MAINE MEDICAL ASSOCIATION

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TESTIMONY OF THE MAINE MEDICAL ASSOCIATION

AND THE

MAINE CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS

IN OPPOSITION TO

L.D. 754, AN ACT TO ENCOURAGE TRANSPARENCY IN DISCLOSING THE INGREDIENTS IN VACCINATIONS FOR CHILDREN

Joint Standing Committee on Health & Human Services
Room 209, Cross State Office Building
Monday, April 29, 2013, 9:00 am.

Good afternoon Senator Craven, Representative Farnsworth, and Members of the Joint Standing Committee on Health & Human Services. I am Jessa Barnard, Associate General Counsel for the Maine Medical Association (MMA). I am speaking in opposition to L.D. 754, *An Act to Encourage Transparency in Disclosing the Ingredients in Vaccinations for Children* on behalf of the MMA and the Maine Chapter of the American Academy of Pediatrics (AAP).

The MMA is a professional association representing more than 3800 physicians, residents, and medical students in Maine whose mission is to support Maine physicians, advance the quality of medicine in Maine, and promote the health of all Maine citizens. The Maine Chapter of the AAP represents more than 200 Maine physicians who specialize in treating children and adolescents.

Unfortunately, L.D. 754 seems to be the latest in a long series of bills before the Maine legislature challenging the value of childhood immunizations, perhaps the single greatest public health accomplishment of the last century and a preventive health measure strongly supported by scientific evidence. Thankfully, the Maine legislature has not been swayed by misinformation.

- The 125th Maine Legislature rejected L.D. 694, *An Act to Encourage Transparency in Disclosing the Ingredients in Vaccinations for Children to Parents and Guardians*;
- The 124th Maine Legislature rejected L.D. 819, *An Act to Encourage Transparency in Disclosing the Ingredients in Vaccinations for Children to Parents and Guardians*;
- The 123rd Maine Legislature rejected L.D. 1446, *An Act to Protect Children from Mercury and Thimerosal Toxicity in Immunizing Agents*;
- The 122nd Maine Legislature rejected L.D. 148, *An Act to Require Certain Physicians to Provide Information About Thimerosal in Vaccines.*

While no medical procedure is without some risks or potential for side effects, I doubt that you would find a physician or public health expert today who would disagree that the benefits of childhood immunizations *far outweigh* the potential risks. Still, pediatricians and family practitioners take the time to respond to parents' questions and concerns about vaccines, particularly when they come in with information from the Internet as is often the case today. A strong ethical and common law basis for the principle of informed consent - and providing families with information about risks and benefits of any given intervention - already govern health care practitioners in Maine. In addition, practices are already required by Federal law to give out Vaccine Information Statements (VISs) before each dose of vaccinations are given. VISs are information sheets produced by the Centers for Disease Control and Prevention that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. I have attached the Vaccine Information Statements from some of the most common childhood vaccinations for your review. You will note that they list mild, moderate and severe side effects from given vaccines in a way that is clear, understandable and accurate.

Finally, I have attached a brief document explaining the Vaccine Adverse Event Reporting System. The National Childhood Vaccine Injury Act of 1986 requires health professionals and vaccine manufacturers to report to the U.S. Department of Health and Human Services adverse events that occur after the administration of routinely recommended vaccines. The Reporting System then analyzes and makes this data

available to the public. You will see that this system has actually been used to identify problems with vaccines and has led to the removal of one product from the market.

The requirements of L.D. 754 add nothing of substance highly regulated area of vaccine administration and safety and will only heighten fears raised by the anti-vaccine movement. We have serious concerns that the requirement to provide additional information about vaccine ingredients will simply reinforce myths and misinformation. In decisions released in February 2009, the U.S. Court of Federal Claims, Office of Special Masters found no link between the MMR vaccine and autism. I have attached for your review as an update on the vaccine controversy, a copy of an article published just weeks ago in the American Medical News, *Study debunks a common autism concern about vaccines*, a 2011 article *Regaining trust after vaccine threat debunked* and a widely available CDC webpage for parents on vaccine ingredients.

