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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. 694, AN ACT TO ENCOURAGE TRANSPARENCY IN DISCLOSING THE
INGREDIENTS IN VACCINATIONS FOR CHILDREN TO PARENTS AND
GUARDIANS**

Joint Standing Committee on Health & Human Services
Room 209, Cross State Office Building
Tuesday, April 5, 2011, 1:00 p.m.

Good afternoon Senator McCormick, Representative Strang Burgess, and Members of the Joint Standing Committee on Health & Human Services. I am Andrew MacLean, Deputy EVP of the Maine Medical Association (MMA), and I am speaking in opposition to L.D. 694, *An Act to Encourage Transparency in Disclosing the Ingredients in Vaccinations for Children to Parents and Guardians* 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 3400 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. 694 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 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*.

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 by Kevin B. O'Reilly entitled, *Regaining trust after vaccine threat debunked* from the January 24, 2011 edition of [American Medical News](#).

Regarding informed consent to vaccinations, 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, most 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

already governs health care practitioners in Maine. The requirements of L.D. 694 add nothing of substance to the current law and will only heighten public concerns raised by the anti-vaccine movement. I have attached as additional background, an excerpt on consent to treatment from a continuing legal education program several years ago.

I am afraid that 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 two years ago, 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!

The MMA and the Maine Chapter of the American Academy of Pediatrics urge you to reject L.D. 694. I would be happy to respond to any questions you may have.

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American Medical News

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, *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.

1 in 8 parents has refused at least 1

"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



Even after *BMJ* condemned his research, Dr. Andrew Wakefield continued to defend his integrity.

"There was no fraud," he told "Good Morning America" on Jan. 17.

[Photo by AP / Wide World Photos]

recommended**vaccine for his or her child.**

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."

The print version of this content appeared in the Jan. 31 issue of *American Medical News*.

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

WEBLINK

"Wakefield's article linking MMR vaccine and autism was fraudulent," *BMJ*, published online Jan. 5 (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 (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 (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 (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 (www.ncbi.nlm.nih.gov/pubmed/9500320)

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

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

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

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

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

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Excerpt from *Health Law in Maine: the Legal Implications of Health Care Delivery
Systems and Managed Care*

National Business Institute, Inc.

September 28, 2004

Prepared by Andrew B. MacLean, J.D.

Vice President & General Counsel

Maine Medical Association

2. CONSENT TO TREATMENT

A. General

As suggested in the discussion of the physician-patient relationship, the patient's consent to medical treatment is a fundamental element of the relationship. Consent to treatment is more than simply having the patient sign a written consent form. It should be a process of communication between the physician and patient resulting in an agreement to pursue a specific medical or surgical course of treatment. In 1914, Judge (later Supreme Court Justice) Benjamin Cardozo described the principle of consent to treatment in writing, "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).

The first judicial opinion to use the term "informed consent" came many years after Schloendorff in Salgo v. Leland Stanford Jr. University Board of Trustees, 317 P.2d 170 (1957). The Salgo Court stated that a patient's documented consent is insufficient if the patient did not understand the physician's description of the treatment. The Court decided that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment." Salgo, 317 P.2d at 181. The AMA Code of Medical Ethics addresses informed consent in Opinion 8.08, *Informed Consent*:

The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient

should make his or her own determination on treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted: (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy. Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment. (I, II, III, IV, V) Issued March 1981.

In short, "consent" means "permission" and "informed consent" means "permission given after a proper explanation." The physician's process of obtaining the patient's informed consent should include these disclosures:

- the nature and purpose of the treatment;
- the risks and consequences involved in the treatment;
- alternative courses of treatment, including the consequences of no treatment; and
- an opportunity for the patient to ask questions.

Consent forms should be drafted as specifically as possible and should provide evidence of the process of obtaining informed consent. A sample consent form is included in the Appendix.