

# Facility Automation Management Engineering (FAME) Systems

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Wednesday, 28 January 2009

To All:

The text following this page is a draft response to: “**Some parents oppose New Jersey’s new flu vaccination law**”, updated 6:06 p.m. EST, by Melissa Morgenweck and Aparnaa Seshadri, which was downloaded late on Friday, 16 January 2009 from:

<http://www.cnn.com/2009/HEALTH/family/01/16/children.flu.vaccines/index.html>.

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This formal response, which is titled: “**A Draft Response To: ‘Some parents oppose New Jersey’s new flu vaccination law’**”, begins on the next page.

## Introductory Remarks

First, to “*simplify*” this response, when portions of the article being reviewed are addressed in the review, the statements in this report will be quoted in a “Times New Roman” font.

Second, remarks by this reviewer, Paul G. King, PhD, will be presented in indented text following the section of the article that is being reviewed.

In addition, this reviewer’s remarks and suggested changes will be in a **dark blue** “News Gothic MT” font except, when he quotes: **a)** from or refers to any US or New Jersey statute or regulation, the text will be in a “Lydian” font or **b)** from other sources, the quotations will be in an “Arial Narrow” font.

When this reviewer quotes from statements made in the authors’ article, this reviewer will use an *italicized* “Times New Roman” font; suggested corrections, *if any*, will be made in **red**.

Finally, should anyone find any significant factual error for which they have published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and revise his views and the final response.

Respectfully,

<ds>

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## A Draft Response To: “Some parents oppose New Jersey's new flu vaccination law”

### INTRODUCTION

Lest anyone take this reviewer's responses as those of someone who is anti-vaccine, this reviewer again reiterates that, *given the scientific information available*, he currently supports national vaccination programs for those vaccines that have *truly* been proven to be both generally safe and, *at least*, societally cost-effective, provided the individual parent's, guardian's, or competent citizen's constitutional right to "due process of law" is neither abridged nor ignored.

Having made clear his position as an advocate for:

- a. Banning the use of mercury compounds in medicine to safen vaccines,
- b. Vaccine safety, and
- c. Medically cost-effective vaccines,

this reviewer will now respond to the title and statements made in this article by its authors, Melissa Morgenweck and Aparnaa Seshadri.

### “Some parents oppose New Jersey's new flu vaccination law”

MORRISTOWN, New Jersey (CNN) -- Since the beginning of the year the family clinic at the Children's Hospital of New Jersey has seen an influx of young children coming in for flu shots.

New Jersey requires children from 6 months to 5 years old to get the flu vaccine to attend daycare or pre-school.

The rush for vaccinations is prompted by a new law that makes New Jersey the only state requiring children between 6 months and 5 years old to get the flu vaccine to attend a licensed daycare or pre-school. The deadline for the flu shot requirement was December 31.”

While the preceding statements simply reflect and report what the public is being lead to believe, the facts are slightly different from those that the authors are reporting:

1. Among other changes, the New Jersey regulations for vaccination were modified in 2008 to add a single annual influenza vaccination for children 6 months to 59 months of age (4 years and 11 months of age and not 5 years [60 months] of age) as per the New Jersey Administrative Code (NJAC) set forth in NJAC 8:57 “Subchapter 4 IMMUNIZATION OF PUPILS IN SCHOOL” at:

“8:57-4.19 **Influenza vaccine**

Children six months to 59 months of age attending any child-care center or preschool facility on or after September 1, 2008, shall annually receive at least one dose of influenza vaccine between September 1 and December 31 of each year”.

2. Though the requirement stated December 31, 2008 as the compliance date, the New Jersey Department of Health and Senior Services (NJ DHSS) set a January 14, 2009 as the date for initial compliance with New Jersey influenza vaccination requirements, but it apparently hasn't rigidly enforced this date.
3. Currently, the requirement for this vaccine only applies to children attending a “child-care center or preschool facility”.
4. This influenza vaccination requirement does not negate satisfying this obligation

by means of a medical exemption (8:57-4.3 Medical exemptions) or a religious exemption (8:57-4.4 Religious exemptions).

5. Though not specified in the regulations, the NJ DHSS has set the exclusion period for children 6 months to 59 months of age not in compliance with NJAC 8:57-4 from about January 1, *the date by which annual compliance is expected*, to March 31, *the nominal date for the end of the influenza season in New Jersey*, of each year.

“Some parents are upset about the requirement. John General and Alnisa Bernabela brought their 4-year-old twins Jahmein and Jameir to the clinic last week for the flu shots.

