

Original: 2142

Oct 1, 2000

Mr. Robert Harrison
14th floor, Harrisburg
333 Market St
Harrisburg, Pa 17101
Near Mr. Harrison,

I have sent a letter to my
State Senator, Rep and the Director
of Immunization Division, and as well
to you. That I am oppose to the
proposed amendment that would
mandate the chickenpox vaccine
for all children in Pennsylvania.
This is a benign childhood illness
and children are recovering vaccine
now, this is too much.
There are many reasons
why a parent may not want
to use this vaccine.

Sincerely,
Mrs. Jennifer Hupp
166 Rt 66
Cupalls, Pa 15613

RECEIVED
2000 OCT 12 AM 10:10
LABORATORY
REVIEW COMMISSION

IRRC

From: Sandra Grafius [sgrafius@csrlink.net]
Sent: Sunday, October 01, 2000 10:17 AM
To: IRRRC@irrc.state.pa.us
Subject: re: pending action on mandate on chicken pox vaccine

I saw, in the October 1st. Williamsport Sun-Gazette, that the public comment period on the mandatory chicken pox vaccine ends on Monday.

I am personally against mandating additional vaccines for students at this time owing to the fact that no conclusive evidence has been given that these and other vaccines are not contributing to an increase in allergies and asthma for these same students and no proof has been shown to exclude the theory that these same vaccines may be contributing to other health problems as well.

There was evidence for a number of years that the pertussis vaccine in use in other countries was known to be a more safe vaccine with fewer side effects than the one in use in the United States but it took many years to license the less harmful vaccine. This decision impacted many families and we, as parents, currently have no way of knowing that the chicken pox vaccine may not yield the same results at some point in the future.

Every vaccine that is mandated leaves the door open for further mandates and more possibility of detrimental impact from problems with certain factors within these vaccines. I will not argue that some of the vaccines have greatly reduced disease and mortality but I also feel that our natural defenses are being circumvented. We cannot possibly know for certain that there will not be an unwanted effect from the use of the increasing number of vaccines. We do know that not every child being immunized would be infected in the natural course of a particular disease.

I also discovered today, through the PA State Government web site, that much assistance has been given to Merck by our state government, and cannot help but wonder if this may have any impact in any decision to mandate this vaccine given the fact that Merck is the only source of the chicken pox vaccine. I was also surprised to note that there are only four vaccine manufacturers in the United States, all located in Pennsylvania. Does this mean that our children will be used to test all future vaccines?

I apologize for the length of this message but know that the Independent Regulatory Review Commission will be making the final decision on this vaccine and wished to make known my concerns. I have also addressed my concerns to Senator Madigan.

Thank you,

Sandra Grafius

1591 West Southern Avenue
South Williamsport, PA 17702

RECEIVED

2000 OCT 10 PM 2:18

LABORATORY
REVIEW COMMISSION



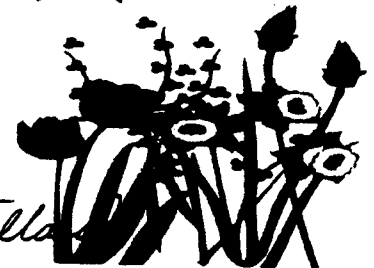
Oct 1, 2000

FROM THE DESK OF
CHRISTINE STALLARD

To all it may concern,

I am 100% against the mandatory
Chicken Pox vaccination. There is not enough
study information openly available. Think
before you do something dangerous to our
children. Maybe 95% would be OK after
the shot. What about the other 5%? Are
you willing to become God and take that
5% chance on one of your children, grand-
children, neighbor or relative? Thank you
for listening.

Sincerely
Christine Stallard



Original: 2142

Jeannie Allshouse Santoro D.C.
1466 Bristol Drive
South Park, Pennsylvania 15129

RECEIVED

2000 OCT 10 PM 2:18

REVIEW COMMISSION



October 1, 2000

Pennsylvania Department of Health
PO Box 90
Harrisburg, Pa 17108

Attn: Alice Gray
Director of Immunization Division

Dear Ms. Gray,

My purpose for this letter is multifaceted. I first want this letter to serve as part of public record that I am vehemently opposed to including the Varicella vaccines into the mandated list of vaccinations for children.

There is considerable research showing the dramatic negative effects of the other mandated vaccinations millions of children are exposed to, yet these poisons are injected into babies and children every day. Adding the Varicella vaccine to this list will only increase the risks to more children.

This disease is not severe to a child. When a child's body is allowed to go through all the steps of proper immune response, permanent immunity to this will result. This is not the case with vaccinations in general, and specific to this case, there has not been research to show how long the supposed immunity will last after the child is immunized.

My opinion is this vaccine's primary purpose is for one's convenience in their work and for their employers. Chicken Pox is quite uncomfortable, and it makes the entire household upset, because it is often passed to other siblings, and the illness period is a week or more per child. This time frame does not often fit conveniently into the parents or their bosses work schedule.

I am acutely aware of the risks of these vaccines, and so is the Federal Government of the United States. The Vaccine Injury Compensation Program was established for that very purpose.

I am opposed to this mandate on the specific reasons stated above, as well as more generally. The decision whether to vaccinate our children, or not should only be the decision of the parents of the child. The state or federal government should, never mandate health care on any level. This country was founded on the basis of freedom from persecution. Implementation of this policy to me would be a persecution of my moral and ethical beliefs, similar to the religious beliefs our founding fathers died to implement and protect.

The key to ultimate health is not found in a syringe filled with weakened, killed, or altered viruses which are made compatible for a long shelf life by additionally adding human fetal cells, formaldehyde, and aluminum. Instead we as a society need to focus on why each individual, when exposed to the same stressor will respond differently.

Please do not make this proposed policy part of the Pennsylvania law. The health of millions of children hangs in the balance of this decision.

As a doctor and mother, I appreciate your time and concern to this important matter. I would appreciate a written response to my letter. You can send it to my home.

Sincerely,


Jeannie Allshouse Santoro D.C.



Original: 2142

October 1, 2000

Ms. Alice Gray

Director, Immunization Division

Pennsylvania Department of Health

P.O. Box 90

Harrisburg, PA 17108

RECEIVED
2000 OCT 10 PM 2:18
VACCINE REVIEW COMMISSION

Dear Ms. Gray:

As a parent and grandparent living in Pennsylvania I am concerned about the issue of the Varicella vaccine for chicken pox and the possibility of its becoming mandatory that all children in Pennsylvania would be required to have this vaccination.

It is my understanding that this vaccine has not been evaluated or tested for the carcinogenic potential, mutagenic potential or the impairment of fertility or reproductive capacity and the duration of protection is unknown at the present time. I worry about the adverse affects and possible death from this vaccine.

Would you please inform me as to why you feel that it is necessary for all children to have this vaccination, or any child for that matter.

I am anxiously awaiting your reply.

Sincerely,

Richard R. Orr

Richard R. Orr

538 Euclid Ave.

P.O. Box 474

Saegertown, PA

16433

Please copy to:

10/00

Original: 2142

Dear MR. Arthur Coccodrilli
MR. Robert Harbison
MR. John Mignea

Please oppose the proposed amendment that would mandate the chicken pox vaccine for all kids in PA. Too many vaccines are already given. It is time for parents to exercise their right to informed consent. Thank you for your consideration.

Sincerely,

Rob + Susan Gauthier

RR2 Box 172

Thompson, PA 18465

INDEPENDENT REGULATORY
REVIEW COMMISSION

2008 OCT -6 AM 9:05

RECEIVED

Original: 2142

Johanna Sanfilippo
225 Talcott Road
Waterford, PA 16441

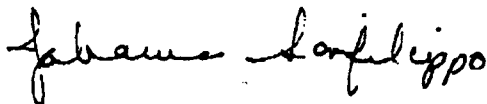
September 30, 2000

Alice Grey
Director, Immunization Division
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

I am writing this letter in response to PA dept. of health's request for public comment. I oppose the proposed mandate for the chicken pox vaccine. I request that this letter is made part of the public record.

I understand that the vaccine can and will be able to be available for parents who want to have it administered to their child. I believe, however, that parents should be the ones to make the decision of whether or not we want our children to receive the vaccine. I do not believe that this vaccine has been around long enough to have been properly evaluated and tested. We are the ones who have to live with the consequences of the vaccine or chicken pox (a benign childhood illness). Please let us, as parents, make the decision whether or not and when to vaccinate our children!

Sincerely,



RECEIVED

2000 OCT -6 AM 9:35

INDEPENDENT REGULATORY
REVIEW COMMISSION

10

Original: 2142

September 30, 2000

Ms. Alice Gray
Division Director of Immunization
P.O. Box 90
Harrisburg, PA 17108
Fax (717) 772-4309

RECEIVED
2000 OCT -6 AM 9:35
REVIEW COMMISSION

Dear Ms. Gray,

Subject: Proposed Changes to the Pennsylvania State Statute Immunization Mandate

I am writing in response to the proposed changes to the present Pennsylvania State Statute Immunization Mandate. I request that you add this letter, and my one attachment to the public comments on this issue.

Of all the changes to the mandate my main concern is the addition of the chickenpox (varicella) vaccine to the required list of vaccinations for entry into school, and for school attendance.

One of the most important considerations is the lack of a public health emergency from the natural chickenpox disease. In addition, there is the absence of significant data accounting for the overall benefit / risk ratio to society at large. No one knows if preventing chickenpox in children is truly in the best interest of society or the public health. This is a medical opinion that cannot be substantiated with any hard scientific data. Not all citizens of the commonwealth, let alone members of the medical community, agree with the attempt at a requirement of chickenpox vaccine for all children in the state.

While it is fortunate that the vaccine is available as a health care option, a mandate, in the absence of a public health crisis, and with the amount of uncertainty surrounding the long term implications for society as a whole, is unwarranted.

According to the Centers for Disease Control (CDC) statistics, the total death rate for chickenpox disease, in the nation, is 0.0023% (falling to 0.0013% in children alone), and the hospitalization rate is 0.25%. This means that 99.75% of all cases are complication free. No illness should be considered trivial, but neither should chickenpox, in most instances, be labeled as "severe". One does not need to be a doctor to comprehend such statistics.

Perhaps, then, it was a mistake to have initiated this vaccine program in the youngest members of society, preventing them from contracting chickenpox as children, and it is potentially dangerous. It might have been more appropriate to recommend vaccination for susceptible adults because they are at highest risk for complications of the disease.

Children should not be denied the opportunity to contract the disease, which is most typically benign in childhood and can offer them lifetime immunity. In fact, the American Medical Association, in their Encyclopedia of Medicine (1989), recommends "all healthy children be exposed to the disease so they can catch it at an age when it is no more than an inconvenience." What has happened in the past 6 years to make the severity of this illness change? Chickenpox is still chickenpox, it is not shingles.

I hope that these points help to clarify why the Department of Health should not follow through with this mandate at this time. Clearly, there are too many unanswered questions and too few definitive answers to mandate this vaccine as a matter of public policy. In the absence of a public health emergency, the right of individuals to make informed health care decisions should be upheld.

Please include the press release from "The National Vaccine Information Center" that I have enclosed in my public comments, for it speaks directly to the issues I am concerned with regarding the mandating of the varicella vaccine.

