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IRRC

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Sent: Thursday, October 19, 2000 11:53 AM
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Subject: regulation # 10-162(#2142), School Immuniation, Department of Health

Microsoft Word 4

For the attention of Robert E. Nyce, Exceutive Director

My Collegue Dr Susan Lett MD, in MA State Health department forwarded the testimonials that helped pass the regulation in MA for Varicella VAccine. I have her permission to forward for your use.(See attached file: Testimonyhearing.doc)

ARGEO PAUL CELLUCCI
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Bureau of Communicable Disease Control

To: Howard K. Koh, MD, MPH
Commissioner, Massachusetts Department of Public Health

Members of the Public Health Council

From: Susan Lett, M.D., M.P.H., Medical Director
Massachusetts Immunization Program (MIP)

Howard Saxner
Deputy General Counsel

Anne H. Sheetz
Director of School Health

Date: May 12,1997

Re: Request for Final Promulgation of Amendments to 105 CMR 220.00: Immunization of Students before Admission to School

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INTRODUCTION

This memorandum summarizes the development of the amendments to the regulations, the testimony submitted and the response of the Massachusetts Department of Public Health (MDPH) staff. It contains the following sections:

TABLE OF CONTENTS

I. BACKGROUND

The Department is granted authority to protect the children of the Commonwealth against vaccine-preventable diseases by requiring certain immunizations at entry to preschool, school and college (MGL Ch. 76, ss 15 and15C). The purpose of 105. CMR 220.000 is to establish specific requirements for childhood immunizations.

Since the school regulations were last amended in 1994, several new vaccines have been licensed, and both the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP) have made additional recommendations concerning the optimum immunization of children. In order to better protect our children against vaccine-preventable diseases, we developed these proposed regulations to incorporate two new vaccines (DTaP and varicella), expanded recommendations for adolescent hepatitis B vaccine, and incorporate the other most recent recommendations of the ACIP, AAP and American Academy of Family Physicians (AAFP) on the schedules for other vaccines. In addition, recent college outbreaks of measles and rubella, which were introduced by students visiting from other countries, have prompted us to propose expanding the scope of college immunization requirements.

Discussions to revise these regulations began in the spring of 1997, prompted by requests from the pediatric care providers and the school and college health communities. Since that time, MDPH staff have attended or held numerous meetings to obtain input from a variety of professional groups and parent organizations. The Massachusetts Medical Society and the Massachusetts chapters of the AAP and AAFP have reviewed and endorsed the proposed changes. The Massachusetts Parent Teachers Association, Parents as Partners (a pediatric advocacy group affiliated with Boston Medical Center) and the New England Primary Immune Deficiency Network have also endorsed the regulations. We did not receive any testimony from any professional groups opposed to the amendments.

II. DESCRIPTION OF AMENDMENTS TO THE REGULATIONS

The final regulations incorporate the following changes:

1. **Definitions:**
   a) **Physicians Certificate Definition:** This term has been changed to "certificate of immunization" and expanded to include a report from the Massachusetts Immunization Information System.
   b) **Student Definition:** This definition now includes students attending specified pre-schools, schools and post-secondary schools, if the educational program is offered on or off-site within the Commonwealth. It will also include foreign students visiting classes or programs as part of formal academic exchange programs.
      - **In the school setting:** The regulations now pertain to all students, elementary through high school, and certain pre-school settings, including those visiting from other states and countries.
      - **In the college setting:** In addition to the current requirements for full-time students and full-time and part-time health science students, the regulations now include students from other countries while on a student or other visa.

2. **Preschool Requirements:** Adds varicella vaccine and requires administration of "vaccines to protect against other communicable diseases, as specified from time to time by the Department" in accordance with the Advisory Committee on Immunization Practices.
   This language would make the requirements for preschool programs, offered by a public school system, similar to those of the Office of Child Care Services, formerly known as Office for Children, in its regulations for day care centers. This will keep regulations uniform for both day care centers and preschools. In addition, it would allow requirements for the most newly licensed and recommended vaccines to be applied to our youngest and most vulnerable group in a more timely manner.

3. **Kindergarten Through 12th Grade**
   a) **Polio:** Makes a requirement of 4 doses (unless the third dose of an *all* oral polio vaccine [OPV] or an *all* inactivated polio vaccine [IPV] series was administered after the fourth birthday).
   This reflects the most recent recommendations of the ACIP and AAP for the sequential schedule, which requires 4 doses in the primary series.

   b) **Varicella:** Requires varicella vaccine for all susceptible students entering kindergarten and 7th grade, beginning in 1999. Beginning in 2005, this requirement

would be extended to all grades K through 12. One or two doses would be required, dependent on the age when the first dose was received.
This reflects the most recent recommendations of the ACIP and AAP.

c) **Hepatitis B:** Extends the requirement for 3 doses at kindergarten entry to all children entering 7th grade in 1999. Beginning in 2005, this requirement would extend to all children in grades K through 12.
This reflects the most recent recommendations of the ACIP and AAP.

d) **Td:** Moves the requirement for a booster from 10th through 12th grade to 7th grade, if it is 5 years or more since the last dose.
This reflects the most recent recommendations of the ACIP and AAP. It standardizes the age for "catch-up" or booster doses and serves to reinforce a routine adolescent health visit for other preventive screening, care and counseling.

4. **College**

a) **Scope:** Changes the scope of the regulations to apply to post-secondary students attending an educational program offered on or off-site in Massachusetts. In addition to the current requirements for full-time students and the full-time and part-time health science students, the regulations apply to students attending a post-secondary institution while on a student or other visa, including foreign students attending or visiting classes as part of a formal academic visitation or exchange program.
This language helps to clarify that colleges are responsible for students on all of their campuses within this state and that the regulations apply to certain foreign or visiting students (who were responsible for the recent measles and rubella outbreaks on college campuses).

b) **Hepatitis B:** Beginning in September 1999, requires 3 doses for health science students, extending this to apply to all college students covered by the regulations in 2005.
This reflects the most recent recommendations of the ACIP, the AAP and the American College Health Association.

III. SUMMARY OF TESTIMONY

On April 7, 1998 the Department held a public hearing on the proposed amendments to the regulations governing the Immunization of Students before Admission to School (105 CMR 220.00. Oral testimony, presented by a total of 34 individuals and representatives of organizations, was equally divided (17 and 17) as to support or opposition to the proposed amendments. In addition to the oral testimony, we received written testimony from 125 in favor of the regulations (including 60 form letters) and 1,490 opposed to the regulations (including 1,457 form letters). Thus, there were a total of 142 pieces of testimony in support and 1,507 opposed to the amendments to the regulations.

Testimony in Favor of Regulations

Seventeen oral presentations of testimony and 125 pieces of written testimony (including 60 form letters) were received, for a total of 142 pieces of testimony. Fifteen professional and three consumer, parent advocacy groups gave strong endorsement of the proposed amendments in entirety, as follows:

Professional Organizations

Infectious Diseases Society of America
Massachusetts Chapter of the American Academy of Pediatrics (AAP)
Massachusetts Chapter of the American Academy of Family Physicians (AAFP)
Immunization Initiative of the MAAP and MAAFP
Massachusetts Medical Society
Massachusetts College Health Association of Nurse Directors
Charles River College Health Association
Eastern Massachusetts Chapter of Pediatric Nurse Associates and Practitioners
Massachusetts School Nurse Organization
Massachusetts School Physicians' Committee
Massachusetts Coalition of School-Based Health Centers
Student Support Services, Boston Public Schools
Massachusetts Health Officers Association
Massachusetts Municipal Public Health Nurses Association
Massachusetts Immunization Action Partnership

Consumer, Parent Advocacy Groups

Massachusetts Parent Teacher Association
Parents as Partners
New England Primary Immune Deficiency Network

Testimony of Note: In addition to these organizations, the Chiefs of Pediatric Infectious Disease at New England Medical Center, The Children's Hospital Medical Center, and the University of Massachusetts Medical Center gave oral testimony strongly supporting the new requirements. Other professionals testifying were the Clinical Director of the Pediatric AIDS Program at Boston University (on behalf of the 250 children with HIV disease in Massachusetts); the Director of the Pediatric Allergy - Respiratory Division at Boston Medical Center (on behalf of the thousands of children in the state who take immunosuppressive drugs to control their asthma), the Director of Communicable Disease Control at the Boston Public Health Commission (on behalf of high risk children and adults); and the Director of the Department of Health and Human Services for Region I (formerly the Commissioner of the Boston Department of Health and Hospitals). The Massachusetts Immunization Action Partnership, a broad-based coalition of health care providers, community-based organizations and consumers also gave testimony in support of the amendments.

Several parents gave testimony about the severe complications of chickenpox in their children, e.g., group A streptococcal infections ("flesh-eating bacteria"), respiratory complications, surgical complications and death. The founder of the New England Primary Immune Deficiency Network spoke on behalf of over 9,400 individuals in Massachusetts who are immunosuppressed and at greatest risk of experiencing the complications of chickenpox.

In addition to the testimony received from Massachusetts residents and organizations, Drs. Samuel Katz (Co-chair) and Bruce Gellin (Staff Director) of the Vaccine Initiative of the Infectious Disease Society of America, provided written testimony. Dr. Katz is currently Davison Professor and Chairman emeritus of the Department of Pediatrics, Duke University Medical Center. Dr. Gellin, currently on leave from the National Institutes of Health, is an Adjunct Assistant Professor, Department of Preventive Medicine at Vanderbilt University Medical Center. Dr. Katz has been a national and international leader and mentor in pediatric infectious diseases and vaccine research. While a staff member at The Children's Hospital here in Boston, he worked with Nobel Laureate John Enders on the development of the measles vaccine formulation, which is now used throughout the world. He has chaired the Committee on Infectious Diseases of the AAP (the Red Book Committee), the Advisory Committee on Immunization Practices, the Vaccine Priorities Study of the Institute of Medicine and several WHO panels. His published studies include more than 100 articles and chapters in textbooks. He is the co-editor of a textbook on pediatric infectious diseases.

Dr. Anthony Robbins, editor of *Public Health Reports*, former director of the National Vaccine Program Office and Assistant Surgeon General of the US Public Health Service, while Director of the National Institute for Occupational Safety and Health, also gave testimony in support of the regulations. Dr. Robbins, when working for the Committee on Energy and Commerce of the US House of Representatives, drafted the legislation for the National Vaccine Program. He has spent over 30 years in public health, with over 10 of them working on vaccine policy.

Description of Written Testimony: In addition to the 17 pieces of oral testimony, the Department received a total of 125 pieces of written testimony from individuals or organizations, for a total of 142 pieces of testimony in support of the amendments . Included in this number is a letter signed by 35 school physicians. Additional letters of support were signed by 30 parents (of which 27 were form letters), 6 public health /school nurses, 38 from physicians (of which 33 were form letters), one director of a local board of health, one senior citizen with neuralgia following shingles, with the remaining from the various professional and parent organizations described above.

Testimony Against Proposed Amendment

Seventeen pieces of oral testimony and 1,490 pieces of written testimony (including 1,457 form letters) were received , for total of 1,490 pieces of testimony. No opposing testimony was received from any professional organizations. Three consumer, parent advocacy groups opposed the proposed amendments, as follows:

National Vaccine Information Center
New England Patients' Rights Group, Inc.
Massachusetts Citizens for Vaccination Choice

Testimony of Note: Representative John Rogers, Chairman of the House Judiciary Committee, gave oral testimony opposing the regulations on behalf of those Massachusetts citizens who believe in parental choice for immunizations and for those who may object to immunizations for religious reasons. In particular, he raised a concern that varicella vaccine might be made from fetal tissue.

Debbie Bermudes, Co-Director, Massachusetts Citizens for Vaccination Choice, which is an organization composed of concerned parents and others who advocate that people be given complete and unbiased information about vaccines and be allowed to make informed vaccination decisions, gave the official testimony on behalf of her organization. Linda DeBenedictis, President, New England Patient's Rights Group, which is a support and advocacy group committed to informing and educating the public about issues concerning patients' rights to accurate, unbiased information, "informed consent (choice)", oversight, accountability, protection and insurance issues, gave testimony on behalf of her constituents. David Barnes, PhD., Assistant Professor, History of Science, Harvard University, also gave testimony opposing the proposed amendments. He cited historical trends and raised issues about the varicella vaccination policy. Two local pediatricians, Drs. Roger Spingarn and Janet Levitan, gave oral testimony opposing the varicella vaccine requirement.

In addition to Massachusetts individuals and organizations, Barbara Loe Fisher, President of the National Vaccine Information Center, a non-profit, education organization, located in Vienna VA, also gave testimony opposing the regulations. Ms. Fisher is the parent of a child who was brain injured as result of an immunization. She is the co-founder of this organization, along with other parents of vaccine injured children. Their goal is the prevention of vaccine injuries and death through education.

Description of Written Testimony: In addition to the 17 pieces of oral testimony, the Department received 1,490 pieces of written testimony against the proposed amendments, (of which 1,457 were form letters signed by parents). Additional letters of opposition were received from 2 physicians and 1 chiropractor. Six legislators submitted written testimony opposing the regulations (Senator Stephen M. Brewer [on behalf of over 300 constituents in his 32-town district who signed petitions or wrote letters in opposition], Senator Robert A. Durand, Assistant Majority Leader, Senator Robert A. Antonioni,

Senator Robert A. Havern III, Representative Anne M. Paulsen, and Representative J. James Marzilli).

Please refer to SECTION VII for a list of selected testimony given by both the proponents and opponents to the amendments. In addition, given the volume of the testimony, Public Health Council members may want to review all of the written testimony, which is currently held at the State Laboratory Institute. You can contact Dr. Susan Lett at 617-983-6800, to make arrangements to inspect the testimony.