"I'm really not okay with it because I think it should have been my choice," said Bernabela.

"By them forcing this, I feel like our rights have been violated," said General, holding his crying son Jameir being vaccinated.”

To the extent that the NJ DHSS has not fully informed parents about all of the means of complying with the requirement for an annual influenza vaccination: medical exemption, religious exemption, or vaccination, then the rights of parents, like “*John General and Alnisa Bernabela*”, have clearly been violated.

These parents may have had a choice besides vaccination.

However, *given the omission of the options besides vaccination from this and other articles*, neither the NJ DHSS nor healthcare providers nor public health officials nor obviously the authors of this article are informing the parents of all their options.

“Last fall, hundreds of parents with the New Jersey Coalition for Vaccination Choice challenged the flu shot requirement at a rally in Trenton, New Jersey. The NJCVC and parents interviewed by CNN, expressed concern about the safety of influenza vaccines and possible long-term effects on young children.”

The NJCVC and parents interviewed by CNN may have “*expressed concern about the safety of influenza vaccines and possible long-term effects on young children*” as the writers report here.

However, in reality, the NJCVC is simply challenging the state government to give the public the right for each parent to choose: **a)** which vaccines are given to each child and **b)** when the vaccines chosen are to be given to each child.

Given:

- The serious adverse reactions that a child may have to a vaccination,
- The increasing number of vaccines and doses of vaccines,
- The failure to ban all use of Thimerosal (49.55% mercury by weight) in the manufacture of all vaccines (and the fact that most doses of influenza vaccine approved for children are Thimerosal preserved),
- The increasing body of evidence that childhood vaccination is linked to epidemic increases in the rates for chronic childhood disease (e.g., asthma, autism spectrum disorders, diabetes, Kawasaki's, cancers [especially certain childhood leukemias], multiple sclerosis, obesity and other autoimmune-linked conditions),
- The failure of vaccine industry and the federal government to only include those

vaccines that are proven to be both: **a)** sufficiently safe and **b)** truly in-use cost-effective in the national vaccination program,

- The failure of the State of New Jersey Department of Health and Senior Services (NJ DHSS) to only add vaccines to the New Jersey schedule where the New Jersey data clearly shows the vaccine is cost-effective and truly provides long-term protection to almost all (>95%) of those children vaccinated from getting the diseases for which they have been vaccinated – not:
  - *Some protection from some of the prevalent strains of the disease (e.g., vaccines for Neisseria meningitidis [Sanofi’s Menactra® and Menomune® meningococcal vaccines] with no protection from others, or, worse,*
  - *Possibly some protection from possibly one or two strains of the strain types of a virus based on what is guessed to be the circulating virus, but, in most years, misses on one or more of the strains in the vaccine (e.g., the current influenza vaccines), and*
- The deaf ear that New Jersey public health officials, the federal and New Jersey government, and the New Jersey healthcare establishment continue to turn to: **a)** the preceding realities and **b)** parental concerns,

the NJCVC is simply advocating for the parents of New Jersey to have the right to choose which vaccines are given to their children and when they are given.

As the recent outbreak of pertussis (whooping cough) in fully vaccinated children in Hunterdon County as well as the US annual rates for pertussis relative to diphtheria (for the DTaP/Tdap vaccines) and mumps relative to measles (for the MMR vaccine) in the vaccinated population clearly indicate, these vaccine components do not provide as complete or long-term protection to many of those who have been vaccinated.

Moreover, in the case of Merck’s MMR® II live-virus measles, mumps and rubella vaccine, for the vaccinated, vaccination appears to postpone the risk for contracting mumps from childhood, *where the risk of serious side effects is small and, in males, the risk of sterility is non-existent, to adulthood, where the risk of serious side effects is significantly higher and, in males, diminished fertility and, in some cases, total sterility are known to occur.*

Given the preceding realities, this reviewer not only understands but also supports the right of a parent to choose which vaccines, and when, to give them to his or her child.

“But the New Jersey Department of Health says the new law is for the public good citing Centers for Disease and Control and Prevention numbers showing an average of 20,000 children under age 5 are hospitalized nationwide each year because of influenza complications.”

