiphtheriaTetanus, acellular Pertusis (DTP/DTaP) vaccine series.”

Again, this commenter is fundamentally opposed to the current proposed rules because they fail to explicitly provide for children who, for whatever reason, are exempt from vaccination.

The current proposed rule with changes reads:

“8:57-4.10 Diphtheria and tetanus toxoids and pertussis vaccine

(a)-(d) (No change.)

(e) Children seven [years of age and older] through nine years of age who have not completed this requirement shall receive tetanus and diphtheria toxoids (adult Td) instead of DTP. Any [appropriately spaced] combination of three doses of DTP, DTaP, DT, or Td in a child [over age] seven through nine years of age shall be acceptable as adequate immunization for this vaccine series.

(f)-(g) (No change.)

(h) Every child born on or after January 1, 1996 and entering or attending Grade Six, or a comparable age level special education program with an unassigned grade on or after September 1, 2007, shall have received one dose of Tdap given no earlier than the tenth birthday.

(i) Children entering or attending Grade Six on or after September 1, 2007 who received a Td booster dose less than five years prior to entry or attendance shall not be required to receive a Tdap dose until five years have elapsed from the last DTP/DTaP or Td dose.

(j) Children born on or after January 1, 1996 and transferring into a New Jersey school from another state or country after September 1, 2007, shall have received one dose of Tdap, provided at least five years have elapsed from the last documented Td dose.”

This commenter suggests changing these provisions to read (proposed changes underlined for emphasis):

“8:57-4.10 Diphtheria and tetanus toxoids and pertussis vaccine

(a)-(d) (No change.)

(e) Unless exempt from vaccination or the child’s parent or guardian provides medical evidence of sufficient antibody titers or childhood disease, children seven [years of age and older] through nine years of age who have not completed this requirement shall receive Thimerosal-free tetanus and diphtheria toxoids (adult Td), when such is available, or, failing that, a Thimerosal-free Tdap vaccine instead of DTP. Unless exempt from vaccination for any valid reason, any [appropriately spaced] combination of three doses of DTP, DTaP, DT, or Thimerosal-free Td (or, Thimerosal-free Tdap in lieu of Td when no Thimerosal-free Td vaccine is available) in a

child [over age] seven through nine years of age shall be acceptable as adequate immunization for this vaccine series.

(f)-(g) (No change.)

(h) Unless exempted from further vaccination or the child's parent or guardian provides medical proof of sufficient antibody titers or childhood disease, every child born on or after January 1, 1996 and entering or attending Grade Six, or a comparable age level special education program with an unassigned grade on or after September 1, 2007, shall have received one dose of Tdap given no earlier than the tenth birthday.

(i) Unless exempted from further vaccination, children entering or attending Grade Six on or after September 1, 2007 who received a Td booster dose less than five years prior to entry or attendance shall not be required to receive a Tdap dose until five years have elapsed from the last DTP/DTaP or Td dose.

(j) Unless exempted from further vaccination or the child's parent or guardian provides medical proof of sufficient antibody titers, children born on or after January 1, 1996 and transferring into a New Jersey school from another state or country after September 1, 2007, shall have received one dose of Tdap, provided at least five years have elapsed from the last documented Td dose."

- An amendment at N.J.A.C. 8:57-4.22(d) to allow for temporary suspension of an immunization requirement for the particular immunization affected by a vaccine supply shortage."

The current proposed rule with changes reads:

"8:57-[4.19]4.22 Emergency powers of the Commissioner of Health and Senior Services

(a)-(c) (No change)

(d) In the event of a national or State vaccine supply shortage as determined by the Centers for Disease Control and Prevention and Commissioner respectively, the Commissioner or his or her designee may temporarily suspend the immunization requirement for the particular immunization affected by the supply shortage after provision of notice to the public, such as through any of the methods below:

1. Electronic posting on the Department's website;
2. Print and electronic news media;
3. The Department's Local Information Network and Communications System (LINCS);
4. The Department's Vaccine Preventable Disease Program; or
5. Any other method reasonably calculated to inform those persons most likely to be affected by or interested in the temporary immunization suspension."

This commenter has no problems with the new 4.22(d).

- An amendment at N.J.A.C. 8:57-4.23(b) to establish that all mandated vaccine doses in subchapter four, when given within four days of the specified minimum age or a stated dose spacing interval in the subchapter, would be counted as valid doses."