IV. REVIEW OF THE ISSUES

The vast majority of the testimony addressed two issues: parental choice and the addition of the requirement for chickenpox immunization. Two individuals raised opposition to the addition of the adolescent hepatitis B requirement. A few individuals raised issues about the notification of parents about the proposed amendments to the regulations and the public hearing process.

In order to address the issues, MDPH staff organized the testimony and response into nine categories, as outlined below:

1. Broad-based immunization programs and school immunization requirements vs. parental choice
2. Seriousness of varicella disease
3. Duration of protection from varicella vaccine and optimal age for vaccination
4. Relationship between varicella vaccine and shingles
5. Vaccine risks (contaminants, side effects, immune system suppression/dysfunction, chronic disease)
6. Use of illegally aborted fetuses for varicella vaccine production
7. Influence of the varicella vaccine manufacturer on vaccine recommendations and requirements
8. Hepatitis B immunization for adolescents
9. Issues relating to notification about proposed amendments and the process

These nine issues are addressed in the following three sections:

A. Testimony in Favor of the Proposed Regulations
B. Testimony Opposed to the Proposed Regulations
C. MDPH Staff's Response to the Testimony

A. Testimony in Favor of the Proposed Regulations

1. Broad-based immunization programs and school immunization requirements vs. parental choice

Synopsis: Proponents of the proposed regulations cited the sharp declines in vaccine-preventable diseases in recent decades due to widespread use of vaccines; the possibility and desirability of reducing varicella incidence, morbidity, and mortality through mandated vaccination of school-children; and the advantage of broad-based vaccination programs in protecting vulnerable sectors of the population who cannot be vaccinated.

Some excerpts from the testimony:

> The widespread use of safe and effective vaccines is responsible for the remarkable declines in vaccine-preventable diseases that we have witnessed just in the past two decades.... We should learn from, not ignore, important historical lessons. In several states, including Massachusetts, a policy that allowed for non-uniform use of rubella vaccine that went on for a decade (1969-1979) resulted in an outbreak in the early 1990s that resulted in over 130 cases of rubella and a case of a congenital rubella infection in Massachusetts. Policies like these that allow for complacency about the use of vaccines foster a growing pool of susceptible children and adults and provide the key ingredients in a recipe for the epidemics which will predictably follow... Should our past success fuel this complacency in Massachusetts, this could well be the focus of the next article in a medical journal about the resurgence of epidemic diseases that had been under tight control. We hope that you will endorse a policy that will not allow history to repeat itself.
>
> -- Samuel L. Katz, MD, Co-Chair, and Bruce G. Gellin, MD, MPH, Staff Director, Infectious Diseases Society of America Vaccine Initiative

> It is through herd immunity that we eradicated polio from this hemisphere. Without a tight regulatory system designed to immunize everyone as early as possible, to immunize all non-immune people who have not had the "wild" disease, we cannot hope to protect those who most need protecting, nor can we ever hope to eliminate the illness, as we have smallpox.
>
> -- Sean Palfrey, MD, pediatrician, Boston Medical Center, speaking on behalf of the Massachusetts Chapter of the American Academy of Pediatrics and the Immunization Initiative of the MAAP and MAAFP

> Immunizations represent the ultimate primary prevention measure...By requiring school-aged children to be immunized we are able to:
>
> 1. assure that their classmates are at considerably reduced risk of contracting vaccine preventable illnesses from them,(a public health benefit)
> 2. 2. Assure the child (and household contact) that they are safe form vaccine preventable illnesses, (a personal benefit).

In many instances, society is compelled to place the good of the public over the personal freedom of the individual. Helmet laws and seat belt laws are simple examples.

> -- Michael R. Rousse, University of Massachusetts Medical School, Department of Family and Community Medicine, representing the Massachusetts Chapter of the American Academy of Family Physicians and the Immunization Initiative of the MAAP and MAAFP

Primary Immune Deficiencies affect approximately one in five hundred children....[Some of these children] cannot receive live vaccines. In order to avoid disease, [they have] to rely on the general population to be relatively free from disease.... Please help me to keep these children healthy by requiring that all immuno-competent children receive the varicella vaccine.

> -- Stan Graziano, parent, Co-Founder, New England Primary Immune Deficiency Network

As a clinical director of a pediatric AIDS program at Boston Medical Center, I'm here to represent the 250 children in Massachusetts with HIV disease. They cannot receive the vaccine because of their fragile immune system.... This population can get varicella repeatedly, each time risking devastating complications. For some, the infection can lead to chronic damage to their central nervous system or other organs. I've seen children with varicella who have undergone stroke, aneurysm, cerebral hemorrhage, or death. Each time a child with HIV disease gets exposed to varicella, they must receive a large-volume intramuscular injection of varicella immune globulin if they know they've been exposed.... Thirty days later they must receive a second dose if they get repeated exposures. This happens multiple times... in just one season.... The only way to safely protect [the immunocompromised] population is to reduce exposures. The only way to do that is to ensure widespread use of the vaccine to decrease the incidence of the disease in the community. ...I ask that you don't forget the most fragile part of [the] public.

> -- Ellen Cooper, MD, Clinical Director, Pediatric AIDS Program, Boston Medical Center

Vaccination coverage protects those children who are not vaccinated or in whom vaccines are not effective.... A decision not to be vaccinated may pose an accepted and acceptable risk to the individual, but it poses an unnecessary and unchosen risk to all fellow citizens in the community.

> -- Anthony Robbins, MD, Editor, *Public Health Reports*

People talk a lot about this issue in terms of parent or child rights. Well, I want to talk about the rights of myself as a parent and my child to not be exposed to people who are not vaccinating their children. I have no problem if people wanted to choose to not vaccinate their children--that's their right to decide for their

family. I have a great deal of problem if they want to then put those children in school or daycare and then increase the risk to my child.

-- Ron Samuels, MD, Associate Director of Community Services and Support Programs, Children's Hospital

The schools of today have many children in attendance with chronic conditions who in years gone by would not have been present in a public school setting. Schools have a legal and ethical responsibility to ensure that all students are protected from the risk of vaccine preventable disease. Students with cancer, heart transplant patients, students on corticosteroid therapy, those who are HIV afflicted and pregnant teens are in our schools. To those students an outbreak of whooping cough, measles or chickenpox could be seriously debilitating or, in some cases fatal.

-- Marcia Buckminster, President, Massachusetts School Nurse Organization

As a school physician, I am committed to improving the immunization rates of school-aged children to provide for community-wide protection against vaccine-preventable diseases. School is the last safety net for immunizations to ensure protection for the vaccination recipient as well as for those most vulnerable who cannot get vaccinated. ...it is the universality of childhood varicella vaccination that will best protect those who are at greatest risk. ...the vaccine...should be required for all students in school in the Commonwealth. The requirement for immunizations for students attending a post-secondary institution while on a visa will the prevent the visiting student from being a source of disease importation. All of these regulations will provide individual protection as well as the necessary population-based immunity for the prevention of epidemics. It is precisely in those communities with the greatest number of exemptions that outbreaks have been documented to occur. We can ensure the safety of all of our children who attend school against vaccine-preventable diseases by requiring broad-based immunization coverage. It is our duty to protect our children, and it is their right to be protected.

-- Carol Podolsky, MD, Co-Chair, Massachusetts School Physicians Committee, Massachusetts Chapter of American Academy of Pediatrics

Universal vaccination by school entry has been a very important individual and public health tool. It assures protection for the recipient, and also provides "herd immunity," which is particularly important for those in the community who cannot safely receive a vaccine for medical reasons.... In situations where important vaccines are not mandated, or parents "choose" to not vaccinate their children, the incidence of the disease always remains high and epidemics do occur [quotations in original].... All major health organizations in the country support chicken pox vaccination. In Massachusetts we are offering this vaccine free to children, and we have the opportunity to eliminate the illness from the entire school age population.

As a result, we can protect many older and at risk individuals in our communities. The only way we can assure this is to require varicella vaccination for school entry.

-- from letter signed by 35 Massachusetts school physicians

My child needs to get chickenpox? My child doesn't need to get chickenpox!

-- Lavinia Frazier, mother of 24-week premature baby (now 14 months old), representing Parents as Partners

One of the best reasons for vaccinating all children before they get to school is to prevent children and adults at risk from getting it from an unvaccinated child, before he even appears sick.... It also makes no sense to have some children, whose parents don't want them vaccinated for personal reasons, putting lots of other people, especially grown-ups at risk. By vaccinating all children, we can protect the whole community.

-- Joyce M. Knippenberg, President, Massachusetts Parent Teacher Association

2. Seriousness of varicella disease and the need for universal vaccination

Synopsis: By oral and written testimony, proponents of the proposed legislation cited the large volume of literature from past, present, and ongoing research regarding the severity of chickenpox disease. They noted that between 9,000 and 15,000 hospitalizations occur per year in the United States, two-thirds of them in children; and there are over 100 deaths per year, approximately half of them in children.

Many of those testifying were physicians and nurses, affiliated with Children's Hospital, the New England Medical Center, and Boston Medical Center, who see first-hand the children with the complications cited in the literature, such as: pneumonia, encephalitis, cellulitis, abscesses, necrotizing fasciititis, which requires extensive surgical debridement and sometimes amputation, and death. Even in uncomplicated cases, chickenpox is a relatively serious disease producing high fevers, hundreds of lesions all over the body--which can and do appear in the mouth, the eyes, the underarms, and genitalia--for up to one week.

Some parents and other family members of children who had experienced complications also gave testimony, describing their childrens' suffering; two of them had lost their children as a result of the complications.

For the reasons stated below in their testimony, the proponents feel that the public should understand that varicella is not a mild disease and that vaccination to protect our children from its complications is indicated.

Some excerpts from the testimony:

I took care of 2 children last year with very serious infectious complications of chickenpox disease, one attended [a] daycare center [in Boston] which had [an] outbreak of invasive strep [group A streptococcal disease]. She required drainage of an abscess. I've seen children die of Reyes syndrome, another brain disease associated with chickenpox. I've seen children with chickenpox pneumonia, which is what most adults die of if they contract fatal chickenpox.

-- Sean Palfrey, MD, pediatrician, Boston Medical Center, speaking on behalf of the Massachusetts Chapter of the American Academy of Pediatrics and the Immunization Initiative of the MAAP and MAAFP

People have come to think of the disease [varicella] as a childhood one and not life-threatening. From my own family's personal experience, the chicken pox is life-threatening and children do die from the disease. Our daughter died in 1993 from the chicken pox and the doctors said that if the vaccine had been approved and she had been vaccinated, that she probably would have lived. Dr. Lett's concern is not only with all children, but the most vulnerable ones. No one, especially this small group that is opposed to the mandatory vaccine, knows which children are more susceptible to this still very deadly disease... Lives are on the line. My family and I do not want anyone else to lose a family member to a 'simple childhood disease.'

-- Margaret H. Flanagan, parent

....if we fail to vaccinate at an early age, we accept the fact that 50 kids (<6 years of age) per year will die of complications [nationally]....It is distressing to watch kids die of a preventable disease. Chickenpox is not a question of a mild disease [because] seemingly simple, uncomplicated chronic conditions can cause death when coupled with chickenpox. Many of the hospitalizations are very severe, leading to deformities, disabilities, and surgical scars that these children will have to wear for life.

-- Ed O'Rourke, MD; Medical Director, Infection Control, Children's Hospital

Chickenpox is not such a mild disease that a vaccine is not needed. The consequences of chickenpox infection are not always benign. Hospitalization rates due to complications of chickenpox among members of a Massachusetts HMO were recently determined to be 0.4% or 1 per 250 people. Among children under 13 years of age, the hospitalization rate is as high as 1 per 200. Chickenpox is now recognized as a major preceding event in the development of group A streptococcal cellulitis, necrotizing fasciitis and streptococcal toxic shock syndrome.

-- Cody Meissner, MD, Chief, Pediatric Infectious Diseases Division, NEMC

I'm worried that for some unsound reasons we in Massachusetts may wait until other young children have either suffered the loss of their limbs or their lives or

come very close to it. My son has no ill effects after this and we're very fortunate. But he does have scars, and they go from here down to here... [shows shoulder-to-hand extent of scars], but to us they're beautiful because they saved his life. But I don't want to see other kids going through this, and the fact that I keep hearing of these reports [of invasive group A Streptococcal disease] is very alarming to me... So I'm asking you to make the choice on chickenpox [vaccine] for Massachusetts children, to make it a choice for the life and health of those children. I urge you to support mandatory immunization.

-- Samuel Coffin, parent of 3-year-old with necrotizing fasciitis subsequent to varicella

...to my family, chickenpox is very expensive.

-- Dottie Smith, had a family member die of varicella complications

I would like to share my perspective as a pediatric pulmonologist primarily engaged in the care of children with asthma. Universal varicella immunization would be very welcome and would provide extra security for my patients, many of whom receive therapy with either high dose inhaled or systemic corticosteroids. There are reports that corticosteroid therapy, certainly when delivered systemically, and even if inhaled, leads to an increased likelihood of disseminated varicella with severe disease and risk of death...These children would be vulnerable to the infection, but a high level of immunity to varicella among friends and classmates will protect them from exposure to the disease and subsequent illness.

-- Suzanne F. Steinbach, MD; Director, Pediatric Allergy-Respiratory Division and Clinic, Boston Medical Center

Although some individuals have attempted to minimize the threat that this childhood disease represents, its prevalence and the severity of its common symptoms are well known to the public. If we can safely and quickly eradicate this disease, we should.

-- Massachusetts Medical Society

3. Duration of protection from varicella vaccine and optimal age for vaccination

Synopsis: Proponent of the regulations cited recent epidemiologic studies in the United States and Japan indicate that protection from varicella vaccine lasts for the whole period for which data are available in each of those countries (10 years in the U.S. and 20 years in Japan), with no apparent decline. According to the testimony, varicella vaccine is a live viral vaccine like MMR, works through similar immunologic mechanisms, and would be expected to confer life-long protection.