Since:

1. This reviewer can find no valid data that shows that vaccination with the influenza vaccine protects those vaccinated from getting influenza – only data showing some percentage (>65%) of those vaccinated develop “adequate” antibody titers against the three strains in the vaccine that was administered,
2. Most of the in-use reviews of effectiveness have shown that this vaccination is not in-use effective in preventing those vaccinated from getting influenza, and
3. Without citing any peer-reviewed published large-scale population studies, the NJ DHHS is “citing Centers for Disease and Control and Prevention numbers showing an

*average of 20,000 children under age 5 are hospitalized nationwide each year because of influenza complications” – which is not the number of children who are hospitalized each year with influenza because the numbers published by the “Centers for Disease and Control and Prevention” [CDC] are known to include those hospitalized with pneumonia during the “influenza season”,*

the only obvious “public good” that this regulation, *not law*, does is to provide the manufacturers of the influenza vaccines approved for use in children, Sanofi, Novartis and MedImmune, more “guaranteed” customers for their vaccines, which, *based on in-use studies*, have been found to be ineffective in protecting the children vaccinated with them from getting influenza.

“‘Parents are certainly concerned about the health and safety of their children,’ says Dr. Christina Tan, state epidemiologist for the New Jersey Department of Health. ‘But it's equally important to understand that the flu vaccine is safe and effective in preventing illness, not only in children, but also among the community as a whole.’”

This reviewer agrees, *“Parents are certainly concerned about the health and safety of their children”*.

However, this reviewer finds that Tan’s:

*“But it's equally important to understand that the flu vaccine is safe and effective in preventing illness, not only in children, but also among the community as a whole”,*

to be, at best, problematic.

First, *regardless of the statements made*, the Thimerosal-preserved formulations of the influenza vaccines have not been proven to be “safe” to the minimum standard, “sufficiently nontoxic ...”, required of the manufacturers by a binding federal current good manufacturing practice (CGMP) regulation (21 CFR § 610.15(a)).

Second, in violation of the binding regulations requiring this proof of safety before a vaccine formulation can be approved by the US Food and Drug Administration (FDA) as set forth in 21 CFR § 601.4(a), the FDA has approved these Thimerosal-preserved drugs and their manufacturers have distributed them without proof of safety.

However, *because they have not been proven safe to one of the requisite CGMP safety standard minimums*, “sufficiently nontoxic ...”, Thimerosal-preserved vaccines are “deemed to be adulterated” drugs under 21 U.S.C. § 351(a)(2)(B).

Thus, these Thimerosal-preserved influenza vaccines are “adulterated” drugs that cannot be legally distributed (see 21 U.S.C. § 331(a)).

Third, this reviewer, one of the authors in the retrospective study<sup>1</sup> that reviewed the in-use effectiveness of the influenza vaccine in the USA from 1979 through 2000, can find no large-scale retrospective effectiveness study, *including the smaller Ontario study, where a universal program has been in place for several years*,<sup>2</sup> which has shown that influenza vaccination programs are in-use effective in preventing those who receive an influenza vaccine from getting influenza.

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<sup>1</sup> Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *JAPS (Journal of American Physicians and Surgeons)* 2006 Fall; **11**(3): 69-74.

<sup>2</sup> <http://www.cbc.ca/health/story/2006/05/02/flu-shots060502.html> - Flu cases didn't drop with Ontario's free shots: study. Last Updated: Tuesday, May 2, 2006 | 4:28 PM ET CBC News

Therefore, based on the preceding facts, this reviewer must conclude that Tan's remarks are, *at a minimum*, unsupported by the published in-use large-scale studies in the USA<sup>1</sup> and the Province of Ontario in Canada<sup>2</sup>.

“Many doctors support the decision, saying it helps protect a higher risk population.”

Here the writers are essentially stating that we should vaccinate our children with influenza vaccines that are ineffective in protecting our children from getting influenza to help “*protect a higher risk population*”.

Since the only large “*higher risk population*” is the “elderly”, it appears that these unnamed “*doctors*” are recommending parents vaccinate their children with an ineffective vaccine (which has a risk of serious side effects, including death, for some children) in order to protect the elderly from contracting influenza since in-use studies have shown that vaccinating the elderly does not protect them from getting influenza. [Note: Even if the flu shot were effective, what ethical society is willing to place its children at risk in order to protect its elderly?]

Carrying these absurdities to their logical conclusion, an avowed vaccine apologist and consultant to most of the manufacturers of US-approved influenza vaccines, W. Paul Gelzen, MD, who reports “receiving consulting fees from Sanofi Pasteur, GlaxoSmithKline, Roche, Novartis, MedImmune, and Merck and research support from MedImmune”, first recognizes that the influenza vaccination programs for children and the elderly are not effective in preventing children and the elderly from getting influenza.