The likely result of this legislation would be to raise needless worry among parents of young children and cause more new parents to forego immunizations for their children. In a discussion about L.D. 819 in the 124th Legislature with one pediatrician at the State House, the doctor expressed a fear that in the next few years, we could be witnessing children dying from diseases that haven't claimed the lives of children in fifty or sixty years! In fact, we are already seeing an increase in the rate of children claiming exemptions from school entry vaccination requirements and a return of vaccine-preventable illness. Between the 2009-2010 and 2011-2012 school years the rate of exemptions increased 18%. Partially as a result, the instances of confirmed and probable pertussis (whooping cough) are going up – from 204 cases in 2011 to 707 in 2012.

The MMA and the Maine Chapter of the American Academy of Pediatrics urge you to reject L.D. 754. I would be happy to respond to any questions you may have.

DIPHTHERIA TETANUS & PERTUSSIS VACCINES

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in up to 2 out of 10 cases.

PERTUSSIS (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can help prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2 Who should get DTaP vaccine and when?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

✓ 2 months ✓ 4 months ✓ 6 months
✓ 15-18 months ✓ 4-6 years

DTaP may be given at the same time as other vaccines.

3 Some children should not get DTaP vaccine or should wait

- Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.

- Any child who had a life-threatening allergic reaction after a dose of DTaP should not get another dose.

- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get another dose.

- Talk with your doctor if your child:
  - had a seizure or collapsed after a dose of DTaP,
  - cried non-stop for 3 hours or more after a dose of DTaP,
  - had a fever over 105°F after a dose of DTaP.

Ask your health care provider for more information. Some of these children should not get another dose of pertussis vaccine, but may get a vaccine without pertussis, called **DT**.

4 Older children and adults

DTaP is not licensed for adolescents, adults, or children 7 years of age and older.

But older people still need protection. A vaccine called **Tdap** is similar to DTaP. A single dose of Tdap is recommended for people 11 through 64 years of age. Another vaccine, called **Td**, protects against tetanus and diphtheria, but not pertussis. It is recommended every 10 years. There are separate Vaccine Information Statements for these vaccines.

5 What are the risks from DTaP vaccine?

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses. Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, lasting 1-7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1-3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105°F (about 1 child out of 16,000)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage.

  These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures. You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual conditions, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If a high fever or seizure were to occur, it would usually be within a week after the shot.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

  Or you can file this report through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.
  VAERS does not provide medical advice

7 The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at **www.hrsa.gov/vaccinecompensation.**

8 How can I learn more?

- Ask your health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit the National Immunization Program's website at **www.cdc.gov/vaccines**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention

MMRV (MEASLES, MUMPS, RUBELLA & VARICELLA) VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Measles, Mumps, Rubella & Varicella

Measles, Mumps, Rubella, and Varicella (chickenpox) can be serious diseases:

Measles

- Causes rash, cough, runny nose, eye irritation, fever.
- Can lead to ear infection, pneumonia, seizures, brain damage, and death.

Mumps

- Causes fever, headache, swollen glands.
- Can lead to deafness, meningitis (infection of the brain and spinal cord covering), infection of the pancreas, painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (German Measles)

- Causes rash and mild fever; and can cause arthritis, (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Varicella (Chickenpox)

- Causes rash, itching, fever, tiredness.
- Can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- Can re-emerge years later as a painful rash called shingles.

These diseases can spread from person to person through the air. Varicella can also be spread through contact with fluid from chickenpox blisters.

Before vaccines, these diseases were very common in the United States.

2 MMRV Vaccine

MMRV vaccine may be given to children from 1 through 12 years of age to protect them from these four diseases.

Two doses of MMRV vaccine are recommended:

– The first dose at **12 through 15 months of age**

– The second dose at **4 through 6 years of age**

These are *recommended* ages. But children can get the second dose up through 12 years as long as it is at least 3 months after the first dose.

Children may also get these vaccines as 2 separate shots: **MMR** (measles, mumps and rubella) and **varicella** vaccines.