This commenter proposes changing the proposed rule changes to read (with underlining added to highlight the changes proposed):

"8:57-[4.20]4.23 Optimal immunization recommendations

(a) Except for children exempt from vaccination, the specific vaccines and the number of doses required under this subchapter are intended to establish the minimum vaccine requirements for childcare center, preschool, or school entry and attendance in New Jersey. Additional vaccines, vaccine doses, and proper spacing between vaccine doses are recommended by the Department in accordance with the guidelines of the American Academy of Pediatrics (AAP) and Advisory

Committee on Immunization Practices (ACIP), as periodically revised, for optimal protection and additional vaccines or vaccine doses may be administered, although they are not required for school attendance unless otherwise specified in this subchapter.

- (b) All vaccine doses included within, and mandated by, this subchapter that are administered less than or equal to four days ~~before~~ after either the specified minimum age or dose spacing interval shall be counted as valid and shall not require revaccination in order to enter or remain in a school, preschool, or child care facility.
- (c) In no case shall a missing or non-valid immunization under paragraph (b) of this section require a revaccination in order to enter or remain in a school, preschool, or child care facility unless that facility determines:
 - (i) with parental or guardian consent and appropriate testing, that the child's immune titers are below the levels established as being protective, or
 - (ii) that the child has not had the disease or diseases in question, or
 - (iii) that the child is not exempt from receiving the vaccination or vaccinations in question.

“The following amendments and new rules would add four vaccines to the subchapter based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services.”

In general, this commenter opposes adding these four vaccines to the subchapter because independent scientific evaluations have found that the benefits, if any, for these vaccines are far less than claimed and/or the risks have been knowingly understated by the CDC and the manufacturers.

- A new rule at N.J.A.C. 8:57-4.18 would require children attending child care centers and preschools that are two to 59 months of age to receive the pneumococcal conjugate vaccine series.”

The commenter's review of the pneumococcal conjugate Prevnar® (Wyeth-Lederle) vaccine finds that it only provides marginal benefit in preventing ear infections in those vaccinated, its purported reason for use, and comes with a high incidence of serious adverse events based on the limited data (estimated at no more than 10% of the actual “adverse event” incidents by the federal government).

In this commenter's view, this vaccine should not be added because it is also not even cost effective.

In addition, the ACIP's recommendations should be taken with a large “grain of salt” because more than a few of the committee's members have clear conflicts of interest.

Thus, the “*new rule at N.J.A.C. 8:57-4.18*” should not be added.

- A new rule at N.J.A.C. 8:57-4.19 would require children attending child care centers and preschools that are six to 59 months of age to receive one annual dose of influenza vaccine.”

The commenter's review of the recently published scientific literature evaluating the in-use effectiveness of influenza vaccines has found that they are not

effective (Geier et al. 2006²) or much less effective than claimed (Jefferson 2006³) in preventing those inoculated from getting influenza.⁴

In addition, since more than 80% of the doses of influenza vaccine approved for use in children six months to 59 months of age are Thimerosal preserved and the majority of the others contain a lesser level of Thimerosal and Thimerosal is 49.55 % mercury by weight, all these vaccine doses, when administered, mercury-poison all those who receive this vaccine to some degree because no level of mercury has been proven, by scientifically sound and appropriate toxicity studies, not to be mercury toxic in humans.

In addition, mercury toxicity has been demonstrated in developing human neurons at levels more than a hundred thousand times lower than the level of Thimerosal in the Thimerosal-preserved influenza vaccines.⁵

Thus, this commenter opposes adding this vaccine to the regulations as a “*new rule at N.J.A.C. 8:57-4.19.*”

Moreover, if the goal is to protect the health of all children, then, should the Department of Health and Senior Services (DHSS) not care that the influenza vaccine is not effective, at a minimum, the proposed language in the proposed “*new rule at N.J.A.C. 8:57-4.19*” should be changed to read (with changes underlined for emphasis):

“8:57-4.19 Influenza vaccine

- (a) Except for children exempt from vaccination, children six through 59 months of age attending any child care center or preschool facility on or after September 1, 2007 shall annually receive at least one dose of an influenza vaccine, which contains no Thimerosal, between September 1 and December 31 of each year.
- (b) Unless quarantined from school for at least 21 day after inoculation, no child may be given any live-virus influenza vaccine.”

that is if the DHSS is committed to protecting New Jersey children from unnecessary exposure to: **a)** mercury – since there is an approved “no Thimerosal” inactivated influenza vaccine or **b)** live influenza virus shed by influenza “Typhoid Marys” – those inoculated with a live-virus influenza vaccine (as the package insert for these live-virus vaccines clearly indicates) can infect others.