Proponents cited the optimal age for varicella vaccination is early childhood. They noted both public health and individual health reasons for this. The incidence of varicella is

highest in early childhood, daycare and school entry requirements ensure widespread coverage, and vaccine-induced immunity is most complete when the vaccine is received in early childhood.

Some excerpts from the testimony:

> It is important to acknowledge that since this vaccine has been tested in humans for "only" 20 years, that is the extent of our knowledge about it. We will continue to evaluate the duration of protection over time but long-term follow-up of studies conducted in Japan in the 1970s provide reassurance that protection persists at least 20 years and that "breakthrough" cases that occur in persons previously vaccinated are far less severe than natural infection.
>
> -- Samuel L. Katz, MD, Co-Chair, and Bruce G. Gellin, MD, MPH, Staff Director, Infectious Diseases Society of America Vaccine Initiative

> ...several observations indicate that loss of immunity does not occur in [varicella-] vaccinated persons:
>
> 1. First, it is clear that more than 95% of vaccinated, healthy children respond to the vaccine and maintain antibody titers for at least 20 years.
> 2. Second, among the small number of vaccinees who experience a fall in antibody titer, at least some immunity is maintained. This is partly because immunity to the chickenpox virus comes not only from antibodies which are easy to measure but also from T cells or cellular immunity which is more difficult to evaluate.
> 3. Third, in healthy vaccinated individuals, mean antibody titers are similar between individuals with and without a history of chickenpox exposure. This suggests that ongoing exposure to chickenpox virus in the community is not necessary to maintain immunity. It appears that the attenuated chickenpox vaccine strain has the ability to periodically stimulate the immune response, preventing antibody concentrations from waning. This is similar to what occurs following infection by the natural chickenpox virus.
> 4. Fourthly, it is important to recognize that breakthrough chickenpox which occurs in previously vaccinated individuals is almost exclusively a mild disease. Neither the incidence nor the severity of breakthrough disease increases with an increasing interval of time since vaccination....
>
> The most effective route to eradication of chickenpox and its complications is to require immunization early in life.
>
> -- Cody Meissner, MD, Chief of Pediatric Infectious Disease, New England Medical Center

4. **Concern about the relationship between varicella vaccine and shingles**

Synopsis: Proponents of the testimony submitted data documenting the decrease in shingles in varicella vaccine recipients, compared to those who have had natural chickenpox infection.

Some excerpts from the testimony:

> There is also recent evidence to suggest that the use of varicella vaccine can reduce the incidence and severity of herpes zoster (commonly referred to as shingles), which represents the emergence of chickenpox virus later in life.
>
> -- Samuel L. Katz, MD and Bruce G. Gellin, MD, MPH, Infectious Diseases Society of America Vaccine Initiative

> I was diagnosed some years ago [with long-term shingles]. The remnant leaves me with a painful eyebrow and itchy painful lumps on my forehead. The best medical treatment ... was unable to induce much improvement for post-herpetic neuralgia. Because of this widespread threat to life enjoyment among our elder citizens, victims of chickenpox in their youth, I strongly urge consideration of the vaccination program...
>
> -- Paul Staples, senior citizen,

5. Vaccine risks (contaminants, side effects, immune system suppression/dysfunction, chronic disease)

Synopsis: Those submitting testimony in favor of the proposed legislation repeatedly stated that varicella vaccine is a very safe vaccine, and it is one of the most widely studied vaccines ever licensed for use in the United States. They also noted that no vaccine is 100% safe or effective, that there is, as with other medication, a risk of adverse reactions or side effects in a small number of patients. They also noted that the side effects associated with varicella vaccine are very minor; and when breakthrough disease occurs, it is very mild, compared to naturally acquired chickenpox. In summary, they felt that the benefits of varicella vaccine far outweighed the risks, when compared to the risks of varicella disease.

Some excerpts from the testimony:

> This vaccine was licensed in the United States in 1995 after more than 20 years of research and testing to assure its safety and efficacy.
>
> -- Samuel L. Katz, MD; Co-Chair, Bruce G. Gellin, MD, MPH, Staff Director, Infectious Diseases Society of America Vaccine Initiative

> Epidemiological data clearly demonstrate that there is no more effective preventive health measure than childhood immunizations and their support through strong state funding and regulation is an important and vital role of government.
>
> -- Robert Hoch, MD, MPH; Co-Chairperson, Massachusetts Immunization Action Partnership & Director of Pediatrics, Carney Hospital

...the lack of immunization has been shown to increase morbidity and mortality... The vaccine injury literature [published by groups opposed to routine immunization] is not nearly as scientific or conclusive.

-- Michael R. Rousse, University of Massachusetts Medical School, Department of Family and Community Medicine, representing the Massachusetts Chapter of the American Academy of Family Physicians and the Immunization Initiative of the MAAP and MAAFP

It is important to recognize that breakthrough chickenpox which occurs in previously vaccinated individuals is almost exclusively a mild disease.

-- Cody Meissner, MD; Chief, Pediatric Infectious Diseases Division, NEMC

In the face of having a safe vaccine which provides a 95% protection rate against severe varicella disease combined with evidence of 20 years duration of protection in immunized populations being followed prospectively, I feel the.....risks from this vaccine preventable disease are unacceptable. As with other new vaccines, the prudent and careful evaluation of the need for booster doses will address the concern of producing protection in childhood and increased risk to these same children as adults.

-- Patricia H. Moffatt, MD; physician in private practice in Waltham

The chicken pox vaccine is extremely safe (much safer than the illness) and is effective in more than 95% of children. Ten years of experience with the vaccine shows no waning immunity. All major health organizations in the country.....urge chicken pox vaccination. In Massachusetts we are offering this vaccine free to children [to] have the opportunity to eliminate the illness for the entire school age population.

-- Tracy Magee, MSN, CNPN; Eastern Massachusetts Chapter, National Association of Pediatric Nurse Associates & Practitioners

6. Use of illegally aborted fetuses for vaccine production

This issue was not addressed in any of the proponents' testimony.

7. Influence of the vaccine manufacturer on vaccine recommendations and requirements

This issue was not addressed in any of the proponents' testimony.

8. Hepatitis B immunization for adolescents

Synopsis: Proponents for the amendments described the importance of protecting adolescents before their period of greatest risk and cited the lack of success of immunization strategies that targeted only high risk groups.

Some excerpts from the testimony:

> I strongly urge promulgation of the proposed changes to the school vaccination requirements...including the expanded hepatitis B immunization requirement, which will serve to prevent this disease with a safe and effective vaccine...it is only through universal immunization of children before adolescence and adulthood, when the risk of infection is greatest, that can one expect to see a reduction in hepatitis-associated liver disease.
>
> -- Carol Podolsky, MD, Co-chair, Massachusetts School Physicians Committee, Massachusetts Chapter of the American Academy of Pediatrics

9. Issues related to notification about proposed amendments and the process

This issue was not addressed in any of the proponents' testimony.

B. Testimony Opposed to the Proposed Regulations

1. Broad-based immunization programs and school immunization requirements vs. parental choice

Synopsis: The opponents stated that vaccination should not be mandated by the state. Parents should have the right to be fully informed of the risks and benefits of vaccines and to decide whether to have their children vaccinated.

Some excerpts from the testimony:

> They [parents] would not have the right to decline, like in those other instances according [to] that information which we have disclosed to them, even when that information compels them to decline, even [when] in their own judgment or their own philosophical objections, they so decline. We take away that right to decline, which is present in truth in advertising, truth in lending and informed consent laws; and in this instance we disenfranchise parents. ... When we tell parents to forfeit their own right over the health care decision of their own children, then we, the government, purport to be ... all knowing.
>
> -- State Representative John Rogers, Chair House Judiciary Committee

> When parents (or prospective parents) ask me my thoughts about vaccination, I tell them the same thing I tell anyone asking my thoughts about any medical procedure—that the decision to accept or reject a proposed intervention should be *informed* consent (or refusal), based on a full and unbiased discussion of the potential risks and benefits of the proposed intervention.
>
> -- Christopher Ryan, MD, physician, West Newton

> Quite simply, these specific interventions [vaccines and therapeutic drugs] played no more than a minuscule role in the historic decline of mortality from infectious

diseases... In the history of American public health policy, the proposed varicella vaccine mandate in Massachusetts represents a strange aberration. We all know that a tiny fraction of the population has such severe immune dysfunction that even otherwise benign illnesses can be life-threatening to them. This fact has been invoked to support the chicken-pox mandate, on the theory that these patients can't be vaccinated themselves, and only mass vaccination of the rest of the population can protect them. Proponents usually fail to point out that....those who are vaccinated will be put at much greater risk of severe varicella infection as adults. I can think of no comparable example in history in which a policy was undertaken to protect the short-term health of a tiny minority at the expense of the long-term health of the vast majority of the population...I can understand how some parents might enthusiastically choose to give [Varivax] to their children. This should be their choice—their informed choice. But the giant leap from option to mandate effectively robs all parents of our informed choice [emphasis in original]. However well-intentioned your motives might be, please don't put all of our children's health at risk later in life.

-- David Barnes, PhD, Assistant Professor of the History of Science, Harvard University

As there has been some confusion about our organization's position about vaccines, I'd like to clarify that MCVC is not opposed to any vaccinations. We are made up of concerned parents and others across the state, some of whom have vaccinated their children, some of whom have chosen not to vaccinate theirs , and some of whom have chosen certain vaccines, but not all. What unites us is the belief that people should be given complete unbiased information and allowed to make informed vaccination decisions...We are opposed to any mandate that would require chickenpox vaccine in the absence of a public health emergency...We've been told that while varicella immunization coverage is necessary to protect the health of our most vulnerable, high-risk children who must rely on the communities to protect them from exposure. Immunocompromised individuals account for an estimated one-tenth of one percent of chickenpox cases. While concern for these individuals is warranted, we must recognize that they are at risk for many otherwise benign illnesses such as the common cold. In addition, we were recently told by one public health official that a varicella vaccine is being developed that could safely be used in such high-risk populations. Therefore, this argument does not justify a mandate...We have been told that the varicella vaccine is routinely recommended by all the expert bodies involved with national vaccine policy. Recommendations by such experts are just that -- recommendations....Clearly there are too many questions and too few definitive answers to mandate this vaccine as a matter of public policy.

-- Debbie Bermudes, Co-Director, Massachusetts Citizens for Vaccination Choice

It is parents' responsibility to oversee the health of their own children. For those of us with an acceptance of the spiritual aspects of human life it is understood that as parents we are divinely appointed to be the caretakers and decision makers for

our children. It is oppressive and presumptuous for anyone else to take that right away from us.... We are moving towards a police state if we accept laws that force us to administer unnecessary vaccines to our children. What next?

-- Lynette Tarkington, parent

The lynch-pin of the medical system is informed consent. The FDA allows the vaccine manufacturers to meet the information portion of this requirement using the package insert. These documents are rarely made available to the parents in a time, manner, and place that allows for thoughtful and reflective analysis with all their questions being answered before making a final decision. The consent portion of this will be all but removed under the proposed regulations. The pressure on parents by the health care and school systems to make a rational health care decision is virtually crushed under the yoke of governmental paternalism.

-- Christopher B. Wood, MS, JD

It is the failure by public health officials to truthfully acknowledge what science does and does not know about vaccine risks; the failure to truthfully communicate disease risks; the over-zealous enforcement of vaccine laws in order to achieve a 100 percent vaccination rate; coupled with the fact that parents are now being told to give their children 34 doses of 10 different [antigens] before they enter kindergarten without the right to informed consent, which has caused a crisis of confidence in the system in the minds and hearts of many conscientious parents.

-- Barbara Loe Fisher, President, National Vaccine Information Center, Vienna, VA

2. Seriousness of varicella disease

Synopsis: Opponents described chickenpox disease as a mild illness--a normal occurrence of childhood. They stated that, based on past information from medical authorities, it is unclear as to why the medical establishment's position on the severity of chickenpox disease suddenly changed when there was a vaccine to be marketed to parents.

Many of those submitting testimony in opposition feel that varicella and its complications can be reduced by being more vigilant about hygiene. Some opponents felt that, indeed, the disease is a danger to immunocompromised, debilitated individuals and that it is those individuals who should receive the vaccine and take necessary precautions to protect themselves, not healthy normal children. However, several opponents felt that the numbers of immunocompromised individuals in the state were too small to be a sufficient reason to mandate vaccination of large numbers of healthy individuals with varicella vaccine. Many of those providing testimony noted that the complications cited by physicians and nurses are extremely rare in healthy children who have no other underlying conditions, and felt that the cases and statistics cited during the testimony were being used as scare tactics to encourage immunization.

Some excerpts from the testimony:

...chickenpox may actually be something positive that contributes to immune system development and functioning.

-- Janet Levatin, MD; pediatrician, Brookline

Consumer groups throughout the nation, physicians, and a growing number of parents are opposed to universal immunization with a live vaccine for a relatively mild childhood illness. Many physicians feel that it's better for children to develop a natural immunity and are concerned and frightened by the 'long term' implications.

-- Linda DeBenedictis, President, New England Patients' Rights Group, Inc..

....extensive arm twisting was not required when vaccines against diphtheria and polio were introduced because these diseases posed sufficient danger to the public, and especially to children. Varicella does not.

-- Roger Spingarn, MD, pediatrician, Newton

A mild disease for most children, chicken pox is caused by the varicella zoster virus, a relative of the herpes virus. The great majority of healthy American children recover from a two to three week bout with chicken pox with no complications [and] are left with permanent immunity to the disease. However, immun[o]- compromised children, such as those with leukemia or kidney disease, frequently develop severe complications from chicken pox leading to brain damage and death. A varicella zoster vaccine was originally developed to protect high risk individuals such as children with leukemia, kidney disease or immune suppression.