1 Shot (MMRV) or **2 Shots** (MMR & Varicella)?

- Both options give the same protection.
- One less shot with MMRV.
- Children who got the first dose as MMRV have had more fevers and fever-related seizures (about 1 in 1,250) than children who got the first dose as separate shots of MMR and varicella vaccines on the same day (about 1 in 2,500).

Your health-care provider can give you more information, including the Vaccine Information Statements for MMR and Varicella vaccines.

Anyone 13 or older who needs protection from these diseases should get MMR and varicella vaccines as separate shots.

MMRV may be given at the same time as other vaccines.

3 Some children should not get MMRV vaccine or should wait

Children should not get MMRV vaccine if they:

- Have ever had a life-threatening allergic reaction to a previous dose of MMRV vaccine, or to either MMR or varicella vaccine.
- Have ever had a life-threatening allergic reaction to any *component* of the vaccine, including gelatin or the antibiotic neomycin. Tell the doctor if your child has any severe allergies.
- Have HIV/AIDS, or another disease that affects the immune system.
- Are being treated with drugs that affect the immune system, including high doses of oral steroids for 2 weeks or longer.
- Have any kind of cancer.
- Are being treated for cancer with radiation or drugs.

Check with your doctor if the child:

- Has a history of seizures, or has a parent, brother or sister with a history of seizures.
- Has a parent, brother or sister with a history of immune system problems.
- Has ever had a low platelet count, or another blood disorder.
- Recently had a transfusion or received other blood products.
- Might be pregnant.

Children who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMRV vaccine. Children who are only mildly ill may usually get the vaccine.

Ask your provider for more information.

4 What are the risks from MMRV vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMRV vaccine causing serious harm, or death, is extremely small.

Getting MMRV vaccine is much safer than getting measles, mumps, rubella, or chickenpox.

Most children who get MMRV vaccine do not have any problems with it.

Mild Problems

- Fever (about 1 child out of 5).
- Mild rash (about 1 child out of 20).
- Swelling of glands in the cheeks or neck (rare).

If these problems happen, it is usually within 5-12 days after the first dose. They happen less often after the second dose.

Moderate Problems

- Seizure caused by fever (about 1 child in 1,250 who get MMRV), usually 5-12 days after the first dose. *They happen less often when MMR and varicella vaccines are given at the same visit as separate shots (about 1 child in 2,500 who get these two vaccines), and rarely after a 2nd dose of MMRV.*
- Temporary low platelet count, which can cause a bleeding disorder (about 1 child out of 40,000).

Severe Problems (Very Rare)

Several severe problems have been reported following MMR vaccine, and might also happen after MMRV. These include severe allergic reactions (fewer than 4 per million), and problems such as:

- Deafness.
- Long-term seizures, coma, lowered consciousness.
- Permanent brain damage.

Because these problems occur so rarely, we can't be sure whether they are caused by the vaccine or not.

5 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling **1-800-338-2382** or visiting their website at **www.hrsa.gov/vaccinecompensation.**

7 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit CDC's website at **www.cdc.gov/vaccines**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

VACCINE INFORMATION STATEMENT

Polio Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 What is polio?

Polio is a disease caused by a virus. It enters the body through the mouth. Usually it does not cause serious illness. But sometimes it causes paralysis (can't move arm or leg), and it can cause meningitis (irritation of the lining of the brain). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine.

2 Why get vaccinated?

Inactivated Polio Vaccine (IPV) can prevent polio.

History: A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 25,000 cases of polio reported each year. Polio vaccination was begun in 1955. By 1960 the number of reported cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries has sparked a world-wide effort to eliminate polio.

Today: Polio has been eliminated from the United States. But the disease is still common in some parts of the world. It would only take one person infected with polio virus coming from another country to bring the disease back here if we were not protected by vaccine. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

3 Who should get polio vaccine and when?

IPV is a shot, given in the leg or arm, depending on age. It may be given at the same time as other vaccines.

Children

Children get 4 doses of IPV, at these ages:

- A dose at 2 months
- A dose at 4 months
- A dose at 6-18 months
- A booster dose at 4-6 years

Some "combination" vaccines (several different vaccines in the same shot) contain IPV. Children getting these vaccines may get one more (5th) dose of polio vaccine. This is not a problem.