Sincerely,

Carolyn Morelli, P.O. Box 173, Mill Village, PA. 16427 (814) 796-0000

September 13, 2000

Press Release

From Barbara Loe Fisher of the National Vaccine Information Center

<http://www.909shot.com>

Calling the FDA report on adverse events associated with Merck's chicken pox (chicken pox) vaccine published in today's Journal of the American Medical Association a "breakthrough" in the follow-up and public disclosure of reports made by doctors and parents to the Vaccine Adverse Event Reporting System (VAERS), the National Vaccine Information Center (NVIC) applauded public release of the VAERS data but challenged the authors' conclusion that the vaccine's risks are minimal.

"We have been getting reports from parents that their children are suffering high fevers, chicken pox lesions, shingles (herpes zoster), brain damage and death after chicken pox vaccination, especially when the vaccine is given at the same time with MMR and other vaccines. This FDA report confirms our concern that the chicken pox vaccine may be more reactive than anticipated in individuals with both known and unknown biological high risk factors," Barbara Loe Fisher, president of NVIC.

In the VAERS data made public today, it was reported that VAERS had received 67.5 adverse event reports per 100,000 doses of chicken pox vaccine sent between March 1995 and July 1998 for a total of 8,574 reports. 82 percent of the adverse event cases occurred in individuals who received chicken pox vaccine only. Admitting that under-reporting made the figures "highly variable fractions of actual event numbers," the authors reported that approximately 4 percent of cases (about 1 in 33,000 doses) were serious, including stroke, convulsions, encephalitis, thrombocytopenia and 14 deaths.

The VAERS data has led to the addition of 17 adverse events to the manufacturer's product label since the vaccine was licensed for use in 1995, including secondary bacterial infections (cellulitis), secondary transmission (infection of close contacts), transverse myelitis, Guillain Barre syndrome and herpes zoster (shingles).

"We have been waiting for the FDA to follow-up on VAERS reports and then disclose and utilize the VAERS data to increase our knowledge about vaccine reactions and possible high risk factors. This is how parents and Congress expected the vaccine adverse event reporting system to be utilized when it was centralized under the National Childhood Vaccine Injury Act of 1986. However, the conclusions drawn by the authors do not match the substance of the data presented," said Fisher.

Based on today's published report on chicken pox vaccine, the National Vaccine Information Center is calling for a halt to simultaneous administration of chicken pox vaccine in combination with other vaccines, particularly MMR, until the vaccine can be further evaluated for short and long term reactivity, particularly in immune compromised individuals such as asthmatics and those sick at the time of vaccination.

"This vaccine should not be mandated," said Fisher. "There are too many questions about the true adverse event and efficacy profile of this relatively new live virus vaccine and it is up to the manufacturer marketing the vaccine and the federal agencies regulating the vaccine to conduct further follow-up on this important VAERS report," said Fisher.

P.O. Box 173
Mill Village, PA 16427
Phone: 814-798-4000
Fax: none



Fax

To: Alice Gray	From: Carolyn Morrell			
Fax: 717-772-4309	Date: October 2, 2000			
Phone: [Click here and type phone number]	Pages: 2			
Re: Chickenpox Mandate: Pennsylvania	CC: [Click here and type name]			
<input type="checkbox"/> Urgent	<input type="checkbox"/> For Review	<input type="checkbox"/> Please Comment	<input type="checkbox"/> Please Reply	<input type="checkbox"/> Please Recycle

Comments: Please enter the following documents in the public comment on chickenpox vaccination mandate.

*Carolyn
Morrell*

Original: 2142

JIM BRADY D.C.
121 HEARTWOOD RD
LEVITTOWN, PA 19056
9-30-2000

ALICE GRAY
DIRECTOR , IMMUNIZATION DIV.
PA DEPT OF HEALTH
PO BOX 90
HARRISBURG, PA. 17108
1717-787-5681

RE: OPPOSITION TO MANDATORY VACCINATION

I AM SUBMITTING THIS LETTER IN RESPONSE TO PDH'S REQUEST FOR PUBLIC COMMENTS. I STRONGLY OPPOSE THE PROPOSED MANDATE FOR THE VARICELLA VACCINES. I REQUEST THAT THIS LETTER BE MADE PART OF THE PUBLIC RECORD AND THAT PDH RESPOND IN WRITING TO MY COMMENTS.

THIS VACCINE AS WELL AS OTHER VACCINATIONS ARE CURRENTLY AVAILABLE TO ANY CHILD IN PA WHOSE PARENT WANTS IT ADMINISTERED; THE ISSUE HERE IS THAT THE PDH'S PROPOSAL WILL MAKE IT ILLEGAL IF A PARENT WANTS TO EITHER DELAY ONE OF THESE VACCINES OR NOT GIVE IT AT ALL.

I URGE PDH TO WITHDRAWAL THESE RULES. THERE ARE MANY VALID REASONS WHY A PARENT MAY NOT WANT THEIR CHILD IMMUNIZED. PARENTS ARE CAPABLE OF MAKING INFORMED DECISIONS ABOUT THE HEALTH CARE OF THEIR CHILDREN AND MUST NOT BE PLACED IN A POSITION IN WHICH EXERCISING A CONSCIENTIOUS OBJECTION TO THE ADMINISTRATION OF THIS VACCINE MEANS BREAKING THE LAW. LEAVE THIS DECISION WHERE IT BELONGS, IN THE HANDS OF THE PARENTS. IT WILL BE THE PARENTS AND THE CHILDREN WHO LIVE WITH THE CONSEQUENCES OF A MEDICAL DISABILITY CAUSED BY THE VACCINE NOT THE PDH.

IS PDH READY TO ASSUME ALL EMOTIONAL AND FINANCIAL RESPONSIBILITY FOR ANY HARM CAUSED TO A CHILD BECAUSE OF MANDATORY VACCINATION ? I THINK NOT.

JIM BRADY D.C.



Original: 2142

418 West Main Street
Evans City, PA 16033
September 26, 2000

SEP 29 2000

RECEIVED

2000 OCT 10 PH 3: 51

REVIEW COMMISSION

The Honorable Mary Jo White
Room 168, Main Capitol Bldg.
Harrisburg, PA 17120

Dear Senator White:

We are writing this letter to you as parents who are living in your district and who oppose the Pennsylvania Department of Health's proposed rules implementing a mandate for the Varicella Vaccines. This vaccine is currently available to any child in Pennsylvania whose parents want it administered; the issue here is that the Pennsylvania Department of Health's proposal will make it illegal if a parent wants to either delay one of these vaccines or not give it at all. These proposals blatantly disregard parental rights and the basic human right of informed consent to medical procedures.

Immunizations are a medical procedure that can cause serious reactions and even death for some. The Vaccine Injury Compensation Program has paid out over 1 billion dollars in damages to families for injuries and deaths caused by vaccines. There are thousands of other families who have reported adverse affects caused by vaccines and have been placed with the burden of proof of determining that vaccines have cause harm to their children. We are a family of the latter.

Our son had a serious reaction to the MMR vaccine. He is now left with autism and mental retardation. We have the difficult job of proving that it indeed was the vaccine that caused his condition. There is no doubt in our minds that the vaccine did cause this damage to our little boy; unfortunately, we are not doctors and cannot perform medical research on our own. We can only explain what our son was like prior to the vaccine and report the events that occurred afterward. Our family suffers every day because of the predicament we were placed in. We thought that we were protecting our son by allowing his doctor to vaccinate him. We wish now that more research had been done on vaccinations and that we were allowed an educated choice. We thought that we were protecting our son; whereas, we allowed someone else's values and choices to determine our son's life. We would like to extend an invitation to you to visit our home and meet our little boys. You will then be able to see first hand what damage can be caused by vaccines and parents who believed in their doctors and medical community. Please take advantage of this invitation and RSVP us at 724-538-5953 so that we can set up a time convenient for all.

There are many valid reasons why a parent may not want to use these vaccines. Parents are capable of making informed decisions about the health care of their children and must not be placed in a position in which exercising a conscientious objection to the administration of this vaccine means breaking the law. Leave this decision where it should be, in the hands of the parents. It will be the parents and children who live with the consequences of a health problem precipitated by this vaccine, not the Pennsylvania Department of Health.

Sincerely,

Davy & Mary Wildman
Davy and Mary Wildman

Original: 2142

Christine Svetz
10365 Nancy Drive
Meadville, PA 16335

September 29, 2000

Independent Regulatory Review Committee
14th Floor
Harristown 2
333 Market Street
Harrisburg, PA 17101

RECEIVED

2000 OCT -3 AM 8:36

INDEPENDENT REGULATORY
REVIEW COMMISSION

Dear Mr. Coccodrilli, Mr. Harbison and Mr. Mizner,

Below is the body of a letter I wrote to the Public Health Department regarding the proposed mandate of the Varicella Vaccine to all Pennsylvania children. I have great concern over the prudence of this decision. Please take a moment to read my concerns and stop this proposal now.

Ms. Alice Gray, Director, Immunization Division:

I am submitting this letter in response to PDH's request for public comments. I strongly oppose the proposed mandate for the Varicella vaccines. I request that this letter is made part of the public record and that PDH respond in writing to my comments.

This vaccine is currently available to any child in Pennsylvania whose parent wants it administered; the issue here is that PDH's proposal will make it illegal if a parent wishes to delay or opt out of giving the vaccine.

I am one of the parents who actually opted to give this vaccine to my children. It is a decision that I greatly regret now that I know more facts about the vaccine. As stated by the manufacturer, varivax vaccine has not been "evaluated or tested for their carcinogenic potential, mutagenic potential or for impairment of fertility" or "reproductive capacity" and "the duration of the protection is unknown at present". Those statements scare me. I now believe all that I have done in giving my sons this vaccine is delayed the disease, potentially to their adult years when it is so much more dangerous to have. Many doctors I have talked to since making this decision have expressed grave concern over this vaccine.

Additionally, my youngest son participated in the Merck vaccine trial through University of Pittsburgh Medical Center, which combined the varicella vaccine with the MMR vaccine. My son is autistic. In light of the recent research done by Dr. Andrew Wakefield and Dr. Vijendra Singh, I have grave concerns about whether the MMR is a contributing factor to my son's autism. And I gave that to him with an additional untested vaccine - I lay awake many nights wondering what kind of damage I may have done to him. My doctor, who recommended we participate in this trial, cannot give me any information about the results of the trial. That makes me very leery.

Please give this proposal very serious consideration. In light of the many proven cases of childhood vaccine damage and the current research signaling more suspicions, mandating a vaccine for a rather harmless childhood disease does not make sense. Let parents decide what is right for their children until such time that proper long-term research has been done. I am living with the possible effects of vaccine damage. You are not.

Sirs, thank you for taking the time to address this important issue. I hope you will listen to the mothers of Pennsylvania and hear their concerns.

Sincerely,


Christine Svetz

Original: 2142

J. Clark and Margaret C. Echols

September 29, 2000

Alice Gray
Director, Immunization Div.
PA Dept of Health
Box 90
Harrisburg, PA 17108

RECEIVED
2000 OCT 10 PM 3:51
LEGISLATIVE
REVIEW COMMISSION

I am writing in response to your request for public comments regarding the proposed mandate for the Varicella vaccines. I request that this letter is made part of the public record.

It appears to me that the proposed mandate would make it illegal if a parent makes an educated decision to delay administering this vaccine, or even choose not to give it at all. This puts parents like us in an untenable position. We desire to be law abiding. At the same time, we believe this vaccine is unnecessary and potentially dangerous.