-- Barbara Loe Fisher, President, National Vaccine Information Center

From my professional perspective, I expect that future historians will look back on the Massachusetts chickenpox mandate episode of 1998 as a instructive case study..., in which Massachusetts state public health authorities reached an illogical extreme, attempting to impose universal vaccination to <u>prevent</u> a routine harmless childhood illness...[emphasis in original]

-- David Barnes, PhD, Assistant Professor, History of Science, Harvard University

3. Duration of protection from varicella vaccine and the optimal age for vaccination

Synopsis: The opponents stated that varicella disease almost always confers life-long immunity. Since the varicella vaccine has been in use only a short time relative to some other vaccines, one cannot be assured that vaccine-induced immunity will last for a lifetime; a vaccinated child may become a susceptible adult, and disease then will be more serious. They were concerned that booster doses may be required to sustain vaccine-induced immunity, especially given the expected lower prevalence of disease and the reduced opportunity for natural boosting (claimed by some) as use of the vaccine increases. For these reasons and the fact that the disease tends to be little more than a

nuisance in childhood, they stated the vaccine should not be mandated for toddlers and schoolchildren but rather should be used only for vulnerable adults, susceptible children as they become young adults, and younger children at high risk for complications should they acquire the disease.

Some excerpts from the testimony:

> The first [concern] is waning immunity, which would transfer the disease into the adult population when it is more serious... Studies spanning twenty years in Japan and 10 years in the U.S. are cited as demonstrating the vaccine's effectiveness. However, they do not show what the titer level might be when a 20-month-old or a five-year-old who is vaccinated reaches the age of thirty years or older.... One response we hear is "There might have to be boosters." Adults do not reliably get boosters and even if such boosters were mandated as a condition of employment, ...no one would know exactly when boosters should be given. In addition, if an adult who was vaccinated as a child has no detectable varicella antibodies, it is not known whether the booster will offer any more "protection" than the current two doses of the vaccine recommended for adults.
>
> -- Joan Batista, parent

> We do not know how long the vaccine remains effective. We do not know the effectiveness of later, subsequent doses of the vaccine should the first dose fail, as it probably will, to provide lifetime immunity. Nor do we know what untoward effects may be caused by later doses of the vaccine. I foresee our citizens having chickenpox at an older age, when it is less well tolerated and when complications and even fatalities are more likely.
>
> -- Janet Levatin, MD, pediatrician, Brookline

> ... policies to universally vaccinate children will serve, over time, to eradicate most, but not all, naturally occurring varicella and its immeasurable booster effect.... If the protective immunity of those immunized wanes as they age, or if non-inoculated children escape disease because contagion becomes rarer, proponents acknowledge that outbreaks of life-threatening varicella may occur, resulting in hundreds of thousands of cases, predominantly in older age groups. ...universally vaccinating toddlers and children entering kindergarten against varicella might make sense when it can clearly be demonstrated that susceptible adults can be successfully immunized.
>
> -- Roger W. Spingarn, MD, MPH, pediatrician, Newton

4. Concern about the relationship between varicella vaccine and shingles

Synopsis: Some opponents of the regulations were concerned that either the effect of the vaccine upon shingles was unknown, or it might increase the incidence of shingles in vaccine recipients.

Some excerpts from the testimony:

> We have been told that the varicella vaccine protects against shingles. Since this vaccine's been studied for just 10 years in the United States, none of the people who first received the vaccine have yet reached the age at which shingles typically occurs. This statement cannot be substantiated and this hypothesis does not justify the mandate.
>
> -- Debbie Bermudes, Co-Director, Massachusetts Citizen for Vaccination Choice

> What research has been done to ensure that 5, 10, 15 years later, this vaccine doesn't cause severe shingles?
>
> -- Christopher J. Quigley, Doctor of Chiropractic, Boston

5. Vaccine risks (contaminants, side effects, immune system supression/dysfunction, chronic disease)

Synopsis: As parents and patients' rights advocates, they are concerned about the lack of data on side effects of varicella vaccine that are not available to the public. They are concerned about an association between vaccination and the development of chronic diseases. They feel that the Department of Public Health and the vaccine manufacturer are hiding behind data on safety without addressing the lack of information on the possible side effects that develop over time. They had concerns about vaccine production in general, noting that ingredients such as fetal bovine serum (FBS) and the human and animal diploid cells are used in the production of vaccines and that these substances could very well prove to be toxic to humans.

Some excerpts of the testimony:

> .....the varicella (chickenpox) vaccine is a live-virus vaccine. Some scientists are concerned about the long-term effects of viral DNA from live-virus vaccines being incorporated into human genes. I personally would rather let my child get the disease naturally and develop life long immunity than risk any long-term side effects that might result from the vaccine.
>
> -- Katharine C. Steeger, Assistant Director, Massachusetts Citizens for Vaccine Choice

> The chickenpox vaccine should be kept for immuno-compromised children, or young adults who have a negative titer. We can only project what the effects will be on the immune system 30 years from now. In light of the extent of immune disorders that have shown themselves in the past 30 years, we have less confidence that we are fixing the

problem by doing massive initial vaccinating and the massive subsequent boosting. What support is there for children who develop adverse sequelae from vaccinations immediately versus an insidious onset of possibly unrecognized symptoms?

-- Catherine LeBlanc, Physician's Assistant

Another concern about the live-virus varicella vaccine which has been raised by several doctors and vaccine researchers is that the DNA in the vaccine (which is more abundant than in any other live-virus vaccine) might set off autoimmune reactions and/or alter our genetic make-up. Contamination is another concern. Although the vaccine may be screened for adventitious agents, the fact [is] that the varicella vaccine is cultured on human diploid cells, embryonic guinea pig cells, and also includes fetal bovine serum.

-- Joan Batista, parent

I am also concerned about the side effects and the unknown relationship between vaccination, chronic illness, and sudden infant death syndrome. We must be honest in admitting that we do not know the impact to our society of multiple exposures of different vaccines on our young children or on society as a whole.

-- Pam Ososky, school psychologist and parent

Side effects of the vaccine and long-term effects are not known. They could be more serious than the measles and mumps vaccine because the chickenpox virus is associated with cancer and herpes zoster. This is a monumental experiment with our children.

--Wendy Payne-Strange

6. Use of illegally aborted fetuses for vaccine production

Synopsis: Some opponents stated their opposition, either personal or religious, to abortion and the use of fetuses to manufacture vaccines. Others were concerned that such fetuses were obtained illegally and continued to be used in vaccine production.

Some excerpts from the testimony:

As a Catholic, I am opposed to abortion and the use of aborted human fetuses and embryos in the propagation of vaccines.

-- Pamela Lorditch

I hope it is wrong, but I've been informed that the vaccine itself is derived from ... human embryonic fetal lung cell tissue, which was derived from a fetus that was aborted before abortion in the Commonwealth was legally recognized ... I find it disturbing in my own regard and on behalf of the countless others that I represent, that this proposal would force parents to have no say in the health care decisions

of their children, when it involves perhaps the most divisive issues in the history of the human race.

-- State Representative John Rogers, Chair House Judiciary Committee

7. Influence of the manufacturer on vaccine recommendations and requirements

Synopsis: Some opponents of the vaccine were concerned that medical and public health recommendations were being influenced by the vaccine manufacturer, who stands to make a profit from increased use of the vaccine. Some opponents were also concerned that employers might be promoting the varicella requirement to simply decrease parental time lost from work to take care of ill children.

Some excerpts from the testimony:

In the first six months of 1997, the chickenpox vaccine resulted in $70 million in sales. Mandating this vaccine throughout the country will be lucrative for a company that had a 20% profit margin.

-- Linda DeBenedictis, President, New England Patient's Rights Group

Again, I cannot think of a single historical parallel in which public health policy was engineered with the primary goal of allowing parents to avoid caring for their children because it might inconvenience their employers.

-- David Barnes, PhD, Assistant Professor, History of Science, Harvard University

8. Hepatitis B immunization for adolescents

Only two individuals opposed the amendment to require hepatitis B vaccine at entry into seventh grade. These opponents felt that hepatitis B was not airborne and therefore constituted less of a public health threat than diseases such as measles or pertussis. They stated that hepatitis B primarily affects those with certain high-risk behaviors or who came from certain other parts of the world. There were also concerns that CDC data on the projected number of cases of hepatitis B and its complications are "soft."

Some excerpts from the testimony:

It seems to me that, if hepatitis B is not an airborne disease, that parents are able to have much more control over whether their children contract this disease than if it were passed by methods other than exchange of bodily fluid. At this time, my daughter is not sexually active and does not use needles for either legal or illegal injections. She considers body piercing to be a bizarre form of mutilation, and she attends a small private school where I can be quite certain she is not shooting up on the playground. Because of several personal factors I, as her mother, have

decided that at this time it is not in her best interests to undergo hepatitis B vaccinations.

-- Jane Arnold, parent,

Hepatitis B is not a highly contagious, dangerous disease among the general population and it is not in epidemic form in Massachusetts or in any state. There were only 111 cases of hepatitis B reported to the CDC in Massachusetts in 1996.

-- Barbara Loe Fisher, President, National Vaccine Information Center, Vienna, VA

9. Issues relating to notification about proposed amendments to the regulations and the process

Synopsis: Some opponents stated that the process for promulgating regulations was not adequate. They felt there was insufficient notification about proposed changes and the time and place of the public hearing, and that the school setting was not utilized to communicate to parents. They felt the location and timing of the public hearing was not optimal. He also requested that they preferred to address their concerns directly to the Public Health Council.

Some excerpts from the testimony:

You and I have inherited a system with notable, but surmountable shortcomings. And while I believe we can overcome them together, first we have to acknowledge them... If this is to be a public hearing, at which the 'public' is welcome, and indeed for who, it is held, **all possible accommodations need to be made...** Word of vaccine requirements is spread through schools, certainly such hearings could be publicized this way. **Such options need to explored and acted upon. Notifications should certainly contain all items to be heard and not, I**

think include decisions to be enacted seven years hence. It would be my hope that Council members would, in the future, be present at such a hearing [emphasis in original].

-- Peter Bermudes. Co-Director, Massachusetts Citizens for Vaccination Choice

C. MDPH Staff's Response to the Testimony

1. Effectiveness of broad-based immunization programs and school immunization requirements vs. parental choice issues

Based on the testimony and the existing scientific literature, we believe that the overwhelming societal benefit afforded by broad-based vaccination, ensured through school entry requirements, outweighs the arguments for individual choice in the matter of vaccination.

We mandate many things to protect the public and maintain the social contract. We mandate immunization because vaccine-preventable diseases are transmissible to others and we have learned over the past 200 years, with smallpox, polio, measles, diphtheria, tetanus, mumps, rubella and *Haemophilus influenzae* b infection, that the successful application of immunization requires as close to universal coverage as possible. In epidemiologic terms, the objective of vaccination programs is to produce herd immunity, that is, to increase the proportion of immune (non-susceptible) people in the population to the point where pathogens from an infected person are not likely to reach any other susceptible people. When herd immunity is achieved, transmission of the infection in the population is blocked.

We disagree with the opponents, who stated immunocompromised groups are small in number, and can take other protective measures, and that a vaccine for use in this group is soon to be available. High vaccination coverage (if it is high enough to produce herd immunity) would protect those in whom the vaccine is not effective and those who cannot be vaccinated, such as people whose immune systems are severely impaired by HIV infection, cancer therapy, transplant procedures, high-dose steroid therapy, or genetic factors. There are several thousand children in these high-risk groups in Massachusetts, and their numbers are growing. Many of these vaccine-preventable diseases can be devastating to people with such conditions; for example, immunocompromised children who get chickenpox have a mortality rate of 10-30%. Although some stated that a new vaccine is being developed that can be safely used in high risk populations, it is still early in its evaluation and licensure is not imminent. These vulnerable individuals, who cannot be safely vaccinated, must still rely on community-wide vaccination for protection from exposure to these diseases

Ample evidence exists that when vaccination is optional, vaccination coverage in the population generally does not reach the level required to achieve herd immunity.

Immunization requirements at school entry, which all states in the U.S. have, are extremely effective in reducing disease incidence. For example, a 1977 study by CDC demonstrated that states with compulsory school immunization laws had a 50% lower incidence of measles than those without such laws; another recent CDC study showed that, since 1980, people with religious or philosophic exemptions were at a 7- to 58-fold higher risk of acquiring measles, compared to those without exemptions. Some countries, such as the United Kingdom, some other countries of Western Europe, some parts of Australia, and Japan, have no school entry requirements and have much higher rates of vaccine-preventable disease than the U.S. For example, a drop in pertussis vaccination levels in the U.K. and Japan led to large outbreaks there, with 13,000 cases and 41 deaths in one year in Japan and 100,000 cases and 36 deaths in a nine-year epidemic in the U.K. (Gangarosa 1998; CDC 1997).

Massachusetts recently experienced the unfortunate effects of non-uniform coverage with rubella vaccine. Routine vaccination of children against rubella began in 1969, but it was not *required* for school entry until 1979. In 1993-1994, the state experienced an outbreak of rubella, in which almost 90% of the 131 cases occurred in unvaccinated young adults, many of whom had gone to school in Massachusetts but had never been vaccinated. Of the 131 cases, seven occurred in pregnant women, with one case of congenital rubella syndrome.

In the case of varicella, which causes more severe complications in adolescents and adults than in children, variable use of the vaccine will decrease the overall incidence of varicella and *increase* the average age at infection. This will happen because varicella vaccine is well accepted and in wide use. Since it was licensed in 1995, over 10 million doses have been distributed nationwide, with over 130,000 in Massachusetts. MDPH staff estimates that approximately 60% of two-year-old children in our state are already vaccinated. The incidence of varicella is decreasing and unvaccinated children will not be exposed to this disease when they are young. This will result in more cases occurring in adolescents and adults, who are at much higher risk of complications (Halloran 1996, Meissner 1998, Shapiro 1997).