Adults

Most adults 18 and older do not need polio vaccine because they were vaccinated as children. But some adults are at higher risk and should consider polio vaccination:

(1) people traveling to areas of the world where polio is common,
(2) laboratory workers who might handle polio virus, and
(3) health care workers treating patients who could have polio.

Adults in these three groups:

- who have **never been vaccinated against polio** should get 3 doses of IPV:
  - Two doses separated by 1 to 2 months, and
  - A third dose 6 to 12 months after the second.
- who have had **1 or 2 doses** of polio vaccine in the past should get the remaining 1 or 2 doses.

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Centers for Disease Control and Prevention

It doesn't matter how long it has been since the earlier dose(s).

- who have had **3 or more doses** of polio vaccine in the past may get a booster dose of IPV.

Your doctor can give you more information.

4 Some people should not get IPV or should wait.

These people should not get IPV:

- Anyone with a life-threatening allergy to any component of IPV, including the antibiotics neomycin, streptomycin or polymyxin B, should not get polio vaccine. Tell your doctor if you have any severe allergies.
- Anyone who had a severe allergic reaction to a previous polio shot should not get another one.

These people should wait:

- Anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine. People with minor illnesses, such as a cold, may be vaccinated.

Ask your doctor for more information.

5 What are the risks from IPV?

Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people don't have any problems at all with it.

However, any medicine could cause a serious side effect, such as a severe allergic reaction or even death. The risk of polio vaccine causing serious harm is extremely small.

6 What if there is a moderate or severe problem?

What should I look for?

- Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

If a serious allergic reaction occurred, it would happen within a few minutes to a few hours after the shot. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

  Or you can file this report through the VAERS website at **www.vaers.hhs.gov** or by calling **1-800-822-7967**.

  VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

8 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
Polio Vaccine
11/8/2011
42 U.S.C. § 300aa-26

Office Use Only

About the VAERS Program

Background and Public Health Importance

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program that collects information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States.

The National Childhood Vaccine Injury Act (NCVIA) of 1986 requires health professionals and vaccine manufacturers to report to the U.S. Department of Health and Human Services (HHS) specific adverse events that occur after the administration of routinely recommended vaccines. In response to NCVIA, CDC and FDA established VAERS in 1990 (Chen, Vaccine, 1994).

VAERS has demonstrated its public health importance by providing health scientists with signals about possible adverse events following immunization. In one instance, VAERS detected reports for intussusception over that what would be expected to occur by chance alone after the RotaShield rotavirus vaccine in 1999. Epidemiologic studies confirmed an increased risk, and these data contributed to the product's removal from the US market. In another example, VAERS determined that there may be a potential for a small increase in risk for Guillain-Barre' syndrome (GBS) after the meningococcal conjugate vaccine, Menactra. As a result of this finding, a history of GBS became a contraindication to the vaccine and further controlled studies are currently underway to research this issue.

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Number of Reports VAERS Receives

VAERS receives around 30,000 reports annually, with 13% classified as serious (e.g., associated with disability, hospitalization, life-threatening illness or death) (CDC VAERS Master Search Tool, April 2, 2008). Since 1990, VAERS has received over 200,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Many different types of adverse events occur after vaccination. About 85-90% of the reports describe mild adverse events such as fever, local reactions, and episodes of crying or mild irritability. The remaining reports reflect serious adverse events involving life-threatening conditions, hospitalization, permanent disability, or death, which may or may not have been caused by a vaccine.

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Objectives of VAERS

The primary objectives of VAERS are to:

1. Detect new, unusual, or rare vaccine adverse events (VAEs);
2. Monitor increases in known adverse events;
3. Identify potential patient risk factors for particular types of adverse events;
4. Identify vaccine lots with increased numbers or types of reported adverse events; and
5. Assess the safety of newly licensed vaccines.

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Frequently Asked Questions (FAQs)

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AMERICAN MEDICAL NEWS

HEALTH

Study debunks a common autism worry about vaccines

■ The research is the latest to show that vaccines don't cause autism spectrum disorder. Doctors can use the findings to ease parental concerns.