“• Amendments at N.J.A.C. 8:57-4.10(h) through (j) would require children born after January 1, 1996 and enrolled in Grade Six or transferring into a New Jersey school from another state or country to receive one dose of the tetanus, diphtheria, acellular pertusis (Tdap) vaccine.”

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- ² David A. Geier, Paul G. King, and Mark R. Geier. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. JAP&S (Journal of American Physicians and Surgeons) 2006 Fall; 11(3): 69-74 (copy enclosed).
 - ³ Tom Jefferson (a world recognized vaccine researcher). Influenza vaccination: Policy versus evidence. BMJ (British Medical Journal) 2006 October 28; 333: 912-915 (copy enclosed).
 - ⁴ This commenter expressed his evidence supported concerns in a 27 December 2006 letter to Dr. Eddy A. Bresnitz, Deputy Commissioner/State Epidemiologist, DHSS, State of New Jersey, P.O. Box 360, Trenton, NJ 08625-0360 (copy enclosed).
 - ⁵ Damini K. Parran, Angela Barker, and Marion Ehrich. Effects of thimerosal on NGF signal transduction and cell death in neuroblastoma cells. Toxicol Sci. 2005 Jul; 86(1): 132-140. Epub 2005 Apr 20 (copy enclosed).

To explicitly recognize that children may be exempt from vaccination and/or evidence of antibody titer or childhood disease should exempt children from receiving unnecessary vaccination, this commenter again proposes to amend the proposed amendments “at N.J.A.C. 8:57-4.10(h) through (j)” to read (with changes underlined for emphasis):

“8:57-4.10 Diphtheria and tetanus toxoids and pertussis vaccine

(a)-(d) (No change.)

(e) Unless exempt from vaccination or the child’s parent or guardian provides medical evidence of sufficient antibody titers or childhood disease, children seven [years of age and older] through nine years of age who have not completed this requirement shall receive Thimerosal-free tetanus and diphtheria toxoids (adult Td), where available, instead of DTP. Any [appropriately spaced] combination of three doses of DTP, DTaP, DT, or Td in a child [over age] seven through nine years of age shall be acceptable as adequate immunization for this vaccine series.

(f)-(g) (No change.)

(h) Unless exempt from vaccination or the child’s parent or guardian provides medical proof of sufficient antibody titers or childhood disease, every child born on or after January 1, 1996 and entering or attending Grade Six, or a comparable age level special education program with an unassigned grade on or after September 1, 2007, shall have received one dose of Tdap given no earlier than the tenth birthday.

(i) Children entering or attending Grade Six on or after September 1, 2007 who received a Td booster dose less than five years prior to entry or attendance shall not be required to receive a Tdap dose until five years have elapsed from the last DTP/DTaP or Td dose.

(j) Unless exempt from vaccination or the child’s parent or guardian provides medical proof of sufficient antibody titers or childhood disease, children born on or after January 1, 1996 and transferring into a New Jersey school from another state or country after September 1, 2007, shall have received one dose of Tdap, provided at least five years have elapsed from the last documented Td dose.”

- A new rule at N.J.A.C. 8:57-4.20 would require children born after January 1, 1996 and enrolled in Grade Six or transferring into a New Jersey school from another state or country to receive and one dose of meningococcal vaccine.”

First, this commenter’s in-depth review of the available “*meningococcal vaccine*” information has found that this vaccine provides no protection against the most prevalent (found in 50% of the clinical cases) strain, the “B” strain, of the disease and, at best, limited duration (< 5-year) protection of not more than 80 % of those vaccinated (**see** enclosed comments presented to VRBPAC committee meeting on September 22, 2004).

Second, the incidence of the disease in children in “Grade Six” for the meningococcal strains (A, C, W, and Y-135) where some protection is afforded is not sufficient to make this vaccination cost-effective for the public although it will certainly increase the vaccine makers’ already substantial revenues.