One opponent stated that the national advisory bodies only recommend varicella immunization, not require it. These bodies are not empowered to implement requirements. To do so would be an infringement of state's rights. However, the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices urge all state legislatures, or other pertinent bodies, to include varicella in their requirements for school entry. They state that these requirements will both foster more rapid control of the disease and decrease the potential numbers of susceptible adults (CDC. ACIP 1996).

Regarding the arguments for informed consent, we point out that parents have the right to complete information about the benefits and risks of vaccines compared with the risks of vaccine-preventable diseases. The package inserts cited by one opponent are not the primary method to inform parents about vaccines. The National Childhood Vaccine Injury

Act (NCVIA) of 1986 mandates that parents and guardians be informed via the Vaccine Information Statements (VISs) before vaccinations are administered. These materials describe the disease and explain the risks and benefits of the vaccines. They were developed in consultation with concerned parents; and are published in the *Federal Register* for public comment. In addition, CDC recommends that parents should discuss any questions about vaccines with their child's health care provider. Other mandates of the NCVIA concerning the monitoring for and reporting of adverse events following vaccination are discussed in item no. 5.

According to the school immunization laws in Massachusetts (MGL Ch. 76, ss. 15 and 15C), There are two exemptions to the school entry requirements: medical and religious. A medical exemption is granted if a physician states that he has examined a child and that the child's health would be endangered by an immunization(s). A parent may oppose immunizations for religious reasons by stating in writing that immunization conflicts with his or her sincere religious beliefs.

We believe the virtual elimination of vaccine-preventable disease, accomplished through many decades of effort, is of great benefit. All of society shares in this huge benefit at the price of mandatory requirements for school attendance and scientifically documented risks that are small. Leaving vaccination up to individual choice would deprive us of this benefit and place our whole society, but especially our most vulnerable members, at risk once more.

2.Seriousness of varicella

We disagree with the opponents' statements that chickenpox is a mild disease that does not warrant immunization. We support the position of those in favor of the regulations that chickenpox disease is not trivial. Children with typical cases have high fevers, up to 400 skin lesions, and are ill for 5-7 days. Varicella disease results nationally in 9,000 - 15,000 hospitalizations and over 100 deaths per year. Complications include pneumonia, central nervous system involvement, and serious skin infections. One of those serious skin infections, group A streptococcal (GAS) infection, appears to be increasing as a complication of chickenpox disease (CDC. ACIP 1996, Peterson 1996).

We also note that chickenpox is a very serious disease in high-risk children. When varicella occurs in newborns whose mothers are infected shortly before or after birth, the mortality rate is up to 30%. These infants will have an increased incidence of shingles at an early age. Immunocompromised children have a mortality rate of 10-30%. Due to medical advances, the number of children and adults surviving treatment for leukemia, organ and bone marrow transplants, and those with other conditions that weaken the immune system is growing. In addition, many children with asthma are now commonly treated with steroids that weaken the immune system. There are several thousand children in these high-risk groups in Massachusetts, and their numbers are increasing (CDC. ACIP 1996, Weller 1996).

The Department of Public Health has also seen the consequences of varicella and its complications first-hand. Last year, there was an outbreak of varicella-associated GAS in a Boston daycare center. There were 4 cases of invasive GAS, and 2 of those cases required hospitalization and extensive medical and surgical intervention. And to date this year, the Department of Public Health has received 11 reports of additional cases of varicella-associated invasive GAS, compared to zero cases reported before the outbreak of 1997. Four of the eleven cases involved instituting control measures in day care and school settings.

Our position is supported by the scientific literature, which has documented the severity of the disease. According to a recent article in the *Journal of Infectious Diseases*, "varicella may also be lethal in patients of any age in the presence of biologic or iatrogenic immunosuppression." (Weller 1996).

We note that some parents, physicians, and others may question the severity of varicella infection. However, most parents, physicians, other health care providers, and their representative organizations (both nationally and in Massachusetts), as described earlier, recognize and appreciate the severe morbidity and complications associated with varicella disease as serious reasons to have a school-entry requirement. MDPH staff concurs.

3. Duration of protection after varicella vaccine

On reviewing the testimony and the existing scientific evidence, we disagree with the argument that uncertainty about the duration of protection afforded by varicella vaccination should exclude it from the school entry requirements. We agree with the proponents' testimony that protection promises to be long-lasting and that the optimal age for vaccination is in early childhood.

According to a recent study published in *Pediatrics*, duration of protection from varicella vaccine lasts for up to 10 years, the longest period for which data are available in the U.S., with no waning of immunity (Johnson 1997). An earlier study, also in *Pediatrics*, provides strong evidence from Japan, where the vaccine has been in general use for longer than in the US, that protection lasts for at least 20 years, again with no evidence of waning immunity (Asano 1994).

Varicella is a live viral vaccine and would be expected to induce immunity of a similar quality and duration as natural infection. Indeed, data for the widely used live viral vaccines, like measles, mumps, rubella (MMR) vaccine, show that one dose confers life-long immunity. The second dose of MMR that is currently required at school entry is not a booster dose, but rather a way to ensure protection of the approximately 5% of measles vaccinees who had an insufficient immune response to the first dose (Wood 1995).

Like measles vaccine, varicella vaccine stimulates both humoral and cell-mediated immunity. Cell-mediated immunity provides immunologic memory. Studies have demonstrated T-cell proliferation responses to varicella vaccine glycoproteins (Johnson

1997). Also, it appears that, in similar fashion to wild-type varicella virus, the attenuated vaccine strain has the ability to periodically stimulate the immune response even in the absence of exposure to natural infection, as pointed out by Dr. Meissner in his oral testimony, as well as in the medical literature (Meissner 1998, Shapiro 1997).
If immunization is to be universal, daycare and school entry are the most effective points at which to require it, as it is notoriously difficult to attain high levels of immunization of adolescents and adults. Moreover, vaccine effectiveness is high in younger aged children and superior to that in adolescents and adults. For these reasons, as well as in order to reduce the overall incidence of disease, varicella vaccine should be given as early after infancy as possible.

4. Relationship between varicella vaccine and shingles

Reviewing the testimony received, we disagree with the opponents' statements that not enough is known about the relationship of varicella vaccine and shingles. We support the proponents' testimony which reviewed the existing data. Over the course of the last 20 years, many studies have documented the decreased incidence in zoster after varicella vaccination. According to the 1996 statement of the Advisory Committee on Immunization Practices, the incidence of shingles is much lower in those who have been vaccinated compared to those who have had natural infection (18 per 100,000 vs. 77 per 100,000) (CDC, ACIP 1996). The journal *Biologicals* recently reported on the use of varicella vaccine as a booster dose to reduce the risk of shingles (Gershon 1997). More expanded clinical trials for booster doses are under way in older adults, whose immunity from natural infection has waned and who are at highest risk for shingles and its complications.

5. Vaccine risks (contaminants, side effects, immune system dysfunction, chronic disease)

We agree with the proponents' statements that the amount of data collected about this vaccine is extensive. It has been one of the most studied vaccines, with 20 years of evaluation pre-licensure. In addition, the Food and Drug Administration (FDA) sets rigorous safety and efficacy standards. In order to further enhance our ability to monitor the adverse events and vaccine safety issues, the NCVIA mandated a unified, nationally-based Vaccine Adverse Events Reporting System (VAERS). Providers are required to report adverse events to this system. CDC supplements this with information from large-linked data bases and other studies in order to identify possible rare events, and ensure the ongoing evaluation of a vaccine's safety profile post-licensure (CDC. National Vaccine Injury Compensation Program 1997, Ellenberg 1997).

We disagree with the opponents of the proposed regulations regarding the association of vaccines with the development of chronic disease. We cite the scientific literature which finds that there are no reliable, conclusive, replicable data available that indicate that vaccines are

associated with chronic conditions such as cancer, diabetes mellitus (DM), inflammatory bowel disease (IBD), or autism. There have been a few articles in the literature exploring the relationship between vaccines and allergy/asthma, IBD and DM ((Wakefield 1998, Kemp 1997, Classen 1996). CDC and others have examined these articles and found them to be methodologically flawed. Vaccine safety research has examined these types of associations and in the more than 40 years of this type of research, there has been no associations found. (CDC. Vaccine safety - general, Vaccine safety - questions and answers, Vaccines and chronic disease, Alternatives to vaccines, What you may have heard about vaccines ...and what you should know 1997, Institute of Medicine 1994, CDC. Summary of Vaccination and diabetes studies - unpublished data.)

We disagree with the opposition's belief that vaccines contain contaminants. The FDA has many procedures in place designed to detect and prevent the presence of adventitious agents in vaccines (CDC. Additives in Vaccines, Concerns about vaccine contamination 1997).

We agree with the federally required procedures and recommendations in place to protect against, minimize, and monitor severe side effects from vaccination with varicella vaccine or any other childhood vaccine. CDC recommends, and we agree, that concerned parents, who want information about the vaccine, in addition to that included in the VISs, should ask their health care provider or pharmacist for a copy of the package insert before the vaccine is given. The package insert lists ingredients in the vaccine and discusses any known adverse reactions. In addition to information about the disease and vaccine, VISs also contain information about how parents can monitor their children for any possible side effects after a vaccine; how to report such events to their provider or to other pertinent agencies; and how to apply to the National Vaccine Injury Compensation Program (CDC. Additives in vaccine, Informing parents, National Vaccine Injury Compensation Program 1997). Issues around the VISs and informed consent were discussed in item no. 2

In addition, many infectious disease experts feel that children and adults are exposed to a variety of infectious agents with many antigens presented to the immune system. Many, even trivial, infectious agents have a much larger antigenic load than that contained in vaccines. Therefore, it unlikely that vaccines can significantly effect changes in the immune system or other body systems described by the opponents, compared with a myriad of minor infectious agents and exposures to antigens in the environment.

For these reasons, we believe that the risk of any type of serious, life-threatening side effect or adverse reaction is minimal and should not be a barrier to the implementation of the proposed regulations.

6. Use of illegally aborted fetuses for vaccine production

Fetal tissue is not used to produce vaccines. Cell cultures originally derived from fetal tissue over three decades ago are used to grow vaccine viruses. Vaccine manufacturers obtain human cell lines from FDA-certified banks in Maryland and in the United Kingdom. The two cell lines involved in the production of varicella vaccine are WI-38 and MRC-5. Both are human diploid cell fetal lung tissue that were obtained over 30 years ago from legally aborted fetuses.

The WI-38 cell line was obtained in Sweden in 1963 and the MRC-5 line in 1966 in the United Kingdom, in a legal manner according to guidelines developed by the National Institutes of Health. These cell lines are also used for various diagnostic and biological purposes, in the manufacture of other vaccines, such as polio, rubella and hepatitis A, and in cancer research. These cell lines were selected because they contain no foreign antigens and are less reactogenic than other media. However, no new fetal tissue is needed or used to produce these cell lines, now or in the future.

All the vaccines produced with these cell lines have greatly reduced the incidence of several serious diseases. Prior to vaccine development, there were 13,000 to 20,000 cases of paralytic disease in the U.S. each year. As a result of global polio eradication efforts, only 3,500 cases were reported worldwide in 1996. In 1964, prior to rubella vaccine licensure, there were an estimated 20,000 babies born with congenital rubella syndrome (CRS) in the United States. When women contract rubella disease during early pregnancy, this often causes miscarriage or neurological damage to the unborn child, resulting in the child suffering blindness, deafness and retardation. In 1996, four cases of CRS were reported, reflecting a 99.9% reduction in this preventable disease since 1964.

According to the school immunization laws in Massachusetts (MGL Ch. 76, ss 15 and15C), if a parent is opposed to any immunizations for religious reasons, such immunizations may be declined by stating in writing that immunization conflicts with his or her sincere religious beliefs.

7. Influence of the vaccine manufacturer on varicella vaccine recommendations and requirements.

The profit of vaccine manufacturers does not play a role in the deliberations of any state or national advisory body. All members must complete conflict of interest forms and disclose any and all affiliations with vaccine manufacturers. In Massachusetts, in accordance with General Laws Chapter 268B, the Financial Disclosure Law, all state employees holding major policy making decisions in a government body must report similar information. In addition, no members of industry or large employers have contacted MDPH staff or provided testimony endorsing the varicella requirement.

MDPH and all advisory bodies make recommendations for additions to the childhood immunization schedule and new school requirements in order to protect children, and

ultimately adults as well, from vaccine-preventable diseases. All decisions are based on carefully analyzed medical and epidemiological data.

8. Hepatitis B immunization for adolescents

We disagree with the opponents' belief that the mode of transmission of hepatitis B is an acceptable reason to exclude it from immunization requirements. It is true that airborne transmission can facilitate the rapid spread of diseases. However, many diseases, which are serious threats to the public health, are transmitted by other methods. Salmonella, typhoid, cholera, cryptosporidiosis and botulism are foodborne or waterborne. Rabies is transmitted by animal bite and HIV infection is transmitted through blood and body fluids, like hepatitis B.

CDC collects data on hepatitis B in a variety of ways. States report acute and chronic cases to their surveillance unit. They supplement this system with information from sentinel counties and cities, where additional data are collected about high risk factors. One opponent stated correctly that in 1996, Massachusetts reported 111 cases of acute hepatitis B to CDC. However, in addition to these acute cases, we also reported 1,122 cases of chronic hepatitis B to CDC in 1996 alone.

Hepatitis B is a serious disease and is responsible for 4,000 to 5,000 deaths each year in the United States due to cirrhosis and liver cancer. These complications of chronic infection often occur in young adults who were infected early in life, during childhood and adolescence. Although hepatitis B infection rates are higher among certain ethnic and other risk groups, up to 25% of cases have no known risk factors for infection. Thus, a broad-based immunization strategy is needed for control of this disease, as well as to protect our children from developing its most serious complication -- liver cancer.