I urge the PA Dept of Health to withdraw these rules. We are perfectly capable of making decisions about the health of our children. Because this is a normal childhood disease, which ought to be allowed to run its course so as to give the child a lifelong immunity.

Please do not put us in the position of having to choose between doing what we believe is best for our children and obedience to the law.

Sincerely,

J. Clark Echols, Jr.

cc: Senator Harold Mowery
Senator Mary Jo White
Representative Guy Travaglio

Original: 2142

To: Alice Gray
Director, Immunization Division Pennsylvania Dept. of Public Health
From: Gary Svetz

Date: September 29, 2000

Re: Chickenpox Vaccine

I wanted to write this letter concerning the newly developed Chick Pox vaccination program.

I am not an anti-vaccination advocate but I am very much aware of the continuous research on the potential negative vaccination impact on our children and the continuous avoidance and head in the sand mentality by the medical profession to say enough is enough of the over vaccination schedule that we put our children through. The research that has been done in regards to the MMR vaccination would give any normal person with any common sense and professionalism a reason to doubt vaccination mercury content and Thimerosal that leads to toxicity levels in our young children's body. Before we were educated and made aware of the potential dangers of multiple vaccines in one and health factors along with parent profiles that lead themselves to a higher percentage of children immune behavioral disorders **WE WERE IN LINE WITH VACCINATION PROCEDURES.** If this is anyway related to economics of the administration of children's health just review the after vaccination impact that parents with children with behavioral disorders that endure personal financial hardship and place a tremendous burden on the health and welfare system in our country. Reference the State of California's investment in the Mind Institute. Prevention is key and the tool to reduce those incidents is not the continuous and blind usage of vaccination. If our three and a half old Autistic son could talk he would echo our thoughts and wishes to you. He was the recipient of the chicken pox / MMR vaccination combination trial at 13 months.

Good decisions our based on data, fact and common sense not medical ego.

Pennsylvania Leader Among States ?

In the Land of the Free , We are Free to do as we are told !

*Comment by a British Doctor and Researcher
Referencing the United States Vaccination Program
DAN Conference 2000*

Sincerely,

Gary M. Svetz

REVIEW COMMISSION
LABORATORY

2000 OCT 9 - 100 0000
AM 9:34

RECEIVED

2000 OCT -6 AM 9:35

REGULATORY
REVIEW COMMISSION

Original: 2142

9-29-00

KERRY A. KEARNEY

255 Park Rd

Atguyppa Pa. 15001

Alice Gray
Immunization Div
Pa Dept Health
PO Box 90
Harrisburg Pa. 17108

RECEIVED
PA DEPT. OF HEALTH
00 SEP 32 PM 2:58
DIVISION OF IMMUNIZATION

Re: Chicken Pox Vaccine
I oppose mandatory

vaccines of chicken pox because the
cost is not outweighed by the
benefit. Even with severe thousand
hospitalizations of chicken pox sufferers,
there are no deaths or serious sequelae.

I have been very involved
with vaccines since the early 1980s.
There is no perfectly safe vaccine.

All have adverse events associated
with them. The risk of serious
allergic adverse event (which
are not well understood by
immunologists and which cannot be
predicted) is greater than the
benefit of the vaccine. If certain
parents want their little ones
vaccinated (and many will),
parents should have that choice.

Terry Kearney
724.378.8819.

J. Clark and Margaret C. Echols

Original: 2142

September 29, 2000

Alice Gray

Director, Immunization Div.

PA Dept of Health

Box 90

Harrisburg, PA 17108

I am writing in response to your request for public comments regarding the proposed mandate for the Varicella vaccines. I request that this letter is made part of the public record.

It appears to me that the proposed mandate would make it illegal if a parent makes an educated decision to delay administering this vaccine, or even choose not to give it at all. This puts parents like us in an untenable position. We desire to be law abiding. At the same time, we believe this vaccine is unnecessary and potentially dangerous.

I urge the PA Dept of Health to withdraw these rules. We are perfectly capable of making decisions about the health of our children. Because this is a normal childhood disease, which ought to be allowed to run its course so as to give the child a lifelong immunity.

Please do not put us in the position of having to choose between doing what we believe is best for our children and obedience to the law.

Sincerely,

J. Clark Echols, Jr.

cc: Senator Harold Mowery
Senator Mary Jo White
Representative Guy Travaglio

RECEIVED
2000 OCT -6 AM 9:34
LEGISLATIVE
REVIEW COMMISSION

RECEIVED
2000 OCT -6 AM 9:35

LABORATORY
REVIEW COMMISSION

Sept. 29, 2000

Alice Gray
Director, Immunizations Division
Pennsylvania Dept. of Health
P.O. Box 90
Harrisburg, Pa. 17108

I am submitting this letter in response to P.D.H.'s request for public comments. I oppose the proposed mandate for the Varicella vaccine. I request that this letter is made a part of the public record and that P.D.H. respond in writing to my comments.

This vaccine is currently available to any child in Pa. whose parent wants it administered, the issue here is that P.D.H.'s proposal will make it illegal if a parent wants to either delay one of these vaccines or not give it at all.

In most children, chicken pox is a benign childhood illness that frequently gives the child lifelong immunity. According to the vaccine manufacturer, this vaccine has not been evaluated or tested for previous children to ^{that} effect. My children & grandchildren are not to be experimented on. Forcing a vaccine on a healthy child is not acceptable.

Immunizations is a medical

procedure that can cause reactions
and death in some. The Vaccine
Injury Compensation Program has paid
out over 1 billion dollars in damages
to families for injuries & death caused
by vaccines.

I urge PDH to withdraw these
rules. There are many valid reasons why
a parent may not want to use this
vaccine. Parents are capable of making
informed decisions about the health
care of their children & must not be
placed in a position in which
they may have to go against an unjust
law. Leave the decision in the hands
of the parents.

Sincerely,
Mrs. Stephanie Vaughn
666 Rt. 66
Apalachicola, Fla 32512

RECEIVED
PA DEPT. OF HEALTH
00 SEP 32 PM 2:55
DIVISION OF REGULATIONS

Original: 2142

September 29, 2000

Alice Gray
Division Director of Immunization
PA Dept of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
2000 OCT -6 AM 9:35
LEGISLATIVE
REVIEW COMMISSION

Alice,

I am writing to you in regard to the proposed change in the existing PA state vaccine mandate. I ask that you add this letter to the public comment.

I am very concerned about the proposed addition of the chickenpox (varicella) vaccine to the list of required vaccinations. These are some of the issues the health department should look at more closely when making their recommendation on this mandate:

- The natural disease offers lifetime immunity, while the vaccine effectiveness wanes. No one knows exactly how or when a booster schedule can be successfully implemented. Merck states in their package insert for the varicella vaccine, "duration of protection is unknown."

- Without the childhood vaccine mandate for chickenpox, anyone who does not contract the disease as a child can choose to be vaccinated as an adult or adolescent.

- Scientists are concerned about the long-term effects of viral DNA from live-virus vaccines being incorporated into human genes.

- The marketing of this vaccine by both the manufacturer, Merck & Co., and the American Academy of Pediatrics, is mainly focused on the economic consideration of parental work loss and the inconvenience of a child missing school, rather than on any pressing health issue facing the public. The chief of the Pediatric Infection Disease Department of New England's Medical Center, who has also participated in the development of the chickenpox vaccine has stated, "Studies suggest that widespread use of the varicella vaccine will be cost effective, primarily through a reduction in the number of work days missed by parents caring for sick children."

- There is insufficient data showing that the administering of the chickenpox vaccine with other vaccines is safe, let alone individually. (Reference JAMA article, "Postlicensure Safety Surveillance for Varicella Vaccine," September 13, 2000)

- According to Merck's own fact sheet on their Varivax Varicella vaccine, "Varivax has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility."

I not only request that Pennsylvania does not mandate the chickenpox vaccine, but also that when looking over the other proposed regulation changes, vaccine safety as a whole, is emphasized. The special expanded issue of the Congressional Quarterly Researcher (Aug 25, 2000, Vol. 10, No. 28, Pages 641-672), entitled "Vaccine Controversy," should be referenced.

Having personally attended the House Government Reform Committee's hearings on vaccine

safety and informed consent, I witnessed Congressman Dan Burton (Indiana, R) investigating childhood vaccine safety issues. These investigations should be of particular interest to the State Public Health Department, who are looking at changing existing vaccine regulations. I would hope they would take time to review this important information.

In closing, I cannot emphasize enough the importance of careful consideration of this mandate. Its ramifications are many and far-reaching, affecting the health of our children and families. Please consider all the facts when making recommendations to our state mandate.

Sincerely,

Carolyn Donikowski

Carolyn Donikowski
10833 Barton Rd.
Waterford, PA 16441
814/825-1071

MR. AND MRS. JOHN D. ANTESBERGER II

Original: 2142

September 29, 2000

Alice Gray
Director, Immunization Division
PA DEPT OF HEALTH
PO BOX 90
HARRISBURG PA 17108

RECEIVED
2000 OCT -6 PM 9:35
IMMUNIZATION DIVISION
PA DEPT OF HEALTH
HARRISBURG PA

Dear Ms. Gray:

We are submitting this letter in response to PDH's request for public comments regarding the Varicella vaccine and do hereby request that this letter be made part of the public record and that PDH respond in writing to its reception.

We stand in firm opposition to the proposed legal mandate of the administering of the Varicella vaccine. We hold that this draconian methodology violates the inalienable rights of the parents in determining the welfare of their children and it also stands in direct opposition to the principle of *subsidiarity* held in our Roman Catholic faith. Parents are more than adequately capable of making informed decisions about the health care of their children and **must not** be placed in a position in which exercising a conscientious objection, based upon religious conviction, to the administration of this vaccine constitutes breaking the law.

We appreciate the rationalized concern for our financial well-being:

Chickenpox is a highly contagious disease that may result in discomfort, severe illness and death to the child. The disease may cause absence from school, which could have a deleterious effect on the child's school career. A child's illness from chickenpox can result in a parent or guardian expending money to treat an otherwise preventable disease, as well as causing worry and absence from work to care for the child.

And we do understand the purely civic financial concerns as well:

The CDC noted in a 1997 study that for every dollar spent for chickenpox (varicella) vaccine, \$5.40 is saved in indirect health benefit costs (work lost) and direct medical costs. Requiring chickenpox (varicella) immunity will therefore save money for both the Commonwealth and the public.

But we strongly oppose the exclusive financial rationale while completely disregarding the religious beliefs of the electorate:

Subsection (b) would make clear that a child in school in this Commonwealth who has not received immunizations as listed in subsection (a), **for whatever reason**, would be required to receive the immunizations listed in subsection (b) as a condition of continued attendance. [Our emphasis]

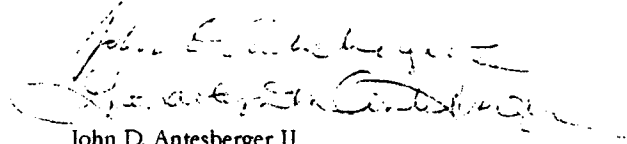
As this vaccine is rushed to market without qualitative empirical evidence and without a substantial need dictating its mandate, in the final analysis, it will only be the parents and children who will have to live with

September 29, 2000

the consequences of any health problems precipitated by the enforced administering of the Varicella vaccine, not PDH; the inevitability consequent legal action, however, could have drastic financial ramifications for both the Commonwealth and the public as well.