However, *citing a prior article that he authored (reference 22) in the recent **New England Journal of Medicine** article*, Gelzen recommends:

“Given strong evidence that immunization of healthy persons benefits the community,<sup>22</sup> I would extend this recommendation to include universal vaccination, although I recognize the need for an improved infrastructure in order to achieve this goal”.<sup>3</sup>

Given:

- a. On-going problems with influenza-strain mismatch in most years,
- b. The lack of disease-prevention effectiveness in the population segments with high uptake percentages (children and the elderly), and
- c. The fact that, *unlike measles*, influenza is not a highly contagious disease,<sup>4</sup>

it is not rational to:

- Recommend universal vaccination (given the proven failure of the Ontario's universal influenza vaccination program to reduce influenza cases),
- Mandate that our children be vaccinated with an influenza vaccine (because vaccinating the population will cause serious adverse reactions, including serious long-term injury and death, for some of those who are vaccinated) in order to protect some “*higher risk population*”,

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“Ontario's free vaccine program doesn't appear to have curtailed annual outbreaks of influenza, but some experts are questioning the study's conclusions and the province's lack of record keeping.

Ontario began paying for flu shots for residents in 2000, at a cost of more than \$50 million a year.”

<sup>3</sup> Gelzen WP. Prevention and Treatment of Seasonal Influenza. *New England Journal of Medicine*, 2008 December; **359**: 2579-2585.

<sup>4</sup> Cannell JJ, Zasloff M, Garland CF, Scragg R, Giovannucci E. On the epidemiology of influenza. *Virology*. 2008 Feb 25; **5**: 29. [Among the issues this paper addresses, this recent electronically published review article reports the lack of high sick-to-well infectivity for human influenza.]

since the in-use studies have clearly shown childhood vaccination does not protect the vaccinated children from getting influenza.

Moreover, if these unnamed doctors truly wished to protect the “*higher risk population*”, then they would be advocating universal testing for the level of 25-OH vitamin D in each person and, *for those with levels below about 50 ng/mL (125 nmole/L)*, recommending appropriate supplementation with vitamin D-3.<sup>5</sup>

This is the case because there is growing evidence that otherwise healthy children and adults who have adequate levels of vitamin D are protected from getting clinical cases of influenza.

“Kids under the age of 5 are targeted by this recommendation because when they get the disease they get sicker than adults do. They also are the ones who are more likely to transmit the flu because they are in closed quarters,” said Dr. Nwando Anyaoku, who heads the clinic at the Children's Hospital of New Jersey. She says influenza tends to peak in New Jersey towards the end of January through early February.”

With respect to Anyaoku’s unsupported assertions:

1. “*Kids under the age of 5 are targeted by this recommendation because when they get the disease they get sicker than adults do*”, and
2. “*They also are the ones who are more likely to transmit the flu because they are in closed quarters*”,

this reviewer must reject them, because:

- The elderly, *who are adults*, are the ones the studies have shown get the sickest in terms of illness intensity, duration and death, and decades of increasingly intensified coverage of the elderly has failed to significantly reduce disease incidence, disease severity, and fatal outcomes in the vaccinated elderly, and
- The reported highest rates of transmission of influenza are in the “workplace” and not at home, where family members, *including children less than 5 years of age*, are usually in closer contact for longer periods than in the “workplace”, where, *for children*, day-care centers and preschool facilities are the “workplace”.

Moreover, the factors governing transmission of influenza are much more complex than simple confinement and exposure.<sup>4</sup>

“Jennifer Frank says she's committed to the public health goal but not on the state's schedule. Her 2-year-old son Caleb was hospitalized twice for extreme eczema as an infant. At one point, he was on a feeding tube, and she says he couldn't get vaccinated.

‘There was literally no clear space to put a needle,’ says Jennifer Frank.

Caleb's doctors were stumped and couldn't make a diagnosis for his condition. Since then, the Franks with their pediatrician's approval, have Caleb on a delayed vaccination schedule. As a result, they didn't meet the state's December 31 flu shot deadline and now their local board of health has banned

Caleb from pre-school.

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<sup>5</sup> a. Cannell JJ, Hollis BW. Use of vitamin D in clinical practice. *Altern Med Rev.* 2008 Mar; **13**(1): 6-20.  
b. Cannell JJ, Vieth R, Umhau JC, Holick MF, Grant WB, Madronich S, Garland CF, Giovannucci E. Epidemic influenza and vitamin D. *Epidemiol Infect.* 2006 Dec; **134**(6): 1129-1140.