Since 1992, we have been vaccinating infants and young children. Adolescent hepatitis B immunization complements these efforts and is part of a comprehensive strategy strongly endorsed by the medical, scientific and public health communities. Due to the collaborative efforts of the MAAP, MDPH, School/Nurses and Rotary Clubs across the state, over half of all adolescents have already received 3 doses of hepatitis B vaccine.

Hepatitis B immunization has been required for day care attendance since 1992 and school entry since 1996. Since sexual contact is the most common risk factor for hepatitis B infection, a seventh grade requirement would protect most of our adolescents before they enter into their period of greatest risk.

9. Issues relating to notification about proposed amendments to the regulations

The official notification process for these amendments consisted of publication of the Notice of Public Hearing in four newspapers around the state, publication in the *Massachusetts Register* and notice to all the parties that have notified the Department of their interest in receiving notification of the proposed regulations. This list includes significant health-related organizations, such as the Massachusetts Medical Society, the Massachusetts Chapter of the AAP and AAFP and other, which may then inform their members. Such publications meet all legal requirements. In addition to these processes, beginning in the spring of 1997, MDPH staff included information on the proposed changes in newsletter articles and memos to the medical, public health and school communities. During this time period, MDPH staff also attended over 130 meetings or gave presentations about the proposed changes, including many meetings with school nurses and physicians. These groups then informed patients and parents; summarized their feedback; and communicated it to us. In addition, MDPH staff attended meetings with advocacy groups.

We believe it is important to accommodate the public. Accordingly, the time of the public hearing , usually held during business hours, was moved to 4 PM at the request of some of the parents who wished to testify. The hearing lasted until 8 PM, and anyone who wished to testify had an opportunity to do so.

Their request to appear before the Public Health Council runs contrary to the well established policy of the Council not to entertain floor discussions on matters before the Council. In this case the parties opposed to the amendments were given a full opportunity to testify at the public hearing. Some opponents also met with the Commissioner, the Assistant Commissioner, Bureau of Disease Control and others to express their views. A copy of some the significant testimony of the opponents is attached.

V. SUMMARY OF MDPH'S REQUEST TO PROMULGATE REGULATIONS

Immunizations are second only to sanitation and safe drinking water in terms of preventive benefits. School immunization requirements further strengthen this important public health safety net. MDPH staff have formulated the proposed regulations, based on the latest recommendations of all the major national advisory bodies including the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians and the Infectious Diseases Society of America. While there may be some parents, physicians and nurses who disagree with these recommendations, a large majority agree with the proposed changes. This includes official endorsement in Massachusetts by the major professional organizations representing them, as well as the Massachusetts Parent Teachers Association (MPTA), who representing the 1 to 2 million parents in the state with children in grades kindergarten through 12th grade.

Specific concerns were raised regarding varicella and hepatitis B vaccines. Since varicella vaccine was licensed in 1995, its widespread use reflects its acceptance and endorsement by over 130,000 parents and thousands of health care providers in Massachusetts alone.

Regarding hepatitis B vaccine, it has been licensed since 1981, and used worldwide. As stated above, in Massachusetts it has been required in daycare since 1992 and for school attendance since 1996. Close to 3 million doses have been distributed in our state for use in these age groups. We have years of experience supporting the safety and effectiveness of hepatitis B vaccine.

We have listened to the concerns raised by those from the National Vaccine Information Center, the Massachusetts Citizens for Vaccine Choice, the New England Patient's Right's group and others. However, the proposed amendments have the support of all professional groups, representing physicians, nurses and public health officials, and the MPTA, representing parents. We request the Public Health Council to approve the promulgation of the amended regulations (Attachment A), as final regulations of the Department.

VI. REFERENCES

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VII. ATTACHMENTS

In addition to the proposed amended regulations (Attachment A), the following 15 samples of testimony are attached:

Infectious Disease Society of America (Attachment 1)
Massachusetts Chapter of the American Academy of Pediatrics (Attachment 2)
Massachusetts Chapter of the American Academy of Family Physicians (Attachment 3)
Massachusetts Medical Society (Attachment 4)
Massachusetts Parent Teachers Association (Attachment 5)
Letter Signed by 35 Massachusetts School Physicians - In Favor (Attachment 6)
Massachusetts School Nurse Organization (Attachment 7
Sample Form letter, Massachusetts Physicians - In Favor (Attachment 8)
Sample Form Letter, Massachusetts Parents - In Favor (Attachment 9)
State Senator Stephen M. Brewer (Attachment 10
National Vaccine Information Center (Attachment 11)
New England Patient's Rights Group, Inc. (Attachment12)
Massachusetts Citizens for Vaccine Choice (Attachment 13)
Sample Form Letter, Massachusetts Parents - Opposed (Attachment 14)
Letter from Dr, David Barnes, Assistant Professor, History Science, Harvard University (Attachment15)

Testimonyhearing.doc (May 12,1998)

Original: 2142

Commonwealth of Pennsylvania

Department of Health

HARRISBURG

October 10, 2000

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health Proposed Regulation No. 10-162
School Immunization Requirements

Dear Mr. Nyce:

The enclosed comments were received after the close of the public comment period. As a courtesy, we are providing you with a copy.

Sincerely, yours,

Yvette M Kostelac (CF)

Yvette M. Kostelac
Assistant Counsel

Enclosure

cc: Alice Gray

Original: 2142

507 W. Elmwood Ave.
Mechanicsburg, PA 17055
October 4, 2000

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

Re: Chickenpox vaccine proposal

I am **against** the health department's proposal to require the chicken pox vaccine for school children.

The disease is not a public safety issue, nor causes epidemic concerns.

Allow parents the choice as to whether their child(ren) should receive this vaccine against this benign childhood disease.

Sincerely,

Dorothy E. Morrissey

Dorothy E. Morrissey

Original: 2142

700 Salem Road
Etters, PA 17319
October 1, 2000

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

RE: Chicken-pox Vaccine

Dear Ms. Gray:

After reading Ellen Lyon's column in the Sunday Patriot News, I felt the necessity to respond.

I do not believe that people are aware of the on-going chicken-pox situations and the myths that it is only a childhood disease. I work in corrections and people would be awed by the recent outbreaks of chicken-pox over the past couple years. I must admit I too was ignorant to the fact and found it difficult to understand how adults were getting it. Like most of the population, I assumed by the time you went to school, you had chicken-pox or had the vaccine. What amazement when they began appearing in prisons/jails. Chicken-pox is not something "fatal" to the majority of the public, however, can be to those with cancer, HIV/AIDS, etc.

I personally feel that it should be a requirement like the other immunizations that are needed by children prior to entering school. This Erie mother/activist should become aware of complications that "her child" may encounter later in life should they get chicken-pox. We cannot choose our children's future health or lifestyles. They need to be protected when we do have some control.

Sincerely,

S. Madden

S. Madden

Original: 2142

RECEIVED
PA DEPT OF HEALTH
2000 OCT -6 PM 2:05
OFFICE OF LEGAL COUNSEL

American Liver Foundation

Delaware Valley Chapter

October 2, 2000

RECEIVED
2000 OCT 12 AM 9:16
REGULATORY REVIEW COMMISSION

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

Dear Ms.Gray,

Please accept this letter on behalf of the Delaware Valley Chapter of the American Liver Foundation the confirmed support of all of our members in implementing the proposed requirement that 7th graders be immunized against hepatitis B.

Most individuals who have chronic hepatitis B were infected as children. Consistent vaccination for children is an effective means to reduce the incidence of hepatitis B in Pennsylvania and as a step towards eradicating this disease in the future.

We respectfully ask your support on the 7th grade hepatitis B vaccination as an important public health issue.

Sincere regards,

Jay Barry Harris, Esq.
Board President

Peggy Gilbey McMackin
Director, Delaware Valley Chapter

1608 Walnut Street, Suite 1704 • Philadelphia, PA 19103 • 215-545-1688 • Fax 215-545-6564
American Liver Foundation National Headquarters 800 GO-LIVER (800-465-4837)
E-Mail: AMERLVFDN@aol.com

Original: 2142

KAREN ABEL
1599 KLIMKOS ROAD
CLARKSBURG, PA 15725

10/1/00

Alice Gray
Director, Immunization Division
Pennsylvania Department of Health
PO 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 become part of the public record and that PDH respond in writing to my comments. My concern is that PDH's proposal will make it illegal if a parent wants to delay or not give the vaccine at all. Parents are capable of making informed decisions about the health of their children. They needn't be put in a position in which conscientiously objecting to the vaccine makes them a criminal. Leave the decision where it should be - with the parents! This is a benign childhood disease that usually gives lifelong immunity. Why force a vaccine on a healthy child for whom the illness will most likely be no more than an inconvenience? Many doctors don't even agree with mandating this vaccine. PDH's reason for mandating this vaccine is that parents have less work disruption due to the 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. Children belong to their parents, <u>not</u> the state.

Sincerely,
Karen Abel

Original: 2142

To: Alice Grey, Director of Immunization Division:
From: Rebecca Piestrak, RN:

Dear Ms. Grey:

I 'm writing to comment on the chickenpox vaccine issue. I 'm the mother of two preschool children and a registered nurse. I do not feel that this vaccine should be mandated by the State in order to enter school. There are a number of questions that need to be answered. There are no long term studies on the effectiveness of the vaccine. Questions such as; What are the side effects? Will booster shots be needed and when? Will the vaccine push chickenpox into the teenage and adult population? If the vaccine push chickenpox into the teenage and adult population, the children you are trying to "protect" will be at a greater risk of having serious complications from the disease if it is acquired later in life. The fatality rate from chickenpox is currently about 0.003%, about 100 cases a year out of 3.5 million. If people acquire chickenpox as adults the fatality rate will increase, and the vaccine will have the opposite of the intended effect of reducing complications and fatality rate. These important questions need to be addressed and answered with the support of scientific study and research. Our children should not be required to be the study group. It is not the states' role to make health care decisions for my children. As a parent it should be my right to choose what vaccinations my child receives. It is a decision to be made by me and my doctor based on the needs of my child.

I cannot help but feel that business and industry are in part behind the push to mandate this vaccine. Because young children are the population that usually gets chickenpox, a parent must miss work to care for the sick child, as the child cannot attend daycare or school. This cost's businesses in lost time and production, which means money. If a working parent wants to get this vaccine for their child to avoid missing work that is their choice. However, I should also have the choice not to vaccinate my child. Again this is a decision for parents to make after they have considered all the pros and cons. It is not the state's role to function as a parent and make parental decisions.

I also want to make you aware that I attempted to contact you at the health department, division of immunizations for two days and was unsuccessful. None of my phone calls were returned. I read about the proposal to require the vaccination in the Sunday, October, 1 edition of my local paper, The last day for public comment was Monday, October 2. The Department of Health should make the public aware of such proposals in plenty of time for the average citizen to comment. When I called your office on Monday, I was told my comments had to be in writing. I was also told that the proposal to mandate the vaccine was published in The Pennsylvania Spotlight. The person I spoke with didn't know how or where I could get a copy of this publication. This information should be published in local papers and distributed in the schools so that parents are made aware of impending decisions that will affect their children.

Thank You:

Rebecca Piestrak
HC 64 Box 18
Huntington Mills, Pa 18622

Original: 2142

Shomper, Kris

From: Barbara.Watson@phila.gov
Sent: Wednesday, October 11, 2000 12:12 PM
To: irrc@irrc.state.pa.us
Cc: jJewett@irrc.state.pa.us
Subject: Information in support of the school immunization regulation

Microsoft Word 4 Microsoft Word 4

Re Regulation #10-162(#2142)
School Immunization, Department of Health

See attached letter to Robert E. Nyce and supporting documents(See attached file: school I support.doc)(See attached file: statereq.doc) I will also fax on headed paper and attach to fax the CDC resource list

Thanks you for your attention

Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr Nyce,

Re: Regulation # 10-162(#2142)
School Immunization, Department Of Health

In order for a virus to survive it needs to find a susceptible host in order to multiply and move on to the next susceptible host. The measles epidemics in the 1970's and 1980's demonstrated the value of school regulation for immunization as a Public Health tool after 1981, as immunization rates of 95% were achieved. Hence immunity of the majority, protected vulnerable children from highly contagious viruses

With the licensure of varicella vaccine (Varivax) in March,1995, varicella can now be considered a vaccine-preventable disease.

IS VARICELLA WORTH PREVENTING?

Pre-licensure approximately 4 million cases, 11,000 hospitalizations and 100 deaths per year are attributable to complications of varicella in otherwise **healthy individuals** in the USA, **3 children** in Pennsylvania **will die each year** secondary to the complications of Varicella. When vaccine first became available to the private sector in 1995-1996 there were 76 deaths, 52 of whom were aged 1-9 years, 80% being previously healthy children. In comparison to deaths from all other currently recommended vaccine preventable diseases for children- deaths from VZV predominate. We in Philadelphia have epidemiologic data, which demonstrates that the chief age of varicella in Philadelphia is the 5-9 year old age group -i.e. school age. These children acquire their disease at school and bring it home to younger and older susceptible individuals, who often have more severe disease and complications. Close to 11,000 previously healthy children are hospitalized secondary to varicella complications each year in the USA, **450** are **hospitalized** in the state of Pennsylvania each year at a cost of approximately **3.7 million dollars.** In children the most common complications are secondary bacterial skin infection, pneumonia and neurological complications.

All this can now be avoided because of a safe and effective immunization. Many who are opposed to the vaccine recall their brush with the varicella virus as benign, however, if your child is the statistic who has had a complication, or you have been the physician taking care of such a child, it makes sense to PREVENT this disease where possible, as we do with all the other contagious diseases that vaccines have been developed for..

The main purpose of a vaccine must is to protect the child from the vaccine preventable disease and in doing this also is for the good for the entire population. Prevention of disease is a physician's highest goal. Look at the success of immunization in preventing disease in our land- see table below.

Vaccine administrations have been the most important health care advance of the last 40 years (Table 1).