We support the primacy of parental choice, we staunchly oppose the usurpation of parental rights and we hold that this approach does not deny health care to our children; conversely, it may actually prevent its future necessity.

Sincerely,



John D. Antesberger II

Gwendolyn M. Antesberger

Original: 2142



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Children's Hospital
Denver, Colorado

ANTHONY S. THALL, MD
Ohio Health Medical Center
Cleveland, Ohio

LEWIS W. TEPFERMAN, MD
New York University Hospital
New York, New York

JAYCE WELLS
Portland, Connecticut

September 29, 2000

Ms. Alice Gray
Director, Division of Immunization
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Ms. Gray,

On behalf of the American Liver Foundation, our Delaware Valley Chapter and thousands of ALF's members in Pennsylvania, I am writing in support of your proposed rule requiring 7th graders to be immunized against hepatitis B.

Hepatitis B virus infection is the leading cause of chronic liver disease. The majority of individuals who have chronic hepatitis B were infected as children. Therefore, routine vaccination of children is clearly the most effective way to reduce the incidence of hepatitis B in Pennsylvania over time.

Currently, the vast majority of infants and children have been routinely immunized for hepatitis B by their pediatricians over the past several years. A huge gap, however, exists among adolescents who were not vaccinated because this practice only became routine recently. This requirement, if implemented, will close this gap in protection against hepatitis B.

We know that the only way to assure that all children in Pennsylvania are protected from hepatitis B is through a school entry requirement. Without this proposed requirement we will not defeat this disease. Immunization of 11-12 year-olds for hepatitis B is in keeping with the recommendations of the Centers for Disease Control and Prevention, American Academy of Pediatrics and American Academy of Family Physicians. The prestigious Hepatitis B Foundation in Doylestown also supports this school entry requirement.

In closing, we urge your support of this important public health measure.

Sincerely,

Alan P. Brownstein
President and CEO, MPH

RECEIVED
2000 OCT -6 AM 9:34
REVIEW COMMISSION



FACSIMILE TRANSMITTAL SHEET

TO: Ms. Alice Gray	FROM: Jason Price
COMPANY: PA Dept of Health	DATE: OCTOBER 2, 2000
FAX NUMBER: 717-772-4309	TOTAL NO. OF PAGES INCLUDING COVER: 2
PHONE NUMBER: 717-787-5681	SENDER'S TELEPHONE NUMBER: 212-668-1000
RE:	SENDER'S FAX NUMBER: 212-483-8179

URGENT
 FOR REVIEW
 PLEASE COMMENT
 PLEASE REPLY
 FOR YOUR INFO

NOTES/COMMENTS:



Original: 2142

Pennsylvania Academy of
FAMILY PHYSICIANS

RECEIVED

2000 OCT -6 AM 9:35

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September 28, 2000

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Ms. Alice Gray, Director
Division of Immunization
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Re: Department of Health Proposed Regulations:
School Immunization

Dear Ms. Gray:

The Pennsylvania Academy of Family Physicians ("the Academy") represents over 4,700 members. The following comments are submitted in response to the Department of Health's proposed regulations related to school immunization which were published at 30 *Pa. Bulletin* 4591-4596 (September 2, 2000). The proposal will reformat the immunization provisions and add to the list of mandated school immunizations the important varicella vaccine.

New Format

The Academy applauds the Department for its fine work in updating and re-formatting the child immunization regulations consistent with current public health concerns and health care priorities. The proposal provides a logical and readable sequence that is easily comprehensible.

Immuno-Compromised Situations

There is no doubt that immunization of children in the manner covered by the regulations is extremely important to public health in the Commonwealth. The Academy has identified, however, certain situations where a medical exemption from child immunization may be needed, but which is not covered in current regulations.

The Department's regulation at 28 Pa. Code § 23.84 (relating to exemption from immunization) provides for a medical exemption in the event a physician determines that the immunization may be detrimental to the health of the child. However, certain situations exist wherein the immunization of a child may be detrimental to the health of those in the home where the child resides. For example, a sibling, parent or other relative who is immuno-compromised and living in the child's home (for example, an

Ms. Alice Gray, Director
September 28, 2000
Page 2

individual suffering from cancer, HIV or AIDS) may suffer serious adverse health effects from the vaccine administered to the child. Likewise, substantial risk may be created in a prenatal situation where a sibling has been immunized with a live virus.

Accordingly, the Academy would ask the Department to consider amending 28 Pa. Code § 23.84 to add the following phrases in subsection (a) thereof:

- (a) **Medical Exemption.** Children need not be immunized if a physician or the physician's designee provides a written statement that immunization may be detrimental to the health of the child **or to another individual (including a prenat) in the home where the child resides.** When the physician determines that immunization is no longer detrimental to the health of the child **or to another individual (including a prenat) in the home where the child resides,** the child shall be immunized according to this subchapter.
- ...

In this way, the public health will be protected without jeopardizing legitimate medical concerns in individual situations.

Reimbursement Concerns

The Academy has identified a certain reimbursement quandary for physicians and others who administer vaccinations under the mandatory provisions of the regulations.

The Academy notes that the Childhood Immunization Insurance Act ("CIIA") provides a detailed reimbursement mechanism in such situations. Unfortunately, the Act permits health insurance plans provided through employers as employment benefits to opt out of CIIA's coverage requirements through this ERISA exemption. The Academy also acknowledges that the federally funded "Vaccines for Children" program provides some reimbursement to enrolled physicians in limited situations. Vaccines for children through the age of 18 who are not covered by any health insurance, or are American Indians or Alaskan natives are provided under the program. Likewise, the Medicaid program provides the cost of the vaccine and a small administration fee for eligible children.

Because the majority of children subject to mandatory immunization are covered by health insurance plans that are exempt from the mandatory provisions of CIIA by virtue of the ERISA exemption, reimbursement streams are severely limited.

While the Academy recognizes that it is not within the jurisdiction of the Department of Health to resolve the reimbursement issue, the mounting costs of immunization

Ms. Alice Gray, Director
September 28, 2000
Page 3

products and administrative costs require an effort on the part of legislative and regulatory authorities to develop an appropriate funding stream.

The Academy thanks the Department for its consideration of the Academy's concerns and comments relating to these important public policy matters. If you have any questions, or would like to discuss any of the issues raised, please contact the Academy at your convenience.

Sincerely,



Kevin P. Shaffer, M.D.
President

cc: PAFP Board of Directors
PAFP Public Policy Commission
Wanda D. Filer, M.D., Chair, Public Policy Commission
John S. Jordan, Executive Vice President
Charles I. Artz, Esq.

Original: 2142

SCHAFFNIT CHIROPRACTIC

11730 EAST MAIN ROAD
NORTH EAST, PENNSYLVANIA 16428
Telephone (814) 725-4038

RECEIVED
2000 OCT -6 AM 9:35
LEGISLATIVE
REVIEW COMMISSION



September 28, 2000

PA Dept of Health
Alice Gray
P O Box 90
Harrisburg, PA 17108

Dear Ms. Gray,

I am submitting this letter in response to PDH's request for public comments. I oppose the proposed mandate for the Varicella vaccines. I request that this letter be made part of the public record and that PDH respond in writing to my comments.

This vaccine is presently available to any child in PA whose parent wants it administered; the issue being that PDH's proposal will make it illegal if a parent wants to either delay one of these vaccines or not give it at all.

I urge PHD to withdraw these rules. There are many valid reasons why a parent may not want to use these vaccines. Leave the decision where it should be in the hands of parents who are more than capable of making informed decisions about the health care of their children.

The issue is freedom of choice. I am surprised that PDH is taking this position. I thought in a Republican administration there would be less interference of government in our lives.

Very truly yours,

Richard L. Schaffnit, D.C.

Original: 2142

**HEPATITIS B FOUNDATION**

700 East Butler Avenue
 Doylestown, PA 18901-2697
 Phone: (215) 489-4900 Fax: (215) 489-4920
 email: info@hepb.org

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2000 OCT -6 AM 9:35

CAUSE FOR A CURE
 www.hepb.org

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September 28, 2000

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PAUL WITTE

Executive Director

MAE O'BRIEN

Ms. Alice Gray
 Director, Division of Immunization
 Pennsylvania Department of Health
 P.O. Box 90
 Harrisburg, PA 17108

RE: Proposed Amendment to #23.83 (school immunization requirements)

Dear Ms. Gray,

The Hepatitis B Foundation applauds the PA Department of Health's initiative in writing a proposed amendment requiring 7th graders to be immunized against hepatitis B. We are a voluntary nonprofit organization located in Pennsylvania that is dedicated to the cause and cure of hepatitis B. Protecting future generations of children from this vaccine-preventable disease represents a significant step forward in eradicating hepatitis B. We fully support your efforts to stop this serious liver infection.

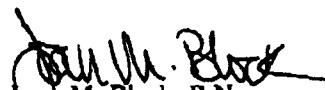
As noted in the rationale for the amendment, hepatitis B is a potentially life-shortening liver disease which can infect any person of any age. Worldwide, 2 billion people have been infected with hepatitis B, and more than 120 million in the U.S. Those who become chronic carriers of the virus live with a risk, 200 times greater than those who are uninfected, of progressing to fatal cirrhosis or liver cancer.

The national infant vaccination program has been successful in helping to reduce hepatitis B infections, however, it has left a "gap generation" unprotected - 11 to 12 year olds. It is important to protect these children before they enter adolescence when the risk of hepatitis B infections is greater due to lifestyle and fashion choices, as well as rougher contact sports, which increase the possibility of blood contact. *The risk to our young is underscored by the Centers for Disease Control's estimate that one-third of all American adult chronic carriers of hepatitis B were infected as infants or children.*

There is no question that childhood vaccinations save lives and promote a lifetime of health. The good news is that the hepatitis B vaccine is considered to be one of the safest and most effective vaccines. The cost of vaccination should no longer be a barrier since most health insurance carriers cover this expense. For families who are under- or un-insured, there is a federally funded program "Vaccines for Children" which provides free vaccinations. Finally, the best news is that the vaccine provides a lifetime of protection, so it is never too early to start.

Thank you for your time and consideration of this strong letter of support for your proposed amendment to #23.83 relating to school immunization requirements in this state.

Sincerely,


 Joan M. Block, R.N.
 President

Original: 2142

Lara Kinney
P.O. Box 106
Mill Village, PA 16427

September 27, 2000

Mr. John Mizner
Independent Regulatory Review Commission
14th floor, Harrisstown 2
333 Market Street
Harrisburg, PA 17120

RECEIVED
2000 OCT -3 AM 8:35
INDEPENDENT REGULATORY
REVIEW COMMISSION

Dear Mr. Mizner,

I am writing to you as a parent living in your district that is strongly opposed to the Pennsylvania Department of Health's proposed rules implementing a mandate for the Varicella vaccines. This vaccine is currently available to any child in PA whose parents feel it is necessary; the issue at hand is that PDH's proposal will make it ILLEGAL if a parent exercises thier discretion to either delay or not administer these vaccines at all. These proposals blatantly disregard parental rights and the basic human right of informed consent for medical procedures.