By TANYA ALBERT HENRY (HTTP://WWW.AMEDNEWS.COM/APPS/PBCS.DLL/PERSONALIA?ID=THENRY) — Posted April 15, 2013

When speaking with parents about vaccinations, physicians have new scientific evidence that the number of vaccines children receive between birth and age 2 are not associated with the risk of autism.

After looking at how many antigens children received on a single day of vaccination and the total number of antigens they received during their first two years, researchers concluded there was no link between the vaccines and developing autism spectrum disorder.

Study authors used data from three managed care organizations to compare 256 children with ASD and 752 children without ASD, and found children in each group received the same number of antigens. They also found that children with ASD with regression did not receive more antigens than children without ASD with regression, according to the study posted online March 29 in *The Journal of Pediatrics*.

"This reinforces the importance of parents having their children vaccinated," said study lead author Frank DeStefano, MD, MPH, director of the Centers for Disease Control and Prevention's Immunization Safety Office. "This should help alleviate fears."

The research is the latest of nearly a dozen studies on the link between autism and vaccines the CDC has published in the past decade. None of them has shown a link between vaccines and autism.

"Parents concerns have evolved," Dr. DeStefano said. "It started with the [measles, mumps and rubella] vaccine 15 years ago. The evidence became convincing that there was not a link between the vaccine and autism. After that, the concern was thimerosal. Again, the evidence on that concluded there was no causal association. ... This addresses the latest evolution of concern that there are too many vaccines too soon."

The study noted that the 2012 routine childhood schedule has several more vaccines than the schedule in the late 1990s, when the children in the study received their vaccines. However, children today are exposed to fewer antigens because of changes in the vaccines.

"The maximum number of antigens to which a child could be exposed by age 2 was 315 in 2012, compared with several thousand in the late 1990s," the study said.

Talking with parents

Rochester, N.Y., pediatrician Susan L. Hyman, MD, chair of the autism subcommittee of the American Academy of Pediatrics' Council on Children with Disabilities, said the new study provides important information for physicians and others counseling and educating families.

"No one study will calm people who are worried, but it calms physicians," Dr. Hyman said.

Study authors noted that a 2011 study published in *Pediatrics* found that 10% of parents of young children refuse or delay vaccinations, with most believing that delaying vaccine doses is safer than providing them on the CDC's recommended vaccination schedule. A 2011 *Health Affairs* study showed that 30% to 36% of parents were concerned about too many vaccines being administered during the first two years of life, too many vaccines being

administered in a single doctor visit and a possible link between vaccines and learning disabilities, such as autism. That number jumped to 55% to 90% among parents who told researchers their children would receive some but not all of the vaccines on the recommended schedule.

Dr. Hyman said physicians need to be partners in their patients' education about vaccines, and the time to educate is before resistance emerges.

"Fear is very difficult to counteract," Dr. Hyman said. "We need to work with families to prevent preventable childhood illness."

She said physicians should counsel patients by sharing knowledge with them and not counteracting fear with fear. "We want parents to understand the science and to make informed decisions," Dr. Hyman said.

Kansas City, Mo., emergency pediatrician Sharon G. Humiston, MD, MPH, said physicians should be sensitive to a parent's needs.

"Some parents need data. For those parents, physicians need to be able to summarize the data," said Dr. Humiston, co-author of the book *Vaccinating Your Child: Questions and Answers for the Concerned Parent*. "Physicians also need to recognize that some parents don't trust science and we need to talk about our personal experience. ... Physicians can't lose sight of the fact that more data isn't going to be enough for all parents."

Barbara Loe Fisher, co-founder and president of the consumer-led National Vaccine Information Center, said the new CDC study "does nothing to reassure parents" that administering a large number of vaccines is safe and unrelated to the increase in autism. She said the study lacked a control group of unvaccinated children and ignored how genetic variation and biological differences between children can affect individual susceptibility to vaccines.

"There is an urgent need for a well-designed, prospective long-term study that includes vaccinated and unvaccinated infants and children conducted by nonindustry, nongovernmental investigators to evaluate not only all morbidity and mortality outcomes, but also to measure pathological changes in the brain and immune function over time in both groups," Fisher said.