DECLINE IN VACCINE-PREVENTABLE DISEASES

Disease	Maximum Cases	Year	1998	Percent Change
Diphtheria	206,939	1921		-100.00
Measles	894,134	1941		-99.97

Mumps	152,209	1968		-98.89
Pertussis	265,269	1934		-97.52
Poliomyelitis (paralytic)	21,269	1952	1 (VAPP)	-99.99
Rubella	57,686	1969	192	-99.67
Congenital Rubella Syndrome	20,000	1964-65	5	-99.98
Tetanus	1560	1923		-96.92

As can be seen in the table, widespread vaccine use has resulted in a significant decline in a number of previously common childhood diseases. Conspicuously absent from this list is varicella, a heretofore unpreventable illness. If economic considerations are included in the equation, the effect of immunization of the general population is more dramatic.

Clinical trials and post-marketing surveillance of 24 million doses distributed in the USA have shown the vaccine to be safe and effective. (Jama: Sept 13,200;vol 284 –Wise et al)

The vaccine is recommended for use by The Academy of Pediatrics(AAP), The Academy of Family Practice (AAFP) and The Center for Disease Control And Prevention (CDC's) that varicella vaccine be administered to all susceptible individuals older than 12 months.

Philadelphia did see outbreaks of disease in the schools in 1997, 1998 and 1999, despite >70% vaccine coverage. Some of these outbreaks put children with HIV, Aplastic anemia or children on steroids at risk. The Board of Health recommended Varicella Vaccine for school entry in September 2000. Philadelphia's experience in implementing the PA State regulation should be an example to all those who care about the welfare of ALL children in the schools of PA.

Being a Physician who has taken care of children with many of the vaccine preventable diseases, worked to improve our immunizations and bring new vaccines to licensure and to the benefit of the public. I also took part in many of the studies since 1987 that were required to bring the varicella vaccine to licensure (including my own children), and know that there were pre-licensure data of the safety of giving the varicella vaccine with MMR as well as other standard pediatric vaccines. Also since being involved with the CDC's surveillance project, know the safety data we have from 5 years post licensure where most physicians in Philadelphia are administering VZV and MMR at the same time. I know that a school regulation will improve the current immunization rates in PA, just as the Hepatitis B school regulation has done. I urge you to support pediatricians and the school system in their goals. I attach a list of resources for your review in addition a list of states who have already passed the regulation.

Yours Sincerely

Barbara Watson MD
Department Of Pediatrics
Albert Einstein Medical Center and Division Of Disease Control Philadelphia

STATES WITH VARICELLA VACCINATION REQUIREMENTS
JULY 2000

State	Day Care Req.	Date Effective	School Req.	Date Effective	Grades	Proof of History	Philosophical Disease Exemptions Allowed	Comments
Alabama	YES	9/1/00	YES	2001-2002 School year	K	Parental history or Physician Documentation	NO	Administrative rule change Varicella coverage - 71.3%
Arkansas	YES	3/1/00	YES	2000-2001 School year	Pre-K & K	Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 58.0%
California	YES	7/1/01	YES	2001-2002 School year	Pre-K & K	Physician Documentation	YES	Legislative mandate (passed Fall 1999). Varicella coverage - 69.7%
Colorado	YES	7/1/00	YES	2000-2001 School year	Pre-K & K	Parental history or Physician Documentation	YES	Administrative rule change. Varicella coverage - 52.9%
Connecticut	YES (born ≥ 1/1/97)	1/1/00	YES	2000-2001 School year	7th Grade & all children born ≥ 1/1/97	Physician Documentation	NO	Administrative rule change. Physician statement can be based upon parental history. Varicella coverage - 62.7%
Florida	NO	1999	YES	2001-2002 School year	Pre-K & K	Parental history or Physician Documentation	NO	Legislative mandate. A parent wh child died of chickenpox spearhea the legislation. In 1998 Florida ha varicella deaths (3 adults & 3 chil Varicella coverage - 50.7%
Georgia	YES	8/1/00	YES	2000-2001 School year	Pre-K & K 6th grade - (2001-2002)	Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 61.7%
Louisiana	YES	9/1/03	YES	2003-2004 School year	Pre-K & K	Parental history or Physician Documentation	YES	Administrative rule change Varicella coverage - 61.0%

Maryland	YES (born ≥ 1/1/97)	9/1/98	YES	2000-2001 School year	Pre-K & K	Physician Documentation	NO	Administrative rule change. Medi Society insisted on allowing physic certification of disease history base upon parental recall. Varicella coverage - 71.7%
Massachusetts	YES (born ≥1/1/97)	8/1/98	YES	1999-2000 School year	Pre-K, K & 7th grade Documentation (K-12 - Fall 2005)	Physician	NO	Administrative rule change. AAP wanted physician certification of disease history based upon parental recall. Varicella coverage - 66.0%
Michigan	YES	1/1/00	YES	2002-2003 School year	Pre-K, K & 6th grade (K-12 - any child entering a school district for the 1st time regardless of grade level)	Parental history or Physician Documentation	YES	Day Care, Pre-K & K requirement through administrative rule chang 6th grade requirement - legislative mandate. Varicella coverage - 43.5
New Mexico	YES	9/1/00	YES	2002-2003 School year	Pre-K & K	Parental history or Physician Documentation	YES	Administrative rule change. Varicella coverage - 53.5%
New York	YES (born ≥ 1/1/98)	1/1/00	YES	1/1/00 (born ≥ 1/1/98)	Pre-K & K	Physician Documentation	NO	Legislative mandate. Varicella coverage - 59.2%
Oklahoma	YES	4/98	YES	1998-1999 School year	Pre-K & K	Parental history or Physician Documentation	YES	Legislative mandate. Varicella coverage - 66.4%
Oregon	YES	9/1/00	YES	2000-2001 School year	Pre-K, K & 7th grade or Physician	Parental history Documentation	NO	Administrative rule change. Varicella coverage - 57.9%
Pennsylvania	YES	1995	PENDING	2001-2002 School year (Pending)	Pre-K, K & 7th grade or Physician	Parental history Documentation	NO	Day Care Centers - Dept. of Public Welfare requirement. Pre-K, K & 7th through administrative rule chang Varicella coverage - 67.0%
Rhode Island	YES (born ≥ 1/1/97)	8/1/99	YES	1999-2000 School year	Pre-K, K & 7th grade Documentation (K-12 - Fall 2005)	Physician	NO	Administrative rule change. Varicella coverage - 76.5%

South Carolina	YES born ≥ 1/1/99)	Fall 2000	NO			Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 65.1%
South Dakota	NO	-	YES	2001-2001 School year	Pre-K & K (K-12: 2005-2006 school year)	Parental history or Physician Documentation	NO	Legislative mandate (Passed 2/25/(Varicella coverage - 17.5%
Tennessee	YES (born ≥ 1/1/99)	9/1/99	NO			Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 56.9%
Texas	YES (born ≥ 1/1/93)	9/1/00	YES	2000-2001 School year	Pre-K & K	Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 58.9%
Virginia	YES (born ≥ 1/1/97)	7/1/99	YES	1999-2000 School year	Pre-K & K (born ≥ 1/1/97	Parental history or Physician Documentation	NO	Legislative mandate (2/27/99). Varicella coverage - 64.6%
West Virginia	YES	1/1/00	NO			Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 51.3%
Washington D.C.	YES	4/1/97	YES	1997-1998 School year	Pre-K & K (K-12 by 2002-2003 School year)	Parental history or Physician Documentation	NO	Administrative rule change. Varicella coverage - 77.9%

NOTE: Varicella vaccine coverage = % of children 19-35 months of age appropriately vaccinated prior to the 2nd birthday, according to the most recent National Immunization Survey (NIS).

Total number of states with varicella vaccination requirements - 23 states plus Washington D.C.

Number of states with Day Care Center requirements - 21 states plus Washington D.C.

Number of states with School requirements - 19 states plus Washington D.C.

Number of states allowing parental history as proof of disease - 17 states plus Washington D.C.

Number of states with a legislative mandate requiring varicella vaccination - 7 states

SOURCE: *IDPH: Immunization Section, prepared for meetings of the Immunization Advisory Committee and State Board of Health.*

Original: 2142

Feger, Lois

From: Kostelac, Yvette
Sent: Tuesday, October 10, 2000 10:19 AM
To: Feger, Lois
Cc: Gray, Alice
Subject: FW: Mandatory Chicken Pox Vaccine

Will you treat this as a comment and prepare and send the appropriate letters? Thanks.

-----Original Message-----
From: Gray, Alice
Sent: Tuesday, October 10, 2000 9:57 AM
To: Kostelac, Yvette
Subject: FW: Mandatory Chicken Pox Vaccine

Yvette, apparently this came as a webmaster request on October 3rd, it was just sent to me today. How do we answer?

-----Original Message-----
From: ARCHYSGAL@aol.com [mailto:ARCHYSGAL@aol.com]
Sent: Tuesday, October 03, 2000 9:47 PM
To: webmaster@health.state.pa.us
Subject: Mandatory Chicken Pox Vaccine

Attn: Alice Gray
Director, Immunization Division

Dear Ms. Gray,

I understand the Pennsylvania Department of Health is about to mandate the Varicella vaccine (chicken pox) and parents will no longer be given a choice as to when or if at all they want it to be given to their children. The 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 it or not give it at all.

For 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 their carcinogenic potential, mutagenic potential, or for impairment of fertility" or "reproductive capacity" and "the duration of protection is unknown at present". Forcing a vaccine on a healthy young child for whom the illness will likely be no more than an inconvenience is a bad idea. I worry about what adverse reactions some children might have to the vaccine. Immunization is a medical procedure that can cause adverse affects and death for some.

I wish to express that, as a parent, I am opposed to mandating this vaccine

for children.

Sincerely,
Karen R. Gabel

Original: 2142

BETTY J DELANCEY
3501 N. THIRD ST
HARRISBURG PA 17110

ALICE GRAY
DEPT. HEALTH
HARRISBURG PA

DEAR MS GRAY:

I AM WRITING TO COMMENT ON THE CHICKEN POX VACCINE ARGUMENT (CHICKEN POX VACCINE PROPOSAL IRKS ACTIVIST, by ELLEN LYON, PATRIOT NEWS REPORTER, SUNDAY OCT. 1), IN WHICH CAROLYN DONAKOWSKI, AS A REPRESENTATIVE FOR PARENTAL AWARENESS, IS CLAIMING THAT THIS VACCINATION IS NOT NECESSARY FOR CHILDREN. SUCH STUPID ARROGANCE!!

MEDICALLY AWARE HEALTH REPRESENTATIVES KNOW THAT THIS IS NOT A BENIGN DISEASE, NOR IS IT STRICTLY A CHILDHOOD DISEASE. THE CHICKEN POX VIRUS CAN LIE DORMANT IN OUR BODIES FOR MANY YEARS AND THEN APPEAR WITHOUT WARNING AS SHINGLES OR OTHER SERIOUS NERVE INVOLVEMENT WHICH MAY BECOME PERMANENTLY PAINFUL. AFTER CHICKEN POX, LIFE-TIME IMMUNITY IS NOT GUARANTEED.

I HAVE EXPERIENCED THE RE-ACTIVATION OF THIS VIRUS IN MY FEET AND LEGS. IT IS EXCRUCIATING PAIN. EVEN MORPHINE CANNOT TAKE IT AWAY. IF MS DONAKOWSKI EVER SUFFERS THIS CONDITION SHE WILL BE MUCH MORE "IRKED" THAN SHE IS NOW.

CHILDREN SHOULD BE IMMUNIZED AGAINST CHICKEN POX BEFORE ENTERING SCHOOL. CHICKEN POX HAS BEEN TRIVIALIZED BECAUSE OF ITS JOKE NAME. PARENTS SHOULD BE ADVISED THAT CHICKEN POX IS NO JOKE.

Betty J DeLancey

Original: 2142

Oct 1, 2000

Mr. John Myers
14th Floor Harristown 2
333 Market St.
Harrisburg, Pa. 17101

Dear John Myers,

I have sent a letter to my State Senate Rep and the Director of Immunization Division and as well to you That I am oppose to the proposed amendment that would mandate Chicken pox Vaccine for all Children in Pa. This is a Vegiun Childhood illness and Children are receiving 8 vaccine now, this is too much.

There are many reason why a parent may not want to use this vaccine.

Sincerely
Mrs. Jeanne Haugh
166 Rt 66
Apollo, Pa. 15613

Original: 2142

Alice Grey

Susan B. Stevens
113 Aspen Way
Johnstown, P.a.
15906

Deciding whether or not to give my son the Chickenpox vaccine has been very hard for me because I always want to do the right thing.

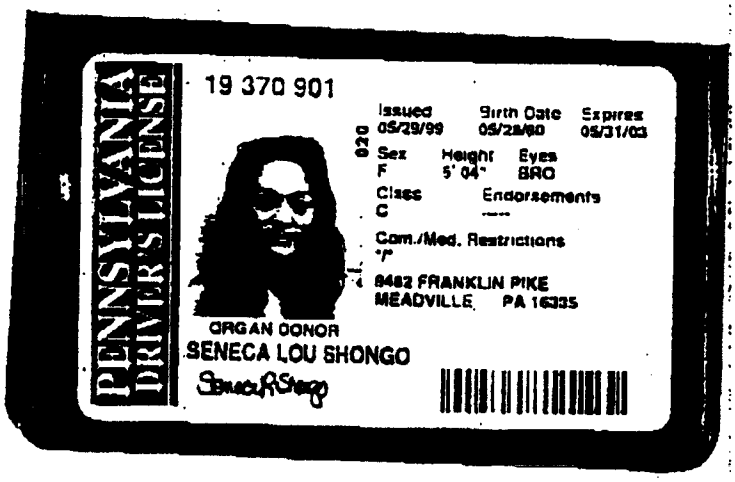
So I decided to read about it in the P.D.R., to help me make a decision. However when I was finished reading, I had more concerns and questions. —

* They reported a high amount of break-through cases after the vaccine.
*They suggest a booster shot for older children.
*They are unsure how long the vaccine lasts?
*They did not list an adequate amount of reactions, or how severe, or other complications from the vaccine.
*Of the 100 fatal cases due to Chickenpox a year how many were babies, or babies to mothers who had never contracted Chickenpox?
*The girls who are vaccinated now will the vaccine protect them and their babies when they get older and decide to get pregnant?
*The deaths due to Chickenpox, are comparable to the required immunization deaths percentage wise.