My three children, as well as most, have all endured this virus naturally and I believe thier immunities are stronger beacuse of it. The more we try to control and defend against any inconvenient or uncomfortable illness, the weaker and more defenseless we make our bodies. Also, I'm concerned about the safety of this, as well as all other, vaccines. The manufacture and preservation of these vaccines require elements such as formaldehyde and aluminum. In the case of word epidemics where death of masses is the result of certain viruses, I can truly see the impact of vaccines, regardless of the ingredients. But, to mandate a medical procedure that is strictly a preventative for a normal, immune-building childhood illness, I feel is taking away yet another right of parents' choice in their child's welfare and health. How many vaccines will be enough? Consider not only what virus you are driving away, but what you are injecting into these small children in mass doses.

Parents know their children, raise thier children, feed them, take care of them when they are sick and should be granted the respect they deserve in decision making about the health care of their children without being legally forced. It will then be the parents and children who live with the consequences of any health problems arising as a consequence of receiving or not receiving this vaccine, not PHD.

Comments received by October 4, 2000 will become part of public record and will be considered by the PHD when deciding whether to accept or reject these rules. Letters may be sent by mail or fax to: Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Thank you for your consideration.

Sincerely,



Lara A. Kinney

Original: 2142

September 27, 2000

RECEIVED

2000 OCT -6 AM 9:35

LEGISLATIVE HISTORY
REVIEW COMMISSION

Alice Gray (Fax 717/772-4309)
Division Director of Immunization
PA Dept of Health
P.O. Box 90
Harrisburg, PA 17108



Alice,

I am writing in regard to the proposed vaccination regulation changes in the PA State Senate. As an expectant mother, I was appalled to hear that the state of Pennsylvania is trying to mandate the chickenpox vaccine. I've been doing some research in this area in preparation for the birth of our child, and have found that the American Academy of Pediatrics state in its brochure on chickenpox (1996), "Most children who are otherwise healthy and get chickenpox won't have any complications from the disease." This group has also stated, "when an adult gets chickenpox, the disease usually lasts longer and is more severe, often developing into pneumonia. Adults are almost 10 times more likely than children under 14 to need hospitalization from chickenpox, and more than 20 times more likely to die from the disease." Based on this, wouldn't the adult population require boosters their entire life to remain protected? Where is the safety and financial data (savings) on this?

From another reputable source, "Many primary care physicians either do not recommend the vaccine or suggest that children be immunized only if they have not developed chickenpox by 12 years of age." (from the Journal of American Medical Association, November 1997) It seems as though the state's main motivation is financial, and in this case money should NOT be the primary motivation. In re-evaluating the regulations of our state's vaccine program, there are areas that need to be fixed instead of trying to add a new vaccine that is not necessary or proven to be safe. I am forwarding copies of this letter to the Senate Health and Welfare committee. This vaccine is available to any parent that feels they want it for their child. Let's not mandate a vaccine that is neither necessary nor proven safe and effective.

Please give this issue your utmost attention.

Sincerely,

Lisa M. Puckly
9711 Perry Hwy.
Waterford, PA 16441

Original; 2142

Lara Kinney
P.O. Box 106
Mill Village, PA 16427

September 27, 2000

Alice Gray
Director, Immunization Division
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, Pa 17108

RECEIVED

2000 OCT -6 AM 9:35

INDUSTRIAL HYGIENE
REVIEW COMMISSION



This letter is being submitted in response to PDH's request for public comments. I strongly oppose the proposed mandate for the Varicella vaccines. I request that this letter is made part of the public record and that PDH respond in writing to my comments.

This vaccine is currently available to any child in PA whose parents feel it is necessary; the issue at hand is that PDH's proposal will make it ILLEGAL if a parent exercises thier discretion to either delay or not administer these vaccines at all.

My three children, as well as most, have all endured this virus naturally and I believe thier immunities are stronger beacuse of it. The more we try to control and defend against any inconvenient or uncomfortable illness, the weaker and more defenseless we make our bodies. Also, I'm concerned about the safety of this,as well as all other, vaccines. The manufacture and preservation of these vaccines require elements such as formaldehyde and aluminum. In the case of word epidemics where death of masses is the result of certain viruses, I can truly see the impact of vaccines, regardless of the ingredients. But, to mandate a medical procedure that is strictly a preventative for a normal, immune-building childhood illness, I feel is taking away yet another right of parents' choice in their child's welfare and health. How many vaccines will be enough? Consider not only what virus you are driving away, but what you are injecting into these small children in mass doses.

I urge PHD to withdraw these rules. Parents know their children, raise thier children, feed them, take care of them when they are sick and should be granted the respect they deserve in decision making about the health care of their children without being legally forced. It will then be the parents and children who live with the consequences of any health problems arising as a consequence of receiving or not receiving this vaccine, not PHD.

Sincerely

A handwritten signature in cursive script that reads 'Lara Kinney'. The signature is written in black ink and is positioned above the printed name.

Lara Kinney

Original; 2142

Renee D. Fairbrother
P.O. Box 45
Fombell, PA 16123

RECEIVED
2000 OCT -6 AM 9:35
MILITARY
REVIEW COMMISSION

September 27, 2000

Alice Gray
Director, Immunization Division
Pennsylvania Dept. of Health
P.O. Box 90
Harrisburg, PA 17108

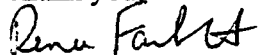
I am submitting this letter in response to PDH's request for public comments. I oppose the proposed mandate for the Varicella vaccines. I request that this letter is make a part of the public record and the PDH respond in writing to my comments.

This vaccine is currently optional, however, the issue here is tha PDH's proposal will make it illegal for a parent to delay or refuse these vaccines. Parents are the decision makers when it comes to their childrens' healthcare and should never be put in the position of "breaking the law" by refusing the administration of a vaccine.

The varivax , according to the manufacturer, has not been evaluated or tested for its short or long term effects on the human body. It is manufactured using lung tissue from two surgically aborted fetuses and contains two toxic chemicals; aluminum which can cause brain damage and formaldehyde which causes cancer. These are a few of the valid reasons why a parent may not want to use this vaccine.

I urge PDH to withdraw these rules and leave the decision to vaccinate in the hands of the parents.

Thank you,



Renee D. Fairbrother

RECEIVED

2000 OCT -6 AM 9:35

Sept. 27, 2000

To: Alice Gray
HEALTHY
REVIEW COMMISSION

As a concerned citizen and parent
I wholeheartedly object to the chicken-
pox vaccine being required for
school children.

Already having a child suffer
from side effects of another vaccine -
I am convinced that much more
research is needed before anyone
of our children suffer.

We need to have a choice in
vaccinating our children - to protect
both them and the public
future health.

Sincerely
Nancy J. Lehman

NANCY J. LEHMAN
2329 MARBURY RD
PITTSBURGH, PA 15221 - 412-731-0795

Original: 2142



Mr. & Mrs. Stephen Eichelberger
11592 Center St.
N. Huntingdon, PA 15642

RECEIVED

2000 OCT -6 AM 9:35

REGULATORY
REVIEW COMMISSION



Ms. Alice Gray
Director, Immunization Division
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108

September 27, 2000

Dear Ms. Gray,

We are writing this letter in response to the Pennsylvania Department of Health's request for public comments regarding the proposed mandate for the Varicella Vaccines. We are opposed to this mandate and request that this letter be made part of the public record and that the PDH respond in writing to our comments.

This vaccine is currently available to children in PA whose parents "choose" to have it administered; the issue here is that the PDH's proposal will make that "choice" for them, making it illegal if a parent wants to delay or chooses to not give the vaccine at all.

We urge the PDH to withdraw these rules. There are many valid reasons why a parent may not wish to have these vaccines administered. We believe that parents are capable of making informed choices about the health care of their children and must not be placed in a position in which exercising a conscientious objection to the administration of this vaccine means breaking the law. We believe the decision where it should be, in the hands of the parents. It will be the decision of the parents and children who live with the possible consequences of a health problem precipitated by this vaccine, not the PDH.

Sincerely,


& Mrs. Stephen Eichelberger



Original: 2142

Lucy A. Cook
Robert A. Cook
141 Rivercrest Drive
Moon Twp., PA 15108

RECEIVED

2000 OCT -6 AM 9:35

REGULATORY
REVIEW COMMISSION



September 27, 2000

Alice Gray
Director, Immunization Division
PA Dept. of Health
P.O. Box 90
Harrisburg, PA 17108
Phone: 717-787-5681

Dear Ms. Gray,

I am submitting this letter in response to PDH's request for public comments. I oppose the proposed mandate for the Varicella Vaccines. I request that this letter is made part of the public record and that PDH respond in writing to to my comments.

This vaccine is currently available to children in PA whose parent wants it administered; the issue here is that PDH's proposal will make it illegal if a parent wants to either delay one of those vaccines or not give it at all.

I urge PDH to withdraw these rules. There are many valid reasons why a parent may not want these vaccines. Parents are capable of making informed decisions about the health of care of their children and must not be placed in a position in which exercising a conscientious objection to the administration of this vaccine means breaking the law. Leave this decision where it should be, in the hands of parents. It will be the parents and children who live with the consequences of a health problem precipitated by this vaccine, not PDH.

Sincerely,

A handwritten signature in cursive script that reads "Lucy A. Cook".

Lucy A. Cook

Original: 2142

RECEIVED

2000 OCT -6 AM 9:35

REGULATORY
REVIEW COMMISSION

Mrs. Carol L. Clevenger
1364 1/2 Davis Avenue
Washington, PA 15301

September 27, 2000

Alice Gray
Director, Immunization Division
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Ms. Gray:

I am submitting this letter in response to the Pennsylvania Department of Health's request for public comments regarding the proposed mandate for the Varicella vaccines. I oppose the proposed mandate for the Varicella vaccines, and I request that this letter be made part of the public record, and that the Pennsylvania Department of Health respond in writing to my comments.

This vaccine is currently available to any child in Pennsylvania whose parent wants it administered; however, the issue here is that the Pennsylvania Department of Health will make me a criminal if I decide to delay this vaccine, or if I choose not to have it administered to my children at all.

I am a parent who is very concerned about my children's health. I am concerned about toxic substances that may be around them, especially carcinogens. I understand that according to the manufacturer, the vaccine has not been evaluated or tested for "carcinogenic potential, mutagenic potential, or for impairment of fertility", or "reproductive capacity", and that "the duration of the protection is unknown" at the present time. With reports currently coming out regarding various fragrances and even disposable diapers causing infertility and other reproductive changes in babies and young children, I believe I would be an uncaring and incompetent parent to agree to the injection of this potentially carcinogenic material into my children's bloodstreams.

Furthermore, to only give my children a limited protection of a benign childhood disease so they can contract it as an adult when the disease is far more dangerous, simply because it might be less disruption to my personal life, is notice to my children that I do not care for their welfare. I do

Alice Gray
Director, Immunization Division
Pennsylvania Department of Health
September 27, 2000
Page 2

care for my children and their health, and I would rather they get chicken pox as a child and have lifetime immunity to this benign childhood disease. The day after our neighbor girl was sent home from school for breaking out with chicken pox, I took my children down so they could give her a hug. My children did not break out with visible chicken pox. I assume that their immune system was simply strong enough to resist it at that time. I will expose them again when I get the next opportunity to double-check their immunity.