Dr. Humiston said concerns among parents are natural.

"It is very understandable that parents would be fearful because the CDC is finding out that the number of kids with autism spectrum disorder is enormous," she said. "The real answer to autism is in science and we, as the pediatric community, as well as the scientific community ... need to really be delving into the grassroots causes."

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EXTERNAL LINKS

"Increasing Exposure to Antibody-Stimulating Proteins and Polysaccharides in Vaccines Is Not Associated with Risk of Autism," *The Journal of Pediatrics*, published online March 29 (link: http://www.ncbi.nlm.nih.gov/pubmed/23545349/)

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PROFESSION

Regaining trust after vaccine threat debunked

■ A leading medical journal says MMR vaccine-autism study was fraudulent. Doctors still face a barrage of safety questions from worried parents.

By KEVIN B. O'REILLY (HTTP://WWW.AMEDNEWS.COM/APPS/PBCS.DLL/PERSONALIA?ID=KOREILLY) amednews staff — Posted Jan. 24, 2011

The tide may be turning in the battle to win parents' trust in the safety of recommended child immunizations.

In early January, the editors of influential British medical journal *BMJ* said Dr. Andrew Wakefield had perpetrated an "elaborate fraud" with his 1998 article in *The Lancet* that purported to link autism and bowel disease to the measles, mumps and rubella vaccine.

BMJ editors concluded that Dr. Wakefield "altered numerous facts about the patients' medical histories in order to support his claim to have identified a new syndrome" and "sought to exploit the ensuing MMR scare for financial gain." The editors based their findings on the work of British investigative reporter Brian Deer, the author of a series of articles on Dr. Wakefield that appeared in the journal.

In 2010, Dr. Wakefield's license to practice medicine in Britain was revoked, and *The Lancet* retracted his article. In 2009, judges in a special U.S. federal court rejected a link between the MMR vaccine and autism. Many studies have rejected any link between autism and vaccines.

These developments come as government officials and physician organizations have improved communicating the benefits of vaccination while addressing safety concerns, doctors say.

Many physicians greeted the *BMJ* revelations with relief, saying Dr. Wakefield's work caused many parents to doubt the wisdom of immunizing their children. MMR vaccine rates had plummeted in Britain, where cases of the measles and mumps soared into the thousands annually. In the U.S., outbreaks of the measles, pertussis and Haemophilus influenzae type b involved children whose parents opted out of immunization.

"This was a house of cards," said Jay M. Lieberman, MD, referring to Dr. Wakefield's research. Dr. Lieberman is professor of clinical pediatrics at the University of California, Irvine School of Medicine and medical director of infectious diseases at Quest Diagnostics Inc. "It just took a decade to understand what fully happened and to expose the complete lack of science behind it and, indeed, the fraud."

After the articles were published in *BMJ*, Dr. Wakefield told CNN that his work was "distorted" and that he is the victim of a "ruthless, pragmatic attempt to crush any attempt to investigate valid vaccine safety concerns."

Dr. Wakefield still has defenders, especially among parents of children with autism. J.B. Handley, who co-founded the activist organization Generation Rescue, now headed by celebrity Jenny McCarthy, told CNN that *BMJ* did "not remotely" discredit Dr. Wakefield's study and merely reprinted Deer's allegations.

The latest news will not dispel every parent's doubts about vaccination, Dr. Lieberman said.

"There's a small, rather hard-core and vocal minority that believes that vaccines are hurting our children," he said. "To the very small minority, no amount of scientific evidence will convince them otherwise. What we'd like to do, as physicians, is reach out to the majority of parents who are simply trying to navigate the information -- and misinformation -- they're getting."

Though parental concerns may persist, physicians can help persuade parents to vaccinate their children by taking time to listen to their worries, directing them to reliable information sources, and advocating for immunization with passion and a personal touch, experts said.

Doctors should go beyond educating patients about the science, said Gary L. Freed, MD, director of the division of general pediatrics at the University of Michigan Health System.

"We should present all accurate available information for parents, including the veracity and the lack of credibility of many of those who have promoted fear of vaccines for their own personal profit and gain," said Dr. Freed, lead author of a March 1, 2009, *Pediatrics* article reporting that one in eight parents has refused at least one recommended vaccine.