Susan B Stevens

Original: 2142

Please stop mandating unneccary Immunizations !!!



THANK-YOU

Original: 2142

Pennsylvania
MEDICAL SOCIETY®

October 2, 2000

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

Re: Proposed Rulemaking #10-162 (#2142) School Immunization Department of Health

Dear Ms. Gray:

I am writing on behalf of the Pennsylvania Medical Society to offer comments on the above captioned proposed rulemaking regarding school immunizations, promulgated by the Department of Health.

The Society supports the changes to the state's requirements for immunization of children seeking to enter and attend schools in the Commonwealth, as contained in these proposed regulations. We believe the changes will help to clarify existing regulations and will help protect children as they enter an environment that is known to present high risk for contracting communicable and potentially dangerous diseases.

The Society does wish to raise a concern regarding future changes to these regulations. We believe that some mechanism should be developed within the regulatory process to permit more expeditious recognition of Advisory Committee on Immunization Practices (ACIP) recommendations and guidelines for reporting of immunization requirements. This would permit faster response to changes recognized within the treatment community.

The Pennsylvania Medical Society appreciates this opportunity to comment on these regulations.

Sincerely,

Carol E. Rose

Carol E. Rose, MD
President

Cc: Secretary of Health
Independent Regulatory Review Committee
Chair, House Health & Human Services Committee
Chair, Senate Public Health & Welfare Committee
PA Chapter, American Academy of Pediatrics

DNM/doc/cor/Gray

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820

Tel: 717-558-7750
Fax: 717-558-7840
E-Mail: staff@psmedsoc.org
www.psmedsoc.org

Pennsylvania
MEDICAL SOCIETY®

Facsimile Cover Sheet

To: John Jewett
Company: IRRC
Phone:
Fax: 783-2664

From: Don McCoy
Company: PA Medical Society
Phone: 717-558-7823
Fax: 717-558-7860

Date: 10/2/00
Pages including this cover page: 2

Comments:

Original: 2142

Pennsylvania MEDICAL SOCIETY®

October 2, 2000

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

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Carol E. Rose

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Cc: Secretary of Health
Independent Regulatory Review Committee
Chair, House Health & Human Services Committee
Chair, Senate Public Health & Welfare Committee
PA Chapter, American Academy of Pediatrics

DNM/doc/cor/Gray

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820

Tel: 717-558-7750
Fax: 717-558-7840
E-Mail: *stat@pamedsoc.org*
www.pamedsoc.org

Original: 2142

Pamela K. O'Laughlin, L.P.T.
577 Cullum St.
Meadville, Pa 16335

October 2, 2000

Ms. Alice Grey
Director of Immunization Division

Dear Ms. Grey,

This letter is in regard to the possible mandating of the chicken pox vaccine by the state of Pennsylvania. I am against this mandate favoring the mandatory administration of the chicken pox vaccine. There have been too many questions about the adverse events and efficacy of this vaccine. This vaccine is a live virus and there has been no long-term follow up from the manufacturer marketing the vaccine.

VAERS has received reports of 67 out of 100,000 adverse events between 1995 and 1998 for a total of 6,574 reports. 82% of these children received the chicken pox vaccine only. There has been an addition of 17 further adverse reactions added to the manufacturers label since 1995.

The parents of these vaccinated children are the source of research and study of these vaccines. The manufacturer can only obtain a list of adverse effects through the contact with parents. My question is, why are the concerns of the parents not being acknowledged? They know their child and are best qualified to report serious problems following a vaccination.

Chicken pox is usually a mild childhood disease and the manufacturer of the vaccine has admitted that immunity is only temporary, I cannot possibly understand where Dr. Barbara Watson is obtaining her data that this vaccine lasts forever. Because this vaccine is only temporary, chicken pox will eventually be pushed into the adult population, where there could be worse complications.

Since unvaccinated children will not be exposed to the virus, then they will be as much at risk of getting chicken pox later in life and suffering more severe complications as will the vaccinated children who only had temporary immunity. This has already been witnessed with the MMR vaccine. There are many women of child bearing age that assume that they have immunity to the measles because they were vaccinated, when in fact, after becoming pregnant, their blood work showed no titer to the MMR. This could pose a serious problem if this unborn child was exposed measles in the womb.

I question where the vaccination policies concerning healthy children are going. They are given so many vaccines now that their immune systems have got to be severely suppressed. We were born with an immune system, so let it work. We all survived the chicken pox, measles and mumps. There are also millions of people, including myself, who have never been vaccinated for diphtheria and hepatitis B and we seem to have survived our childhood quite well.

Let our bodies do what they were meant to do and let parents decide what is right or not right for their child. Let us have full access to information about the risks and complications of both the diseases and the vaccines and then give us the right to make an informed decision.

Thank you for your time.
Pamela K. O'Laughlin
Pamela K. O'Laughlin

Alden Physical Therapy, PC
638 Alden Street, Meadville,PA, 16335
Phone (814) 337-9535
Fax (814) 337-8140

FAX TRANSMITTAL

DATE 10-2-00

TO: Alice Gray

FROM: Pam O'Laughlin

NUMBER OF PAGES TO FOLLOW: 1

(If any of this transmission is not complete or legible, please contact

_____)

Messages or Comments: comment on mandating chickenpox vaccine

THANK YOU!!

Original: 2142

Dr. Ms. Gray,

I think that it is a good idea to require Chickenpox vaccine. I choose to wait to have my children vaccinated until they were school-age (I have a 9, 7 & 5 y/o) My oldest was vaccinated at age 6 & my other 2 had the chickenpox. My concern is that a "black & white" rule requiring a vaccination would mean that children with their own acquired immunity would either need an unnessecary injection or a lab result proving they have immunity (costly & painful) Please carefully consider this when writing the rules. The average patient with chicken pox does NOT go to be seen by a

physician. In fact, the should NOT, because they are contagious.

I understand the seriousness of chickenpox having worked in a pediatric critical care setting. My only concern is a law requiring a child to have a vaccine for an illness that they've already had.

Sincerely,

Christianne Wright RN, CCRN
538 Belair Dr.
Lewisburg. PA
17837
(570) 522-0188

CARDIOVASCULAR OUTPATIENT MONITORING UNIT
Geisinger Medical Center
Danville, PA 17822

FAX # 570 271-8882

FAX TRANSMITTAL COVER SHEET

Date and Time: 10/2/00 1006

To: Alice Corey
Director of the Immunization
Division of the Health Dept.

From: Christianne Wright RN, CCRN

Pages to follow: 2

IF TRANSMITTAL IS NOT RECEIVED IN LEGIBLE FORM, PLEASE NOTIFY US IMMEDIATELY.

MESSAGE/ SPECIAL INSTRUCTIONS:

Re: Chicken pox
vaccine

Original: 2142

Pennsylvania MEDICAL SOCIETY®

October 2, 2000

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

Re: Proposed Rulemaking #10-162 (#2142) School Immunization Department of Health

Dear Ms. Gray:

I am writing on behalf of the Pennsylvania Medical Society to offer comments on the above captioned proposed rulemaking regarding school immunizations, promulgated by the Department of Health.

The Society supports the changes to the state's requirements for immunization of children seeking to enter and attend schools in the Commonwealth, as contained in these proposed regulations. We believe the changes will help to clarify existing regulations and will help protect children as they enter an environment that is known to present high risk for contracting communicable and potentially dangerous diseases.

The Society does wish to raise a concern regarding future changes to these regulations. We believe that some mechanism should be developed within the regulatory process to permit more expeditious recognition of Advisory Committee on Immunization Practices (ACIP) recommendations and guidelines for reporting of immunization requirements. This would permit faster response to changes recognized within the treatment community.

The Pennsylvania Medical Society appreciates this opportunity to comment on these regulations.

Sincerely,

Carol E. Rose

Carol E. Rose, MD
President

Cc: Secretary of Health
Independent Regulatory Review Committee
Chair, House Health & Human Services Committee
Chair, Senate Public Health & Welfare Committee
PA Chapter, American Academy of Pediatrics

DNM/doc/cor/Gray

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820

Tel: 717-558-7750
Fax: 717-558-7840
E-Mail: staf@pamedsoc.org
www.pamedsoc.org

Original: 2142

TO: Alice Gray
Director of Immunization Division
PA Dept. of Health

717-772-4309

I strongly object to Mandatory Chicken Pox Vaccination! The MMR w/o Chicken Pox Vaccine already poses enough Risk to Children. The M.M.R. is directly linked to Autism from what I've researched. There are many reasons for my objection - Mercury, Formaldehyde, and the attack on the Central Nervous System to name a Few.

Thankyou -

Shawnel Lee

Shawnel Lee
Concerned Parent

Original: 2142

DR. GERALD J. KRUBA
Chiropractor

6077 Spring Rd.
Shermans Dale, Pennsylvania 17090
Telephone: (717) 582-7900

October 2, 2000

Dear Ms. Gray,

I am writing to voice my disapproval with the PA Dept. of Health's plan to require the chicken pox vaccine prior to a child's entrance to school. This is just another attempt by the medical establishment to force a procedure, with unknown future consequences, on our children.

Ample evidence has come to light in recent years that the chicken pox vaccine, along with all of the others, may be responsible for formerly rare childhood conditions that are now on the increase. These conditions include autism, SIDS, MS, juvenile diabetes, ADD/ADHD, cerebral palsy, epilepsy and post-encephalitic syndrome. Physicians who have been misled about the risks continue to administer the vaccines and then deny any vaccine connection when children die, get ill or have seizures.

I respectfully ask that the PA Dept. of Health not risk damaging our children's immune systems on attempting to get rid of a benign childhood disease.

Sincerely,

Dr. Gerald J. Kruba, D.C.

Dr. Gerald J. Kruba, D.C.

Original: 2142

Attn: Alice Gray, director of immunization division
From: Jill Hobson, mother and grandmother

I am writing to inform you the chickenpox vaccine should NOT be mandated. The FDA is requesting the AMA/ Heath Depts. eliminate mercury from the ingredients in vaccines...until that has been done I am one of those anti vaccine people Dr Watson, medical director of the Philadelphia Dept of Public health [illegible] Mercury exposure has been responsible for behavior d[illegible] centuries..and injecting it into our children is ludicrous. And [illegible] the PA Parents for Vaccine Awareness, vaccines should be [illegible] and foremost. The fact that children are developing behavioral problems immediately after their series of shots should be a big red [illegible] those manufacturing, distributing, promoting and PROFITTING from the industry. These sometimes deadly symptoms should not be ignored or brushed off as "fire where there is no fire" as Watson has. Wake up health dept. the parents and grandparents are not imagining these horrific side effects occuring to their babies, and you have been at the core of these injustices for generations. Eliminate mercury, formaldehyde and aluminum from the ingredients and maybe we'll prevent ADD, ADHA and autism from becoming epidemic. Or inform parents that these ingredients exist and see how many would want their new borns exposed to them...not one

Also, please quit training your health care workers to treat parents like they're abusing their children if they choose not to assault their babies' bodies with [illegible] life threatening injections..

I can be reached at 814-789-2034, [illegible]

Original: 2142

October 2, 2000

69 Oatfield Lane
Palmyra, PA 17078

Alice Gray, RN
Director
Bureau of Communicable Diseases
Division of Immunization
2635 Paxton St.
Harrisburg, PA 17108

Dear Ms. Gray:

I am writing this letter to commit my support for the Chicken Pox vaccine being added as one of the required immunizations required for our children to receive before attending school. In deed this is a very dangerous and devastating disease.

In August of 1974, my beautiful daughter, Jennifer Gill, died at the age of two and half from a heart condition called MYOCARDITIS. Upon her autopsy, it was discovered that the virus, which attacked her heart, had come from the chick pox virus that she had over a year earlier. It is hard to visualize a grave marker reading 1972 to 1974.

We were just the average family with a son in kindergarten and a one and half year old at home. Life was good and we were very happy. When Scott came home with chicken pox in May of his kindergarten year, we hardly knew that our lives would change forever. Scott battled with chicken pox first, with Jennifer following just two weeks later. This childhood disease, which many find harmless, cost us our daughter and our family. Our family unit was never able to recover from this loss and years later our marriage dissolved in divorce. The death of a child is just devastating.

Although many feel that chicken pox is just a rite of passage, I can attest to the fact that it is much, much more. If a vaccine had been available in 1974, perhaps I would be sharing my life with a beautiful twenty eight year old daughter instead of holding onto memories.

Sincerely,

Dianna S. Bush

Dianna S. Bush

HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

FAX # (717) 783-4525

DATE: 10-2-2000

SENDING TO:

Telecopy Number: (717) 772-4309

Department/Company: _____

Name: _____

Number of Pages Including Cover Sheet: 2

Message: Our office phone number
is - 787-2798.

SENT FROM:

Name: Diane

Representative's Office: Lucyk

Original: 2142

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

October 1, 2000

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

Attn: Mr. Arthur Coccodrilli

Dear Mr. Coccodrilli,

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 of convinces for parents who work and for their employers. Chicken Pox is quite uncomfortable for the child, 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.

Cc: Senator Gerlach
Senator Mowrey
Senator Hughes
Senator Kitchen
Senator Schwartz
Senator Waugh
Senator White
Mr. Coccodrilli
Mr. Robert Harbison
Mr. Mizner