I also oppose injecting the varicella vaccine because it is manufactured using human fetal cells and because it contains formaldehyde and aluminum. Immunization is a medical procedure that can cause reactions and even death for some. The Vaccine Injury Compensation Program has paid out over 1 billion dollars in damages to families for injuries and deaths caused by vaccines. If immunization is the cause of a severe reaction or cause of death to my child, it is not the Pennsylvania Department of Health who will be affected; it is my family who will have to live with the consequences.

I strongly urge the Pennsylvania Department of Health to withdraw this mandate and scrap the rules. As a parent, I am fully capable of making informed decisions about the health care of my children, and I do not believe I should be placed in a position in which my conscientious objection to the administration of this vaccine means breaking the law. Please leave this decision where it should be: in the hands of the parents.

Sincerely,


Carol L. Clevenger

Original: 2142

September 27, 2000

Alice Gray
Division Director of Immunizations
Fax--717-772-4309

As a parent, I feel that chicken pox should NOT be added to the mandate. There are many reasons this vaccine should not be added. To mention a few—the risks from this vaccine have not been made clear to parents, chicken pox is typically not a life threatening disease, and the reason for mandating this seems to be financial. Is the main reason for trying to eradicate chicken pox just so parents don't need to miss work?

Please include my letter with the public comments on this issue.

Michele L. Cessna
11135 Tamarack Road
Waterford, PA 16441

Original: 2142

418 West Main Street
Evans City, PA 16033
September 26, 2000

Alice Gray, Director, Immunization Division
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED

2000 OCT -6 AM 9:35

PENNSYLVANIA REGULATORY
REVIEW COMMISSION



Dear Ms. Gray:

We are writing this letter in response to the Pennsylvania Department of Health's request for public comments. We want to convey our opposition to the proposed mandate for the Varicella Vaccines. We would also like to request that this letter be made a part of the public record and that the Pennsylvania Department of Health respond in writing to our comments.

Currently, this vaccine is available to any child in Pennsylvania whose parents want it administered; the issue here is that the Pennsylvania Department of Health's proposal will make it illegal if a parent wants to either delay one of these vaccines or not give it at all.

Immunization is a medical procedure that can cause reactions and death for some. The Vaccine Injury Compensation Program has paid out over 1 billion dollars in damages to families for injuries and deaths caused by vaccines. There are thousands of other families who have reported adverse affects caused by vaccines that have been placed with the burden of proof of determining that vaccines have cause harm to their children. We are a family of the latter.

Our son had a serious reaction to the MMR vaccine. He is now left with autism and mental retardation. We have the difficult job of proving that it indeed was the vaccine that caused his condition. There is no doubt in our minds that the vaccine did cause this damage to our little boy; unfortunately, we are not doctors and cannot perform medical research on our own. We can only explain what our son was like prior to the vaccine and report the events that occurred afterward. Our family suffers every day because of the predicament we were placed in. We thought that we were protecting our son by allowing his doctor to vaccinate him. We wish now that more research was done on vaccinations and that we were allowed an educated choice. We thought that we were protecting our son; whereas, we allowed someone else's values and choices to determine our son's life.

We urge the Pennsylvania Department of Health to withdraw these rules. There are many valid reasons why a parent may not want to use these vaccines. Parents are capable of making informed decisions about the health care of their children and must not be placed in a position in which exercising a conscientious objection to the administration of this vaccine means breaking the law. Leave this decision where it should be, in the hands of the parents. It will be the parents and children who live with the consequences of a health problem precipitated by this vaccine, not the Pennsylvania Department of Health.

Sincerely,

A handwritten signature in cursive script that reads 'Davy + Mary Wildman'.

Davy and Mary Wildman

Original: 2142

Grant R. Twiss
3920 Sassafras St.
Erie, PA 16508

September 26, 2000

Alice Gray
Director, Immunization Division
Pennsylvania Dept. of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
2000 OCT -6 AM 9:35
REGULATORY
REVIEW COMMISSION

Dear Director,

I am submitting this letter in response to your department's request for public comments related to the proposed mandate of the Varicella vaccine. I request that this letter be made part of the public record and that your department acknowledge in writing the receipt of my comments.

This vaccine is currently available to any child in Pennsylvania whose parent wants it administered; the issue is that your department's proposal will make it illegal if a parent chooses to delay or not have the vaccine administered to their child.

With the growing body of evidence related to the side effects of the already eight vaccines required at this time I think more study should be required before we subject young children to any further vaccines. As a parent of an autistic child damaged by the MMR vaccine I can only tell you of the challenges that my child and family have to face everyday. Children who are affected by these side effects will not recover they are life long.

Your department's main reason for mandating this vaccine is that parents and guardians will experience less work disruption due to a child's illness. It is not the function of a health agency to determine how much work parents are allowed to miss to care for their children. The varicella vaccine is manufactured using human fetal cells and contains toxic substances such as formaldehyde and aluminum. It is time that the Pennsylvania Dept. of Health to respect that children belong to their parents and not the state.

Sincerely,



Grant R. Twiss



Original: 2142

Rogers Kyle, MD
President

September 26, 2000

RECEIVED
2000 OCT -6 AM 9:35

LABORATORY
REVIEW COMMISSION

Ms. Alice Gray
Director
Division of Immunization
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Re: Response to Proposed Rulemaking on School Immunizations

Dear Ms. Gray:

I am writing to submit my comments regarding the Department of Health's (DOH) recent proposed rulemaking setting forth amendments to the immunization requirements for children seeking to enter and attend school in Pennsylvania. See 30 Pennsylvania Bulletin 4591.

I am a licensed physician in Pennsylvania and Board Certified in internal medicine. I have practiced, full and part time, continually in this state for almost twenty years. I have also served in senior executive administrative roles at a community based, not-for-profit healthcare delivery system in the Philadelphia region, and as a senior medical director and board member of one of the pre-eminent academic healthcare systems in Philadelphia. I am currently working with a private company that seeks to provide a more accurate and user-friendly method of completing the documentation required on students for enrollment and attendance in school and similar organizations. I only offer these facts to establish my credentials, and the bias for my opinions.

The importance of adequately immunizing children (and others) against preventable communicable diseases is aptly stated in your proposed amendment. The economic and epidemiologic arguments for the expansion of requirements for Hepatitis B and the new requirements for varicella in the proposed amendment are well established. As you also point out, the guidelines follow the recommendations of the Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), and Centers for Disease Control and Prevention (CDC). Rarely do we get this much concordance of opinion in medicine.

My comments are more directed to the statements made in Preamble Sections C. (Affected Persons) and D. (Cost and Paperwork Estimate). The historical effort, and cost, each year for schools, parents and guardians, and medical offices to handle the required submission of immunization and communicable disease histories for attendance is well known to almost everyone. Parents, schools and medical offices each year spend countless hours attempting to provide the required, authenticated immunization (and other medical and personal) information to those who assume responsibility for their children during the school day. Over the years parents and medical offices have coped with the need to provide immunization dates and physician signatures on appropriate forms with a myriad of ad hoc systems. Coordinating the effort alone is an annual exercise in frustration for everyone. In



Rogers Kyle, MD
President

In addition, the majority of this information is still gathered each year by distributing blank forms to parents and guardians to be completed by hand, reviewed, completed or edited by medical offices and submitted to schools, often for the school nurse to interpret and enter into the school's records. Transcription errors are inevitable with so many people involved in the process.

The complexity of the information required has also increased with the important advances in immunizations. In addition, parents are asked to interpret the various acceptable methods for compliance for each disease or immunization. They are faced with options ranging from written parental statements of history of immunity, to evidence of serologic testing, to documenting appropriately administered vaccines of appropriate type and at appropriate intervals. While it is not under the purview of the DOH, the need to also supply schools with immunization or other medical information not necessarily regulated by the state but required by an individual school confuses parents, and medical offices, even more. These pressures and confusion produce what has generally become an unpleasant task for everyone. Unfortunately, this also impacts the accuracy of records on school children, let alone the timeliness of form submission.

With the assumption that any related efforts should support the ultimate goal of immunization registries, what additional steps can be undertaken to improve the accuracy of information collected on our children?

We believe that existing technology can improve the process of communication between parents, schools and their children's medical providers. If the yearly distribution, completion, verification and submission of yearly school forms can be simplified, everyone would benefit – particularly if the simpler process produced more accurate, longitudinal records. Parents, schools and medical offices would experience less frustration around the form submission process and accuracy would improve.

Our company has developed a web-based approach to the transmission and authentication of this information to facilitate the accurate and timely transmission of information among parents, schools and physician offices. Access is limited to those with secure User ID's and Passwords, and encrypted data is transferred through a stand-alone application server to a firewall protected database server array. We believe that our system creates a more complete, updateable, more accurate and convenient, and less expensive, alternative to current processes. Schools have a secure database that parents can access, as can their children's medical offices. Information may be added anytime, authenticated by the appropriate person or entity, and reviewed periodically for completeness. The parent or guardian always controls access to an individual child's record. Information that is entered or authenticated is logged by time and author. Communication via e-mail adds an asynchronous medium for reminders, requests, policy changes, and information resources.

There are many efforts underway to improve the entire process of these records on school children. National level efforts (i.e., CDC's Healthy People 2010) to establish immunization registries are unquestionably necessary. Accurately capturing and recording the 16 to 20 doses of vaccine that the approximately 11,000 children born each day in the United States will need by age 2 in a central electronic database should and must be the goal.

Rogers Kyle, MD
President

Adhering to the Health Level 7 standards should be expected for the accurate exchange of vaccination records. Also, compliance with FERPA, HIPAA and any similar privacy related legislation is expected.

Given the rapid advance of technology it seems unlikely that the paper based form completion process for school attendance will still exist in a few years. Whether ours, or similar systems, in competition or partnership, will replace the status quo remains to be seen. Encouraging and supporting the conduct of transactions electronically, through electronic signature processes and other means, is a well-recognized federal and state policy as a result of the recent enactment of the federal Electronic Signatures in Global and National Commerce Act and the Pennsylvania Electronic Transactions Act.

Our request is that the DOH continues to consider and encourage the incorporation of evolving technologies into this important process. As we discuss our systems and approach to maintenance and transmission of this information with parents, school officials and physician offices we often face questions about how state regulators will view the maintenance and transmission of this information electronically using a web based approach. In order to provide clarity and guidance in this important matter, we suggest that a provision be inserted in the final regulation (or, at a minimum, in the Preamble) stating that the DOH will recognize the validity of immunization and related health information provided under the regulatory requirements whether such information is prepared, signed, transmitted or maintained in paper or electronic format.

I appreciate the opportunity to comment on this important matter. If I can be of further assistance in answering any questions or providing additional information about the matters discussed in this letter, please feel free to contact me at (610) 825-7516 or trkyle@mdofficelinx.com.

Sincerely,



T. Rogers Kyle, M.D.

Original: 2142

RECEIVED
2000 OCT -6 AM 9:35
PITTSBURGH
REVIEW COMMISSION

4711 West Lawnview Drive
Pittsburgh, PA 15227
September 26, 2000

Alice Gray
Director, Immunization Division
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Ms.Gray:

I understand that the PA Department of Health is proposing a mandate for the Varicella Vaccines. I request that this letter be made part of the public record and that your department respond in writing to my comments.

I feel this vaccine is currently available to any child in Pennsylvania whose parents may wish it administered. The issue here is that the PDH's proposal would make it illegal for parents who wish to delay the vaccine or not give it at all.

I feel that chicken pox is not life threatening and there are valid reasons why parents may not wish their children to receive it. Chicken pox, in my opinion, is simply an inconvenience, not a threat to public health.