In addition, the multi-dose formulation of the Menomune vaccine is preserved with Thimerosal and presents an unnecessary risk of mercury poisoning to varying degrees to those administered this vaccine formulation.

Furthermore, though the manufacturer has proved that antibody titers can be boosted by additional doses, the other meningococcal vaccine, Menactra, has not been proven to stop those immunized from contracting meningococcal meningitis and has been linked to a higher-than-expected risk of Guillain-Barré syndrome.

For all of the preceding reasons, this commenter must oppose the addition of this vaccine to “*children born after January 1, 1996 and enrolled in Grade Six or transferring into a New Jersey school from another state or country*” because, above all, the current vaccines do not truly protect against the “*meningococcal*” disease and have other problems that the vaccine makers and the CDC have not fully disclosed.

Should the DHSS choose to ignore this commenter’s recommendation, then, if the DHHS is truly concerned about protecting children from unnecessary mercury exposure, the DHHS will, at a minimum, change the proposed “*new rule at N.J.A.C. 8:57-4.20*” to read (with changes underlined for emphasis):

“8:57-4.20 Meningococcal vaccine

- (a) Unless exempt from vaccination or they have a history of an adverse reaction to other vaccines, every child born on or after January 1, 1996 and entering or attending Grade Six or a comparable age level special education program with an unassigned grade on or after September 1, 2007 shall have received one dose of a Thimerosal-free meningococcal containing vaccine, such as the medically preferred meningococcal conjugate vaccine.
- (b) Unless exempt from vaccination or they have a history of an adverse reaction to other vaccines, every child born on or after January 1, 1996 and transferring into a New Jersey school from another state or country on or after September 1, 2007 shall have received one dose of Thimerosal-free meningococcal vaccine.”

“In addition, the Department is proposing to publish an Appendix to incorporate by reference as part of the subchapter, the required Annual Immunization Status Report and applicable instructions for completion.”

While this commenter has no problem with the preceding recommended change, the commenter notes that changes are being proposed for other portions of N.J.A.C. 8.57-4 and would propose changing the proposed text as follows (proposed changes are underlined for emphasis):

“8:57-4.7 Records required

- (a) Provided the child’s parent or guardian consents, every school, preschool, or child care center shall maintain an official State of New Jersey School Immunization Record for every pupil. This record shall include the date of each immunization and shall be separated from the child’s educational record and other medical records for purpose of immunization record audit. For those parents who do not consent, the school, preschool, or child care center shall recognize the right of privacy for the child’s parent or guardian and maintain the records of refusal in the child’s other medical records and no disclose said records without obtaining prior consent from the child’s parent or guardian prior to each disclosure.
- (b)-(e) (No change.)”

“8:57-4.11 Poliovirus vaccine

- (a) Except for those children who are exempt, every child less than seven years of age shall have received at least three doses of live, trivalent, oral poliovirus vaccine (OPV), or inactivated poliovirus vaccine (IPV) either separately, [or] in combination, or as a combination vaccine containing inactivated poliovirus, one dose of which shall have been

given on or after the child's fourth birthday or, alternatively, any [appropriately spaced] combination of four doses.

(b)-(c) (No change.)

(d) Except for those children who are exempt, for children seven years of age and older, any [appropriately spaced] combination of three doses of OPV or IPV shall satisfy the poliovirus vaccine requirement.

(e) (No change.)”

“8:57-4.12 Measles virus vaccine

(a) Except for those children who are exempt, every child born on or after January 1, 1990 shall have received two doses of a live measles-containing vaccine, or any vaccine combination containing live measles vaccine, such as the preferred measles, mumps, and rubella (MMR) vaccine, prior to school entrance. [for the first time into Kindergarten, Grade One, or a comparable age entry level special education program with an unassigned grade.] The first dose shall have been administered on or after the child's first birthday, and the second dose shall have been administered no less than one month after the first dose.

[(b) Except for those children who are exempt, every child born after January 1, 1990 attending or transferring into a New Jersey school from another state or country shall have received two doses of a live measles containing vaccine.]

Recodify existing (c) and (d) as (b) and (c) (No change in text.)

[(e)] (d) Except for those children who are exempt, children born on or after January 1, 1990, and enrolling in school (Kindergarten [or], Grade One, or a higher grade) [for the first time after September 1, 1995,] with no documented doses of measles vaccine, shall receive the second dose of measles or another measles- containing combination vaccine, no sooner than one month and no later than two months after receiving the first dose.