‘When he gets his shots, that same rash flares up,’ says Joshua Frank, the father of Caleb. ‘You know, it’s frightening. It’s very real. And for them to say, ‘Well, we don’t care, even though your doctors agree with you,’ is outrageous.’

“The Franks have appealed the local board of health’s decision all the way to the state level, but officials have not wavered. While New Jersey does offer medical exemptions for some children, the rules are specific, and eczema is not considered a valid medical reason for delaying the flu vaccine.”

This reviewer, accepting the accuracy of the information reported, finds that the preceding is an example of an uncaring “public health” bureaucracy that has failed to address, much less, protect the health of this child.

Thus, this example clearly confirms the need for the “conscientious exemption” legislation contained in New Jersey bills: A 260 and S 1071.

“‘By allowing broader exemptions this could potentially erode the very core of protection,’ says Tan.”

Based on the data, compiled by the State of Florida in 2008, from the CDC’s “Summary of Notifiable Diseases --- United States, 2006”, as published in the on-line version of the *MMWR*, 2008 March 21; **55**(53); 1-94, and census population estimates for the percentages of the population, this reviewer has taken the reported disease case information and, after verifying its general accuracy, calculated estimates of how the reported numbers reflect on the incidence of disease cases in the 18 states, where about 42% of the population of the USA resides, which have a full conscientious/ philosophical exemption, as compared to the USA as a whole.

The results of the reviewer’s efforts can be found in **Table 1**, which can be found on the next page.

Overall, since there was no significantly higher overall disease incidence in the 18 states with a “conscientious” exemption than in those without, Tan’s concerns seem to be unfounded and they most certainly are not supported by the reported experience data.

Moreover, the proposed “conscientious exemption” law would:

1. Grant equal protection under the law to those parents and guardians who, *because they are not religious (e.g., agnostics and atheists) or the religious schools their children attend do not recognize religious exemptions, currently cannot elect to exempt their children from vaccination.*
2. *Because it would permit selective vaccination exemption, allow the parent or guardian the flexibility to permit certain vaccinations and only seek exemption from each vaccination for which the parent or guardian held an objection unlike the current religious exemption which exempts the child from all future vaccinations until revoked.*
3. Provide the flexibility the Franks are seeking because there is nothing that prevents them from changing their mind about the conscientious exemption for each vaccine for which they currently seek an exemption at a time when, *based on their sincerely held objection, they no longer object to giving their child a particular vaccine.*



**Table “1”: 2006 Comparison of Vaccine-Preventable Disease Cases, Among States with Philosophical Exemptions for Immunizations, Florida and U.S.**