Sincerely,



Mrs. Maria Aul

RECEIVED

9-25-2000

2000 OCT -6 AM 9:34

LABORATORY
REVIEW COMMISSION

Dear Alice Gray,

I am writing to you in reference to the proposed mandate for the varicella vaccines. I am strongly opposed of this mandate. I feel as a parent I should have every right to decide whether my children receive one or not. There has not been enough research for long term effects. Chicken pox is a childhood illness that usually gives the child life long immunity. The varicella vaccine is made using human fetal cells and contains formaldehyde and aluminum. ~~What does that mean to my children in years to come?~~

The decisions about my childrens health care are mine. And I am fully capable of making informed decisions. I do not want that right taken away.

My six year old son was born a healthy, happy and calm baby. He recieved his

Original: 2142

June C. Wood
922 West 30th St.
Erie, PA 16508

September 24, 2000

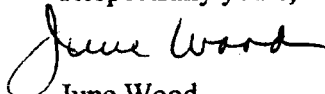
Alice Gray
Director, Immunization Division
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA. 17108
Phone: 717-787-5681

I am submitting this letter in response to PDH's request for public comments. I strongly oppose the proposed mandate for the Varicella vaccines. I request that this letter is made a part of the public record and that PDH respond in writing to my comments.

This vaccine is currently available to any child in PA whose parent wants it administered; the issue here is that PDH's proposal will make it illegal if a parent wants to either delay one of these vaccines or not give it at all.

I urge PDH to withdraw these rules. There are many valid reasons why a parent may not want to use this vaccines. Parents are capable of making informed decisions about the health care of their children and must not be placed in a position in which exercising a conscientious objection to the administration of this vaccine means breaking the law. Leave this decision where it should be, in the hands of the parents. It will be the parents and children who live with the consequences of a health problem precipitated by this vaccine, not PDH or any governing body. To make it mandatory thereby removes the freedom of choice for which this country stands.

Respectfully yours,


June Wood

Original 2142

Atten: Alice Gray - Director of Immunization
For Public Comment

September 23, 2000

Senator Tim Murphy

Dear Senator Murphy:

We are writing in regard to the proposed vaccination regulation changes in the Pennsylvania Senate. We are the parents of an adult child who we believe suffered a permanent adverse reaction to a vaccination as a child.

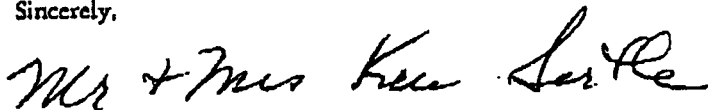
We are against the mandating of the chickenpox (varicella) vaccine for the following reasons:

- Chickenpox is not typically a life threatening illness
- The basis for mandate appears to be financial in nature
- The risks from the vaccine have not been made clear to parents
- Parents should have the right to make a choice about this vaccine, and should be fully informed that they have the right to choose.

As you are redoing the regulations, we ask that you not only choose not to mandate chickenpox, but that you look closer at other vaccine mandates that lack sufficient scientific data to back up a request for mandate. Please refer to the United States Congressional Hearings in the Committee for Government Reform on the issue of Vaccine Safety. You will find a library of information on the web site of Congressman Dan Burton from Indiana.

Please read, and include, the attached press release from The National Vaccine Information Center with my public comments.

Sincerely,



Mr. & Mrs. Ken Sorth

Cc: Sen. Jay Costa Sen. James Gerlach Sen. Melissa Hart
Sen. Shirley Kitchen Sen. Alison Schwartz
Sen. Michael Waugh Sen. Mary Jo White
Sen. Jane Earl

Cc: Independent Regulatory Commission:
Arthur Cocodrilli
Robert Harbison
John Mizner

7227 DUTTON ROAD
HARBORCREEK, PA 16421

September 13, 2000

Press Release

From Barbara Loe Fisher of the National Vaccine Information Center.

National Vaccine Information Center
512 W. Maple Ave., Suite 206, Vienna, VA 22180
(703) 938-DPTJ FAX: 938-5768

Calling the FDA report on adverse events associated with varicella zoster (chicken pox) vaccine published in today's Journal of the American Medical Association a breakthrough" in the follow-up and public disclosure of reports made by doctors and parents to the Vaccine Adverse Event Reporting System (VAERS), the National Vaccine Information Center (NVIC) applauded public release of the VAERS data but challenged the authors' conclusions that the vaccine's risks are minimal.

"We have been getting reports from parents that their children are suffering high fevers, chicken pox lesions, shingles (herpes zoster), brain damage and dying after chicken pox vaccination, especially when the vaccine is given at the same time with MMR and other vaccines. This FDA report confirms our concern that the chicken pox vaccine may be more reactive than anticipated in individuals with both known and unknown biological high risk factors," Barbara Loe Fisher, president of NVIC.

In the VAERS data made public today, it was reported that VAERS had received 67.5 adverse event reports per 100,000 doses of chicken pox vaccine sold between March 1995 and July 1998 for a total of 6,574 reports. 82 percent of the adverse event cases occurred in individuals who received chicken pox vaccine only. Admitting that underreporting made the figures "highly variable fractions of actual event numbers," the authors revealed that approximately 4 percent of cases (about 1 in 33,000 doses) were serious, including shock, convulsions, encephalitis, thrombocytopenia and 14 deaths.

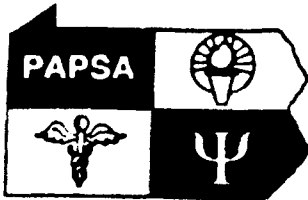
The VAERS data has lead to the addition of 17 adverse events to the manufacturer's product label since the vaccine was licensed for use in 1995, including secondary bacterial infections (cellulitis), secondary transmission (infection of close contacts), transverse myelitis, Guillain Barre syndrome and herpes zoster (shingles).

"We have been waiting for the FDA to follow-up on VAERS reports and then disclose and utilize the VAERS data to increase our knowledge about vaccine reactions and possible high risk factors. This is how parents and Congress expected the vaccine adverse event reporting system to be utilized when it was centralized under the National Childhood Vaccine Injury Act of 1986. However,

the conclusions drawn by the authors do not match the substance of the data presented," said Fisher.

Based on today's published report on chicken pox vaccine, the National Vaccine Information Center is calling for a halt to simultaneous administration of chicken pox vaccine in combination with other vaccines, particularly MMR, until the vaccine can be further evaluated for short and long term reactivity, particularly in immune compromised individuals such as asthmatics and those sick at the time of vaccination.

"This vaccine should not be mandated," said Fisher. "There are too many questions about the true adverse event and efficacy profile of this relatively new live virus vaccine and it is up to the manufacturer marketing the vaccine and the federal agencies regulating the vaccine to conduct further follow-up of this important VAERS report," said Fisher.



Original: 2142

Pennsylvania Association of Pupil Services Administrators

Executive Secretary
Dr. Robert B. Cormany
1883 Douglas Drive
Carlisle, PA 17013
(717) 243-6413 (phone/fax)

September 19, 2000

2000-2001 Officers
President
Ms. Karen Williams
Supervisor of Special Education
Baldwin Whitehall School District
4900 Curry Road
Pittsburgh, PA 15236
(412) 885-7583 (office)
(412) 885-7802 (fax)

Alice Gray, Director
Division of Immunization
Department of Health
P. O. Box 90
Harrisburg, PA 17108

President-elect
Ms. Bobbie Pinckney
Supervisor of Pupil Personnel Services
Colonial Intermediate Unit
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Easton, PA 18045
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(610) 559-7103 (fax)

Past President
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Director of Pupil Services
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(814) 874-6119 (fax)

Secretary
Ms. Eloise Stoehr
Supervisor of Pupil Services
Upper Saint Clair School District
1820 McLaughlin Road
Pittsburgh, PA 15241
(412) 833-1600, ext. 2214 (office)
(412) 833-5535 (fax)

Treasurer
Ms. Barbara Tomlinson
Supervisor of Special Education
Deer Lakes School District
Box 10, East Union Road
Russellton, PA 15076
(724) 265-5300 (office)
(724) 265-2259 (fax)

Board of Directors
Mr. Wayne Fausnaught (2001)
Mr. Fred Shipman (2001)
Dr. Ted Foor (2002)
Dr. Michael Murphy (2002)
Dr. Todd Fay (2003)
Mr. Donald Teti (2003)

Dear Ms. Gray:

I have reviewed the proposed revisions to the Immunization Regulations for Schools and wish to respond on behalf of our organization. As Pupil Services Administrators, our members are the central office administrators responsible for health services in the schools and with oversight for the immunization process.

It is our opinion that the revisions do provide a clearer set of definitions and are arranged in a more understandable format than in previous versions. We concur with the need for Varicella immunization and for the expanded Hepatitis B coverage. We support the adoption of the revised regulations as expeditiously as possible.

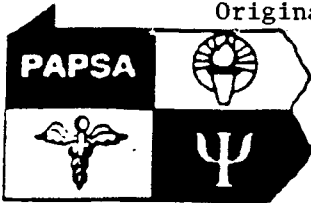
Our thanks to the Department of Health staff for the opportunity to be involved on the focus group which established these proposed changes. If we can be of further assistance in the future, please contact my office.

Sincerely,

Robert B. Cormany, Ed.D.
Executive Secretary

cc: Robert E. Nyce, IIRC

RECEIVED
2000 SEP 21 AM 10:27
DEPARTMENT OF HEALTH
IMMUNIZATION
REVIEW COMMISSION



Pennsylvania Association of Pupil Services Administrators

Executive Secretary
 Dr. Robert B. Cormany
 1883 Douglas Drive
 Carlisle, PA 17013
 (717) 243-6413 (phone/fax)

September 19, 2000

2000-2001 Officers
President
 Ms. Karen Williams
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 Department of Health
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 Harrisburg, PA 17108

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It is our opinion that the revisions do provide a clearer set of definitions and are arranged in a more understandable format than in previous versions. We concur with the need for Varicella immunization and for the expanded Hepatitis B coverage. We support the adoption of the revised regulations as expeditiously as possible.

Our thanks to the Department of Health staff for the opportunity to be involved on the focus group which established these proposed changes. If we can be of further assistance in the future, please contact my office.

Sincerely,

A handwritten signature in cursive script that reads "Robert B. Cormany".

Robert B. Cormany, Ed.D.
 Executive Secretary

cc: Robert E. Nyce, IRRC

RECEIVED
 2000 OCT -6 AM 9:35
 REVIEW COMMISSION

Gray, Alice

From: jims@IRRC.STATE.PA.US
 Sent: Friday, October 27, 2000 4:19 PM
 To: agray@state.pa.us
 Subject: RE: Areas for discussion on School Immunization (IRRC #2142)

RECEIVED

2000 OCT 30 PM 4:32

REGULATORY
REVIEW COMMISSION

IRRC's fax is 783-2664

Original: 2142

Thanks,
 Jim Smith
 IRRC
 783-5439

-----Original Message-----

From: Gray, Alice [mailto:agray@state.pa.us]
 Sent: Friday, October 27, 2000 4:12 PM
 To: 'jims@IRRC.STATE.PA.US'
 Cc: Kopelman, Janice; Kostelac, Yvette
 Subject: RE: Areas for discussion on School Immunization (IRRC #2142)

Regarding your question during our meeting on October 26, 2000 regarding potential danger to an immunocompromised household contact of a child receiving varicella vaccine.