[(f)] (e) Children who present documented laboratory evidence of measles immunity shall not be required to receive the first or second dose of measles vaccine.

[(g)] (f) (No change in text.)”

“8:57- 4.15 Haemophilus influenzae type b (Hib) conjugate vaccine

(a) Except for those children who are exempt, every child from two to 11 months of age enrolling in or attending any child care center shall have received a minimum of two age-appropriate doses of a separate or a combination Hib conjugate vaccine, or fewer as appropriate for the child's age.

[(a)] (b) Except for those children who are exempt, every child from 12 to 59 months of age enrolling in or attending any child care center or preschool facility shall have received at least one dose of a separate or combination Hib conjugate vaccine, on or after the first birthday.

[(b)] Every a child from two months to 11 months of age enrolling in or appropriate doses of a separate or combination Hib conjugate vaccine, or fewer as appropriate for the child's age.]

Given the incidence of significant long-term adverse health problems associated with the hepatitis B vaccine, the actions of the government of France to abandon recommending universal vaccination of middle-school-age children because of the long-term increase in childhood diabetes and multiple sclerosis that it produced), the low incidence of hepatitis B in children whose mothers do not have hepatitis B in the United States (< 2 cases per million population), the failure of the immunization program to curtail hepatitis B cases in the vaccinated population indicating that antibody titers do not translate into long-term protective immunity (in spite of vaccination, the claimed percentage of those infected with hepatitis B is still the same 5% claimed before the federal government recommended universal hepatitis B vaccination), and the difficulty in transmitting this disease other than by contaminated blood transfusion, needle sharing by drug addicts, or intimate sexual contact, this section should be stricken since: a) hepatitis B is not an easily communicable disease in the United States and b) based on the decade plus of “in use” experience, vaccination has not significantly

decreased the disease incidence in the U.S. Therefore, this commenter recommends changing 8.57-4.16 to simply read:

“8:57-4.16 Hepatitis B virus vaccine

- (a) ~~Effective September 1, 2007, no child shall be required to have any hepatitis B vaccinations as a condition for attendance at any public or private school.~~
- ~~(a) Every child born on or after January 1, [1996]1990 shall have received three doses of hepatitis B vaccine, or any vaccine combination containing hepatitis B virus, prior to school [entrance]entry [for the first time] into a Kindergarten[,] through Grade [1]12, or a comparable age [entry] level special education program with an unassigned grade.~~
- ~~[(b) Children born on or after January 1, 1996, attending or transferring into a New Jersey school from another state or another country shall have received three doses of hepatitis B vaccine.]~~
- ~~[(c)] (b) Children born on or after January 1, [1996] 1990 attending or transferring into a New Jersey school [(Kindergarten and Grade 1), for the first time after September 1, 2001,] with no documented doses of hepatitis B vaccine, shall receive the first dose before entering school and shall receive a second dose of a hepatitis B-containing vaccine, no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose.~~
 - ~~1. A child entering school with one documented dose shall have no longer than six months to complete the three dose hepatitis B series.~~
 - ~~2. A child entering school with two documented doses shall have no longer than four months to complete the three dose hepatitis B series.~~
- ~~[(d) Every child born on or after January 1, 1990 and entering Grade 6, or a comparable age level special education program with an unassigned grade, on or after September 1, 2001 shall have received three doses of hepatitis B vaccine, or any vaccine combination containing hepatitis B virus.~~
- ~~(e) Children born on or after January 1, 1990 and transferring into a New Jersey school at the Grade Six or a higher grade level from another state or country on or after September 1, 2001, shall have received three doses of hepatitis B vaccine.~~
- ~~(f) Children born on or after January 1, 1990, attending or transferring into a New Jersey School from another state or country on or after September 1, 2001 with no documented doses of hepatitis B vaccine, shall receive the first dose before entering school, and shall receive a second dose of hepatitis B-containing vaccine no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose.]~~
- ~~[(g)] (c) Unvaccinated children 11 through 15 years of age who have not begun or completed the hepatitis B vaccine series, [and subject to the Grade Six hepatitis B requirement commencing September 1, 2001,] can be given two doses of any hepatitis B vaccine licensed and approved for a two dose regimen to satisfy the hepatitis B requirement. If the child is age eligible to receive the two dose regimen, the second and final dose shall be received no later than six months following the first dose.~~
- ~~[(h) Unvaccinated children 11 through 15 years of age who have not yet begun or completed the hepatitis B vaccine series, and subject to the Grade Six hepatitis B requirement commencing September 1, 2001, and who are eligible to enter, attend, or transfer into a New Jersey school in provisional status following receipt of the first dose of any hepatitis B vaccine licensed for a two dose regimen shall receive the second and final dose to complete that two dose series no later than six months following the first dose.~~
- ~~(i) Every child born on or before January 1, 1990 entering, attending, or transferring into a New Jersey school in Grades Nine through 12 or in a comparable age level special education program after September 1, 2003, shall have received three doses of a hepatitis B virus containing vaccine, or alternatively any two doses of a hepatitis B-containing vaccine licensed and approved for a two dose regimen administered to children 11 through 15 years of age.~~
- ~~(j) Unvaccinated children born on or before January 1, 1990 entering, attending, or transferring into a New Jersey school in Grades Nine through 12 on or after September 1, 2003 who have not completed the hepatitis B vaccine series are eligible to attend school in provisional~~