2006	Measles* (incidence/ 100,000)	Mumps** (incidence/ 100,000)	Rubella* (incidence/ 100,000)	Tetanus* (incidence/ 100,000)	Pertussis* (incidence/ 100,000)	Hep B acute* (incidence/ 100,000)	Polio (paralytic)*	Diphtheria**
Arizona	0	40 (0.631)	0	1 (0.016)	508 (8.01)	unreported	0	0
Arkansas	0	8 (0.282)	0	1 (0.035)	112 (3.95)	87 (3.07)	0	0
<b>California</b> [12% of US pop.] % of US Total [% of 12%]	<b>6</b> (0.016) <b>10.9</b> [90.9] <sup>1,3</sup>	<b>31</b> (0.085) <b>0.471</b> [3.93] <sup>1,3</sup>	<b>1</b> (0.003) <b>9.09</b> [75.8] <sup>1,3</sup>	<b>11</b> (0.030) <b>26.8</b> [223] <sup>2,3</sup>	<b>1,749</b> (4.78) <b>11.2</b> [93.3] <sup>3</sup>	<b>427</b> (1.17) <b>9.06</b> [75.5] <sup>3</sup>	<b>0</b>	<b>0</b>
Colorado	1 (0.021)	51 (1.04)	0	0	710 (14.6)	34 (0.70)	0	0
Idaho	0	7 (0.47)	0	0	88 (5.87)	15 (1.0)	0	0
Louisiana	0	3 (0.07)	0	3 (0.07)	24 (0.56)	63 (1.47)	0	0
Maine	0	0	0	0	174 (13.2)	26 (1.97)	0	0
Michigan	1 (0.001)	84 (0.079)	1 (0.001)	3 (0.003)	632 (6.27)	141 (1.40)	0	0
Minnesota	1 (0.019)	180 (3.46)	0	0	320 (6.16)	32 (0.616)	0	0
New Mexico	0	3 (0.152)	0	0	147 (7.46)	24 (1.22)	0	0
North Dakota	0	14 (2.19)	0	1 (0.156)	43 (6.72)	1(0.156)	0	0
Ohio	0	45 (0.392)	0	3 (0.026)	644 (5.62)	123 (1.07)	0	0
Oklahoma	0	10 (0.276)	0	1 (0.028)	64 (1.77)	96 (2.65)	0	0
<b>Texas</b> [7.8% of US pop.] % of US total [% of 7.8%]	<b>0</b> <b>0.88</b> [11.4] <sup>4</sup>	<b>58</b> (0.243) <b>0.88</b> [11.4] <sup>4</sup>	<b>0</b> <b>2.4</b> [31.2] <sup>4</sup>	<b>1</b> (0.004) <b>2.4</b> [31.2] <sup>4</sup>	<b>954</b> (3.99) <b>6.1</b> [79.2] <sup>4</sup>	<b>833</b> (3.48) <b>17.7</b> [230] <sup>4</sup>	<b>0</b>	<b>0</b>
Utah	0	5 (0.189)	0	1 (0.038)	779 (29.4)	26 (0.98)	0	0
Vermont	0	0	0	0	110 (17.7)	4 (0.64)	0	0
Washington State	2 (0.031)	42 (0.649)	0	0	377 (5.83)	74 (1.14)	0	0
Wisconsin	0	842 (15.0)	0	0	221 (3.94)	33 (0.59)	0	0
<b>Total of states above</b> % of US Total [% of 36%] <sup>5</sup> [% of 42.5%] est. pop % in 18 states}	<b>11</b> (0.008) <b>20.0</b> [55.6] {47.1}	<b>1,423</b> (1.09) <b>21.6</b> [60.0] {50.8}	<b>2</b> (0.0015) <b>18.2</b> [50.5] {42.8}	<b>26</b> (0.020) <b>63.1</b> [176] {148%}	<b>7,656</b> (5.89) <b>49.0</b> [136] {115%}	<b>2,039</b> (1.57) <b>43.3</b> [120] {102}	<b>0</b>	<b>0</b>
<b>Florida</b> [6% of US pop.] % of US Total [% of 6%]	<b>4</b> (0.022) <b>7.3</b> [122] <sup>6</sup>	<b>15</b> (0.082) <b>0.23</b> [3.8] <sup>6</sup>	<b>1</b> (0.005) <b>9.1</b> [152] <sup>6</sup>	<b>2</b> (0.011) <b>4.9</b> [81.7] <sup>6</sup>	<b>228</b> (1.25) <b>1.5</b> [25.0] <sup>6</sup>	<b>420</b> (2.30) <b>8.9</b> [148] <sup>6</sup>	<b>0</b>	<b>0</b>
<b>U.S. Total</b>	<b>55</b> (0.180)	<b>6,584</b> (2.15)	<b>11</b> (0.004)	<b>41</b> (0.013)	<b>15,632</b> (5.11)	<b>4,713</b> (1.54)	<b>0</b>	<b>0</b>

\* Confirmed Cases \*\*Confirmed and Probable Cases

<sup>1</sup> Since the vaccine given is the MMR vaccine, the average of the percentages should show effect of philosophical exemption if and only if the MMR average is > 100% of the expected level based on the population. For MMR, the average percentage is 90.9% of the expected % based on California’s total population.

<sup>2</sup> For the DTaP vaccine, taking Diphtheria as “0” and excluding Pertussis, that average is 46.7% of the expected level – indicating that California’s “exemption effect is, if anything to REDUCE disease incidence over expected. [Note: Pertussis excluded because vaccine is not truly effective.]

<sup>3</sup> Moreover, for California, the most populous state, excluding Tetanus and Hepatitis B cases because most cases in California occurred in adults and Pertussis because the vaccine is not in-use effective, the average level for the other 3 diseases, where cases were reported in the USA in 2006, is less than 57% of the expected percents.

<sup>4</sup> For Texas, the second most populous state, excluding Pertussis and Hepatitis B cases because most cases occur in adults, the average level for the other 4 diseases, where cases were reported in the USA in 2006, is less than 11% of the expected percents.