I believe this question/concern was posed from the Pennsylvania Chapter of the Academy of Family Physicians.

Please email me your fax number and I will return information from the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR) and from the American Academy of Pediatrics Policy Statement that discusses Varicella immunizations and household contacts of Immunocompromised Persons.

I have also had a conversation with Dr. Barbara Watson from the Philadelphia Department of Health who is considered a leader in varicella vaccine/immunization research. She stresses the point that it is more important for children to receive varicella vaccine when there are immunocompromised household contacts since if there is breakthrough varicella rash from the immunization with infection of contacts; the infection is less severe than if the contact were infected as a result of disease brought into the household. If there is contact infection from vaccine, the timeframe for infection is anticipated to be the same incubation time as from disease. (However, there is very little research information available about this.)

Also, Dr. Watson explained that there just isn't research information available; but vaccine associated disease is very rare, that if there is vaccine associated disease it is milder and not transmissible. Immunocompromised household contacts are not a contraindication for varicella immunization.

Contraindications and Cautions

1. Immunocompromised patients

a. *General recommendation.* Varicella vaccine should *not* be given routinely to immunocompromised individuals, such as those with congenital immunodeficiency, blood dyscrasias, leukemia, lymphoma, symptomatic HIV infection, and malignancy for which they are receiving immunosuppressive therapy. The exceptions include children with acute lymphocytic leukemia under study conditions (see below). Asymptomatic HIV infection also is a contraindication for immunization, but since the risk in these persons is currently only theoretical, routine screening for HIV is not indicated. Immunodeficiency should be excluded before immunization in children with a family history of hereditary immunodeficiency. The presence of an immunodeficient or HIV-seropositive family member does not contraindicate vaccine use in other family members.

b. *Households with potential immunocompromised contacts.* Transmission of vaccine-type VZV from healthy individuals has been infrequently if at all documented. Thus, even in families with immunocompromised individuals, including those with HIV infection, no precautions need to be taken after vaccination of healthy children who do not develop a rash. Vaccinees who develop a rash should avoid contact with immunocompromised susceptible hosts for the duration of the rash. If contact inadvertently occurs, the use of varicella zoster immune globulin is not recommended currently because transmission is rare and disease, if it develops, is mild.

c. *Children receiving steroids.* The potential risks of vaccination with the attenuated virus must always be weighed against the potential risks of becoming infected with wild type VZV infection, which has an increased risk of severe disease.

Varicella vaccine should not be administered to individuals who are receiving high doses of systemic corticosteroids (2 mg/kg/d or more of prednisone, or its equivalent or 20 mg/d of prednisone if their weight is >10 kg) for >1 month. After steroid use at this dosage has been discontinued for 3 months, according to generic recommendations for the use of live-virus vaccines, a child may be immunized. Most experts agree, however, that with varicella vaccine an interval of 1 month or more after discontinuation of steroid use is probably sufficient to safely administer the vaccine.

Children with no history of varicella who are receiving systemic steroids for conditions such as nephrosis and asthma may be immunized if not otherwise immunosuppressed, assuming that they are receiving <2 mg/kg/d of prednisone or its equivalent (or <20 mg/d if their weight is >10 kg). Some experts, however, suggest discontinuing steroid use for 2 to 3 weeks after immunization if possible. In studies in Japan, children with nephrosis receiving these doses of systemic steroids were immunized safely when steroid use was also suspended for 1 to 2 weeks before immunization.[32] Most experts agree that immunization of children receiving only inhaled steroid would not increase the risk of disease from varicella vaccine, although no studies in such children have been performed.

d. *Acute lymphocytic leukemia (ALL).* The current vaccine is not licensed for routine use in children with malignancies. Immunization should be considered when a child with ALL has been in continuous remission for at least 1 year and has a lymphocyte count over 700/ μ L and platelet count over 100000/ μ L 24 hours before vaccination. Immunization has been shown to be safe, immunogenic, and effective in these children, and the vaccine may be obtained free for use in a research protocol. (To immunize a child with ALL, the following organization should be consulted: The Varivax Coordinating Center, Bio-Pharm Clinical Services, Inc, 4 Valley Square, Blue Bell, PA 19422; telephone, 215-283-0897). This protocol monitors and evaluates safety and requires approval by the appropriate institutional investigative review board.

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Household Contacts of Immunocompromised Persons

Immunocompromised persons are at high risk for serious varicella infections. Disseminated disease occurs in approximately 30% of such persons who have primary infection. Vaccination of household contacts provides protection for immunocompromised persons by decreasing the likelihood that wild-type varicella virus will be introduced into the household. Vaccination of household contacts of immunocompromised persons theoretically may pose a minimal risk of transmission of vaccine virus to immunocompromised persons, although in one study, no evidence of transmission of vaccine virus was found after vaccinating 37 healthy siblings of 30 children with malignancy. Available data indicate that disease caused by vaccine virus in immunocompromised persons is milder than wild-type disease and can be treated with acyclovir. More information is needed concerning the risk for transmission of the vaccine virus from both vaccinees who have and who do not have varicella-like rash following vaccination. On the basis of available data, the benefits of vaccinating susceptible household contacts of immunocompromised persons outweigh the potential risk for transmission of vaccine virus to immunocompromised contacts.

VACCINE-ASSOCIATED ADVERSE EVENTS

Varicella virus vaccine has been well tolerated when administered to >11,000 healthy children, adolescents, and adults during clinical trials. Inadvertent vaccination of persons immune to varicella has not resulted in an increase in adverse events. In a double-blind, placebo-controlled study of 914 healthy, susceptible children and adolescents (76), pain and redness at the injection site were the only adverse events that occurred significantly more often ($p < 0.05$) in vaccine recipients than in placebo recipients.

Persons 12 Months-12 Years of Age

In uncontrolled clinical trials of approximately 8,900 healthy children (Merck and Company, Inc., package insert) who were administered one dose of vaccine and then monitored for up to 42 days, 14.7% developed fever (i.e., oral temperature ≥ 102 F [≥ 39 C]); these febrile episodes occurred throughout the 42-day period and were usually associated with intercurrent illness. A total of 19.3% of vaccine recipients had complaints regarding the injection site (e.g., pain/soreness, swelling, erythema, rash, pruritus, hematoma, induration, and stiffness), 3.4% had a mild, varicella-like rash at the injection site consisting of a median number of two lesions and occurring at a peak of 8-19 days postvaccination, and 3.8% had a nonlocalized, varicella-like rash consisting of a median number of five lesions and occurring at a peak of 5-26 days postvaccination. Febrile seizures following vaccination occurred in <0.1% of children; a causal relationship has not been established.

FAX TRANSMITTAL

BUREAU OF COMMUNICABLE DISEASES
DIVISION OF IMMUNIZATIONS

Original: 2142

PLEASE DELIVER AS SOON AS POSSIBLE

TO: Jim Smith

ASB/10/30

4 PAGES, INCLUDING THIS COVERSHEET.

FAX NO.: 783-2664 TELEPHONE NO.:

SENT BY: Lynn Ferson / Alice Gray

DATE & TIME: 10/30/00 3:30

MESSAGE: F.Y.I

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PA DEPARTMENT OF HEALTH
DIVISION OF IMMUNIZATIONS
PO BOX 90
HARRISBURG PA 17108

REVIEW COMMISSION

2000 OCT 30 PM 4:32

RECEIVED

Original; 2142

Christine Svetz
10365 Nancy Drive
Meadville, PA 16335

September 29, 2000

Alice Gray
Director, Immunization Division
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
2000 OCT -6 AM 9:35
LABORATORY
REVIEW COMMISSION

Dear Ms. Gray,

I am submitting this letter in response to PDH's request for public comments. I strongly oppose the proposed mandate for the Varicella vaccines. I request that this letter is made part of the public record and that PDH respond in writing to my comments.

This vaccine is currently available to any child in Pennsylvania whose parent wants it administered; the issue here is that PDH's proposal will make it illegal if a parent wishes to delay or opt out of giving the vaccine.

I am one of the parents who actually opted to give this vaccine to my children. It is a decision that I greatly regret now that I know more facts about the vaccine. As stated by the manufacturer, varivax vaccine has not been "evaluated or tested for their carcinogenic potential, mutagenic potential or for impairment of fertility" or "reproductive capacity" and "the duration of the protection is unknown at present". Those statements scare me. I now believe all that I have done in giving my sons this vaccine is delayed the disease, potentially to their adult years when it is so much more dangerous to have. Many doctors I have talked to since making this decision have expressed grave concern over this vaccine.

Additionally, my youngest son participated in the Merck vaccine trial through University of Pittsburgh Medical Center, which combined the varicella vaccine with the MMR vaccine. My son is autistic. In light of the recent research done by Dr. Andrew Wakefield and Dr. Vijendra Singh, I have grave concerns about whether the MMR is a contributing factor to my son's autism. And I gave that to him with an additional untested vaccine - I lay awake many nights wondering what kind of damage I may have done to him. My doctor, who recommended we participate in this trial, cannot give me any information about the results of the trial. That makes me very leery.

Please give this proposal very serious consideration. In light of the many proven cases of childhood vaccine damage and the current research signaling more suspicions, mandating a vaccine for a rather harmless childhood disease does not make sense. Let parents decide what is right for their children until such time that proper long-term research has been done. I am living with the possible effects of vaccine damage. You are not.

Sincerely,



Christine Svetz

Original: 2142

Gray, Alice

From: jims@IRRC.STATE.PA.US
Sent: Friday, October 27, 2000 4:19 PM
To: agray@state.pa.us
Subject: RE: Areas for discussion on School Immunization (IRRC #2142)

IRRC's fax is 783-2664

Thanks,
Jim Smith
IRRC
783-5439

-----Original Message-----

From: Gray, Alice [mailto:agray@state.pa.us]
Sent: Friday, October 27, 2000 4:12 PM
To: 'jims@IRRC.STATE.PA.US'
Cc: Kopelman, Janice; Kostelac, Yvette
Subject: RE: Areas for discussion on School Immunization (IRRC #2142)

RECEIVED
2000 OCT 30 AM 10:21
REVIEW COMMISSION

Regarding your question during our meeting on October 26, 2000 regarding potential danger to an immunocompromised household contact of a child receiving varicella vaccine.

I believe this question/concern was posed from the Pennsylvania Chapter of the Academy of Family Physicians.

Please email me your fax number and I will return information from the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR) and from the American Academy of Pediatrics Policy Statement that discusses Varicella immunizations and household contacts of Immunocompromised Persons.

I have also had a conversation with Dr. Barbara Watson from the Philadelphia Department of Health who is considered a leader in varicella vaccine/immunization research. She stresses the point that it is more important for children to receive varicella vaccine when there are immunocompromised household contacts since if there is breakthrough varicella rash from the immunization with infection of contacts; the infection is less severe than if the contact were infected as a result of disease brought into the household. If there is contact infection from vaccine, the timeframe for infection is anticipated to be the same incubation time as from disease. (However, there is very little research information available about this.)

Also, Dr. Watson explained that there just isn't research information available; but vaccine associated disease is very rare, that if there is vaccine associated disease it is milder and not transmissible. Immunocompromised household contacts are not a contraindication for varicella immunization.

AMERICAN ACADEMY OF PEDIATRICS Vol 95, No 6 May 1995

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