~~status following the receipt of the first dose of any hepatitis B vaccine dose. The child granted provisional status shall receive a second dose of hepatitis B containing vaccine no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose. If the child is age eligible to receive the two dose regimen, the second and final dose shall be received no later than six months following the first dose.]~~

[(k)] (d) (No change in text.)”

Failing the preceding, this commenter must recommend the text be changed to read:

“8:57-4.16 Hepatitis B virus vaccine

- (a) ~~Except for those children who are exempt, every~~ child born on or after January 1, [1996]1990 shall have received three doses of hepatitis B vaccine, or any vaccine combination containing hepatitis B virus, prior to school [entrance]entry [for the first time] into a Kindergarten[,] through Grade [1]12, or a comparable age [entry] level special education program with an unassigned grade.
- (b) Children born on or after January 1, 1996, attending or transferring into a New Jersey school from another state or another country shall have received three doses of hepatitis B vaccine.]
- [(c)] (b) ~~Except for those children who are exempt, children~~ born on or after January 1, [1996] 1990 attending or transferring into a New Jersey school [(Kindergarten and Grade 1), for the first time after September 1, 2001,] with no documented doses of hepatitis B vaccine, shall receive the first dose before entering school and shall receive a second dose of a hepatitis B containing vaccine, no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose.
 - 1. A child entering school with one documented dose shall have no longer than six months to complete the three dose hepatitis B series.
 - 2. A child entering school with two documented doses shall have no longer than four months to complete the three dose hepatitis B series.
- (d) Every child born on or after January 1, 1990 and entering Grade 6, or a comparable age level special education program with an unassigned grade, on or after September 1, 2001 shall have received three doses of hepatitis B vaccine, or any vaccine combination containing hepatitis B virus.
- (e) Children born on or after January 1, 1990 and transferring into a New Jersey school at the Grade Six or a higher grade level from another state or country on or after September 1, 2001, shall have received three doses of hepatitis B vaccine.
- (f) Children born on or after January 1, 1990, attending or transferring into a New Jersey School from another state or country on or after September 1, 2001 with no documented doses of hepatitis B vaccine, shall receive the first dose before entering school, and shall receive a second dose of hepatitis B containing vaccine no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose.]
- [(g)] (c) ~~Except for those children who are exempt, unvaccinated~~ children 11 through 15 years of age who have not begun or completed the hepatitis B vaccine series, [and subject to the Grade Six hepatitis B requirement commencing September 1, 2001,] can be given two doses of any hepatitis B vaccine licensed and approved for a two dose regimen to satisfy the hepatitis B requirement. If the child is age eligible to receive the two dose regimen, the second and final dose shall be received no later than six months following the first dose.
- [(h)] Unvaccinated children 11 through 15 years of age who have not yet begun or completed the hepatitis B vaccine series, and subject to the Grade Six hepatitis B requirement commencing September 1, 2001, and who are eligible to enter, attend, or transfer into a New Jersey school in provisional status following receipt of the first dose of any hepatitis B vaccine licensed for a two dose regimen shall receive the second and final dose to complete that two dose series no later than six months following the first dose.