<sup>5</sup> Presuming that, on average, the 18 states have a total population that is about the same % of the U.S total population as the 18 states are of the 50 states, then the data indicate that the philosophical exemption’s only significant effect on cases observed is seen with the DTaP and the Hep B vaccines. Since no cases are seen for diphtheria, the effect for the DTaP vaccine again indicates that this vaccine may not provide adequate long-term protection for the tetanus (most cases in the elderly) and overall protection for the pertussis component. For Hep B, one could argue that philosophical exemption may have contributed to an apparent “20%” excess in disease cases; however, this is probably an artifact because most cases of acute hepatitis B are found in adults and not in Hep-B vaccinated children.

<sup>6</sup> For Florida, with the 4<sup>th</sup> highest population and no philosophical exemption, excluding Pertussis and Hepatitis B cases because most cases occur in adults, the average level for the other 4 diseases, where cases were reported in the USA in 2006, is less than 90% of the expected percents.

Thus, *unlike Tan's view*, this reviewer finds that adding the "conscientious exemption" would permit parents that have a "sincerely held ... objection" only for the influenza vaccines to omit it from the vaccination schedule for their children and, thus, improve the "*core of protection*" for the other vaccines in New Jersey's current mandated program.

"But the Franks believe the new law should include an appeal procedure, especially for families like theirs that are willing to vaccinate their children."

Given the current language proposed in A 260 and S 1071, with underlining added for emphasis:

"'Conscientious exemption' means an exemption from a mandatory immunization on the grounds of a sincerely held or moral objection to the immunization",

it is clear that this exemption permits a parent or guardian to select the one or more vaccines to which he or she objects but does not require the parent or guardian to object to all vaccines.

Thus, the current bills need no "*appeal procedure*" as only any "sincerely held ... objection" is all that is required – "*especially for families... that are willing to vaccinate their children*" but *currently* have sincerely held objections to the schedule for one, or more, vaccines, but not for all because the proposed bills read:

" 2. a. The department shall provide to all local health departments a standardized form to be used by a student, or if the student is a minor, by the student's parent or legal guardian, claiming a conscientious exemption from a mandatory immunization. A local health department shall make the form available upon request.

The form shall state that the student, or parent or legal guardian, understands the potential benefits of immunization and the risks in not immunizing. The form shall require, at a minimum, all of the following:

(1) a statement claiming exemption from a specific immunization signed by the student, or if the student is a minor, by the student's parent or legal guardian, witnessed by the local health officer or the local health officer's designee;

(2) the name and address of the person who signs the form;

(3) the name of the student seeking exemption from the immunization; and

(4) the school at which the student is enrolled.

b. Upon receipt of a completed form by a local health department, the designated local health officer shall grant a conscientious exemption from a mandatory immunization to a student. A student who is granted a conscientious exemption shall provide the form granting the exemption to officials at the student's school."

"New Jersey Republican Assemblywoman Charlotte Vandervalk has been working on legislation to allow parents to decide which vaccines they want their child to receive.

"The bill gives conscientious objection so that people can opt out of certain vaccines. Maybe they want some vaccines and not others and this would give them the right to do that," said Vandervalk."

This reviewer finds that, *as written*, the bills in both houses of the New Jersey legislature currently permit the flexibility alluded to by Assemblywoman Vandervalk.

"For now, though, Caleb must remain out of school. He's confused as to why he can't return.

"He doesn't understand what's going on," says Jennifer Frank. "It's been hard to explain it to him."

This reviewer understands how hard it can be to explain to a child why he cannot go to school.

“The New Jersey Department of Health says it won't immediately know what kind of effect the new flu shot requirement will have on the state's population.

‘As far as trying to identify whether there's actually a drop in disease incidence in the community, that's going to be a longer term type of evaluation that we're starting to look at,’ says Tan.”

Since all of the previous scientifically sound large-scale in-use retrospective studies for influenza vaccination in children and/or the population of the USA or, *where universal influenza vaccination was offered*, the population of the Province of Ontario in Canada have failed to find any statistically significant change in influenza infection rates after correcting for all of the confounding factors, this reviewer understands that Tan's closing remarks are designed to postpone any assessment of the effectiveness of this program for as long as possible because, *for the reasons previously stated*, influenza vaccination programs are not effective in preventing clinical influenza cases in those who have been inoculated with an influenza vaccine.

Further, *based on limited evidence*, the reality is that the live bio-engineered influenza vaccines made by MedImmune can and, *in some instances*, actually have, spread the influenza virus from those who are inoculated to others and, *since viral mutation is possible*, the viruses that the live-virus flu vaccines contain may interact with other viruses to become much more virulent than the original strain from which they are derived.