The survey of 1,552 parents also found that 25% agreed with the statement, "Some vaccines cause autism in healthy children."

The delicate conversation about immunization safety can turn sour quickly, said Francesco "Chek" Beuf, MD, a Boulder, Colo., pediatrician.

"Discussing vaccination with certain people is like discussing religion or politics," Dr. Beuf said. "It's a matter of deep feelings, rather than facts.

"I try to educate people. I try not to make them feel like idiots."

Physicians should capitalize on their established relationships with patients, said Doug Campos-Outcalt, MD, the American Academy of Family Physicians' liaison to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

"The foremost point is that people trust their doctors," Dr. Campos-Outcalt said. "Physicians should talk to patients confidently and answer their questions in a straightforward way and listen to their concerns."

Advocating for health

At All Star Pediatrics in Exton, Pa., a Philadelphia suburb, parents receive a vaccine policy statement expressing the group's belief in the effectiveness and safety of vaccines.

Parents are discouraged from delaying vaccination, and those who refuse to vaccinate are advised to "find another health care provider who shares your views."

The five-physician practice has been using the statement since 2007 to help allay parents' concerns. Still, the questions keep coming at virtually every visit, said Bradley J. Dyer, MD, the group's founder.

Despite telling parents who refuse immunization to go elsewhere, Dr. Dyer describes his conversations with parents as congenial.

"The approach we use is to say, 'There's bad science, or no science, behind the detractors. We want to do what's best for your child. We're on the same team here,' " Dr. Dyer said.

Physicians definitely should steer clear of chastising worried parents, said Ari Brown, MD, an Austin, Texas, pediatrician and co-author of *Baby 411: Clear Answers and Smart Advice for Your Baby's First Year.*

"Doctors need to remember that these are not bad parents -- they are scared parents, and there is a difference," Dr. Brown said. "Don't make your interactions leave the parent feeling like they are a bad parent for not vaccinating or waiting to vaccinate. ... Parents just want to feel like they are doing all they can to protect their child."

Dr. Brown said concern about vaccines seemed to peak in about 2008 in her practice, and that the tide has begun to turn since then.

"It's been a long decade," she said. "Hopefully, we can close this chapter and move on and have more parents feeling confident in vaccinating their kids."

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ADDITIONAL INFORMATION

Stoking vaccine fears with research fraud

February 1998: *The Lancet* publishes an article by Dr. Andrew Wakefield and 12 co-authors that described eight "previously normal children" showing symptoms of colitis and developmental regression shortly after receiving the measles, mumps and rubella vaccine. In a news conference, Dr. Wakefield calls for a suspension of the MMR vaccine pending further research.

December 2001: Dr. Wakefield resigns from the Royal Free Hospital.

February 2004: British investigative journalist Brian Deer reports in *The Sunday Times* that some of the parents whose children's cases were described in *The Lancet* article were recruited by a lawyer pursuing a lawsuit against manufacturers of the MMR vaccine, and that the Royal Free Hospital received nearly $90,000 from a legal board for the research. Ten of Dr. Wakefield's co-authors retract their original interpretation in the 1998 article.

December 2006: *The Sunday Times* reports that Dr. Wakefield was paid more than $600,000 to conduct his research.

January 2010: After a 217-day hearing, Britain's General Medical Council finds that Dr. Wakefield acted unethically and "with callous disregard for the distress and pain" that children would experience after being subjected to blood draws, lumbar punctures and other tests that were clinically unnecessary and not approved by his hospital's ethics committee. *The Lancet* retracts Dr. Wakefield's 1998 article.

February 2010: Dr. Wakefield resigns as executive director of Austin, Texas-based Thoughtful House Center for Children, which advocates alternative treatments for children with autism and other developmental disorders.

May 2010: The General Medical Council revokes Dr. Wakefield's license to practice in the United Kingdom.