- (i) Every child born on or before January 1, 1990 entering, attending, or transferring into a New Jersey school in Grades Nine through 12 or in a comparable age level special education program after September 1, 2003, shall have received three doses of a hepatitis B virus containing vaccine, or alternatively any two doses of a hepatitis B containing vaccine licensed and approved for a two-dose regimen administered to children 11 through 15 years of age.
 - (j) Unvaccinated children born on or before January 1, 1990 entering, attending, or transferring into a New Jersey school in Grades Nine through 12 on or after September 1, 2003 who have not completed the hepatitis B vaccine series are eligible to attend school in provisional status following the receipt of the first dose of any hepatitis B vaccine dose. The child granted provisional status shall receive a second dose of hepatitis B containing vaccine no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose. If the child is age eligible to receive the two-dose regimen, the second and final dose shall be received no later than six months following the first dose.]
- [(k)] (d) (No change in text.)”

In addition, this commenter would be recommending adding a new 8.57-4.24 and changing the proposed 8.57-4.24 to 8.57-4.25 as follows:

“8:57-4.24 Informed consent

- (a) The parent or guardian shall be advised in writing by school officials of the availability of an exemption for religious or medical reasons prior to each vaccination, required to sign that each has been informed of his or her exemption rights and understands those rights, given a copy of the document they have signed, and a copy of that signed notification of exemption form placed in the child’s admission records whenever a child is enrolled in a school.
- (b) For children currently enrolled, the school shall obtain a signed copy of a notification of exemption and place it in all of the enrollment records for each student enrolled within 120 days of the effective date of this regulation.
- (c) The penalty for a school to obtain a signed notification of exemption document shall be the loss of state funds for that student for each day that student is enrolled after the date that document is required to be a part of each child’s school admission records.”

“8:57-[4.24] 4.25 Penalties

Except as provided in 8:57-4.24, each violation of this subchapter shall be subject to the penalty set forth at N.J.S.A. 26:1A-10.”

“The Department will convene a public hearing on the proposed amendments and new rules between 10:00 A.M. and 12:00 P.M. on Friday, January 26, 2007 at the New Jersey Department of Health and Senior Services, First Floor Auditorium, Health and Agriculture Building, 369 South Warren Street (at Market Street), Trenton, NJ 08608. Persons wishing to comment on the proposal at the public hearing who wish to be placed on the list of speakers are requested to telephone Ms. Chari Otero at (609) 588-7520 by January 19, 2007 and to bring an extra written copy of their remarks for submission to the public record.

The public has until February 16, 2007 to comment on the notice of proposal. Persons wishing to comment on the proposal must submit their comments in writing to Angela Sorrells-Washington, Acting Program Manager, Vaccine Preventable Disease Program, Division of Epidemiology, Environmental, and Occupational Health, New Jersey Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369. Written comments on the proposal must be postmarked on or before February 16, 2007, which is the close of the 60-day public comment period. The proposed new rules and amendments, if adopted, would become operative on September 1, 2007 for the affected children in child care centers, preschools, and schools. Anyone with questions about the Vaccine Preventable Disease Program may call the Program at (609) 588-7520 or visit the Program website at <http://www.state.nj.us/health/cd/vpdphome.htm>.”

Hopefully, those reading these comments and the enclosed supporting documents will see that the commenter’s suggestions should be implemented.

Enclosures:

- David A. Geier, Paul G. King, and Mark R. Geier. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. **JAP&S (Journal of American Physicians and Surgeons)** 2006 Fall; **11**(3): 69-74.
- Tom Jefferson (a world recognized vaccine researcher). Influenza vaccination: Policy versus evidence. **BMJ (British Medical Journal)** 2006 October 28; **333**: 912-915.
- 27 December 2006 letter to Dr. Eddy A. Bresnitz, Deputy Commissioner/State Epidemiologist, DHSS, State of New Jersey, P.O. Box 360, Trenton, NJ 08625-0360.
- Damini K. Parran, Angela Barker, and Marion Ehrich. Effects of thimerosal on NGF signal transduction and cell death in neuroblastoma cells. **Toxicol Sci.** 2005 Jul; **86**(1): 132-140.
- Comments to VRBPAC September 22,2004 meeting on Aventis' Menactra® vaccine by public commenters Joseph Patrick Kepferle and Paul G. King, PhD