### **Concluding Remarks**

As a supporter of vaccines and vaccination programs that are reasonably safe and at least societally cost-effective, the author understands that the current New Jersey mandated vaccination programs have:

- A few safety issues (e.g., all vaccine programs that allow vaccines that: **a**) are Thimerosal-preserved at the “30- to 100-ppm” level of Thimerosal (“15-50 ppm” for mercury) or **b**), *by inference*, those that contain a reduced level of Thimerosal at the “2-ppm” level (“1 ppm” of mercury) as well as all vaccines that contain live viruses,
- Some overall in-use effectiveness issues (e.g., **a**) the influenza vaccines as a group, the childhood vaccines for herpes varicella zoster [Merck's Varivax®] “varicella” vaccine], **b**) the hepatitis B vaccines for children, **c**) the pneumococcal conjugate vaccine [Wyeth's Prevnar®], **d**) the Haemophilus influenzae type b conjugate [Hib] vaccines [Sanofi's ActHIB®, GlaxoSmithKline's OmniHIB®, Merck's PedvaxHIB®, and Wyeth' HibTITER®], **e**) the meningococcal vaccines [Sanofi's Menomune® and Menactra® vaccines] and **f**) the combination vaccines containing any of the preceding vaccine actives as a component),
- Many cost-effectiveness problems (in general, all of the vaccines that are not in-use effective as well as the now 5-DTaP doses plus 1-Tdap dose [plus boosters of Tdap every “ten” years] for diphtheria, tetanus and pertussis, and **b**), in cases where a third dose is being recommended after giving birth or before college, the Merck's MMR® II measles, mumps, and rubella vaccine),

which the NJ DHHS should immediately address.

Since the USA and the State of New Jersey are facing hard economic times, this would be an ideal time for the NJ DHSS to reassess the cost-effectiveness issues and remove

from its mandates for any vaccination program that is not in-use effective or not truly cost-effective — substituting improved patient health and hygiene as well as the alternative treatment measures that are currently used for each mandated vaccination program that might be removed from New Jersey’s vaccination program mandates.

Moreover, the NJ DHSS should address the problems with its vaccination program mandates in a manner that is:

- Truly public-health cost-effective and
- Free of the pernicious influence of those who directly and/or indirectly profit from:
  - More vaccines and/or
  - Expanding mandated vaccination programs that are intentionally blind to the rise in, *and the long-term costs of*, the chronic childhood diseases, which the affected children, their families and the public must bear.

If the NJ DHSS continues to oppose the current “conscientious exemption” bills and the language contained therein, then public health officials and the NJ DHSS should be prepared for their intransigence to be the proverbial “last straw” that will trigger a movement to repudiate all vaccination mandates because they will be knowingly ignoring the actual fiscal and physical harm that those vaccination mandates, *which are scientifically indefensible*, have caused, are causing, and will cause.

Finally, in conjunction with this response, this reviewer recommends that the writers, the NJ DHSS and the parents should carefully study this reviewer’s in-depth two-part review of the September 2008 report issued by the Florida Department of Health, and the report itself, as posted in the “**Documents**” section on the CoMeD Internet website: <http://www.mercury-freedrugs.org><sup>6</sup>.

### **About the Reviewer:**

Information about this reviewer, Paul G. King, PhD, can be found on the Internet at: <http://www.dr-king.com/>.

This reviewer received no compensation for this review; and, other than his advocacies, has no conflicts of interest.

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<sup>6</sup> These reviews are freely available for download from the “**Documents**” web page of the CoMeD Internet website: <http://www.mercury-freedrugs.org/>. For example, the most recent 2-part review, “**A Draft Review of: 'Florida Governor' Task Force on Autism Spectrum Disorders- Task Force Requests to the Florida DoH', Part 1** (17 October 2008; 68 pages)” and “**A Draft Review of: 'Florida Governor' Task Force on Autism Spectrum Disorders- Task Force Requests to the Florida DoH', Part 2** (17 October 2008; 77 pages)” [along with the report that was reviewed, “**Florida’s Governor’s Task Force on Autism Spectrum Disorders - Task Force Requests to the Florida DoH** (16 Sept. 2008; 49 pages)”], contains a detailed analysis of the current childhood vaccination programs that *dispassionately* assesses the in-use medical cost-effectiveness of the current vaccines and their associated vaccination programs.