January 2011: Editors of the influential British medical journal *BMJ* say Dr. Wakefield perpetrated an "elaborate fraud" with his 1998 article in *The Lancet*. The journal runs a series of articles by Deer describing how Dr. Wakefield altered medical case histories and detailing his conflicts of interest. In a Jan. 17 interview on ABC's "Good Morning America," Dr. Wakefield says: "There was no fraud. There was no falsification. There was no hoax. ... What I did was respond to parental concerns."

Sources: News accounts, *American Medical News* archives, television show transcripts

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EXTERNAL LINKS

"Wakefield's article linking MMR vaccine and autism was fraudulent," *BMJ*, published online Jan. 5 (**link: http://www.ncbi.nlm.nih.gov/pubmed/21209060/**)

"Secrets of the MMR scare: *The Lancet*'s two days to bury bad news," *BMJ*, published online Jan. 18 (**link: http://www.bmj.com/content/342/bmj.c7001**)

"Secrets of the MMR scare: How the vaccine crisis was meant to make money," *BMJ*, published online Jan. 11 (**link: http://www.ncbi.nlm.nih.gov/pubmed/21224310/**)

"Secrets of the MMR scare: How the case against the MMR vaccine was fixed," *BMJ*, published online Jan. 5 (**link: http://www.ncbi.nlm.nih.gov/pubmed/21209059/**)

"Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children," *The Lancet*, Feb. 28, 1998, retracted on Feb. 6, 2010 (**link: http://www.ncbi.nlm.nih.gov/pubmed/9500320/**)

"Parental vaccine safety concerns in 2009," *Pediatrics*, April 2010 (**link: http://www.ncbi.nlm.nih.gov/pubmed/20194286/**)

"Evaluating Information About Vaccines on the Internet," National Network for Immunization Information, July 12, 2010 (**link: http://www.immunizationinfo.org/issues/general/evaluating-information-about-vaccines-internet**)

American Academy of Pediatrics' Immunization Alliance (link: http://www.aap.org/immunization/about/immunizationalliance.html)

Vaccine Education Center, Children's Hospital of Philadelphia (link: http://www.chop.edu/service/vaccine-education-center/)

Centers for Disease Control and Prevention on vaccine safety (link: http://www.cdc.gov/vaccinesafety/)

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For Parents: Vaccines for Your Children

Vaccines Home
Vaccines & Immunizations

Vaccine Ingredients

Vaccines contain ingredients, called antigens, which cause the body to develop immunity. Vaccines also contain very small amounts of other ingredients--all of which play necessary roles either in making the vaccine, or in ensuring that the vaccine is safe and effective. These types of ingredients are listed below.

Type of Ingredient	Examples	Purpose
Preservatives	Thimerosal (only in multi-dose vials of flu vaccine)	To prevent contamination
Adjuvants	Aluminum salts	To help stimulate the body's response to the antigens
Stabilizers	Sugars, gelatin	To keep the vaccine potent during transportation and storage
Residual cell culture materials	Egg protein	To grow enough of the virus or bacteria to make the vaccine
Residual inactivating ingredients	Formaldehyde	To kill viruses or inactivate toxins during the manufacturing process
Residual antibiotics	Penicillin, sulfa drugs	To prevent contamination by bacteria during the vaccine manufacturing process

Today, except for some flu vaccines, none of the childhood vaccines used routinely in the United States contain mercury (thimerosal) as a preservative. Although no evidence suggests that there are safety concerns with thimerosal, vaccine manufacturers stopped using it as a precautionary measure. Now it is contained in very tiny amounts only in multi-dose vials of flu vaccine. Thimerosal is necessary in vaccines that come in multi-dose vials because they require that each individual vaccine dose be drawn from the vial with a new needle and syringe. With each needle inserted, there is the potential for introducing microbes into the vial.

There is no evidence of harm caused by the small amounts of thimerosal in flu vaccines, except for minor reactions like redness and swelling at the injection site. Flu vaccines that do not contain thimerosal are available.

Related Pages

- Possible Side-effects of Each Vaccine
- Mercury and Thimerosal

Other topics related to **Parents: Making the Vaccine Decision**

- Vaccines and Your Child's Immune System
- How Vaccines Prevent Disease
- Vaccine Side Effects
- Vaccine Ingredients
- Ensuring Vaccine Safety