The Measles: Background and Federal Role in Vaccine Policy

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Summary

The earliest accounts of measles date back over 1,000 years. This report presents basic information about this infectious disease, its history in the United States, available treatments to prevent individuals from contracting measles, and the federal role in combating measles—from funding, to research, to the authority of the federal government in requiring mandatory childhood vaccinations. The report provides additional resources for information on measles and recommendations for vaccination against the disease.

According to the U.S. Centers for Disease Control and Prevention (CDC), “measles is a highly contagious virus that lives in the nose and throat mucus of an infected person.” It is transmitted through coughing and sneezing, and it can live for up to two hours on a surface or in an airspace where an infected person coughed or sneezed. Someone who is not immunized against measles and comes into contact with the virus has a 90% chance of becoming infected.

According to the CDC, in 2013 (the most recent year in which data are available) “the overall national coverage for MMR vaccine among children aged 19-35 months was 91.9%.” However, MMR (measles, mumps, rubella) vaccine coverage levels continue to vary by state, with 10 states reporting 95% of children aged 19-35 months receiving at least one dose of MMR vaccine, while in 17 other states, less than 90% were vaccinated.

The President’s FY2016 budget request for the CDC reports that “from January 1 to November 29, 2014, CDC received reports of 610 measles cases from 24 states in the United States. This is the highest number of cases reported in the United States, including the largest single measles outbreak, since the Vaccines for Children (VFC) Program was established in 1994.” Thus far in 2015 (through January 30), CDC has received reports of 102 measles cases located in 14 states. While the overall U.S. MMR annual vaccination rate has exceeded 90% since 1996, the increased number of imported measles cases, combined with pockets of unvaccinated individuals, has resulted in a larger number of outbreaks in recent years.

The role of the federal government in vaccine policy, particularly in the development of guidelines for when to administer specific vaccines (and when not to) and to what populations is extensive. The federal government also has a major role in the purchase and distribution of vaccines, particularly childhood vaccines. However, the role of the federal government is much more limited and constrained in its ability to mandate the use of specific vaccines by individuals—this responsibility rests primarily with state and local officials.
Introduction

Despite measles having been declared eliminated in the United States 15 years ago, there have continued to be occasional outbreaks of the virus that have raised questions about the virus itself, the medications available to prevent its transmission, and the federal government’s role in ensuring that vaccine-preventable diseases, such as measles, do not reestablish themselves in the United States. This report presents basic information about this infectious disease, its history in the United States, available treatments to prevent individuals from contracting measles, and the federal role in combatting measles—from funding, to research, to the authority of the federal government in requiring mandatory childhood vaccinations.

What Is Measles?1

According to the U.S. Centers for Disease Control and Prevention (CDC), “measles is a highly contagious virus that lives in the nose and throat mucus of an infected person.” It is transmitted through coughing and sneezing, and it can live for up to two hours on a surface or in an airspace where the infected person coughed or sneezed. Someone who is not immunized against measles and comes into contact with the virus has a 9-in-10 chance of becoming infected.

Symptoms associated with the measles start to appear approximately 7 to 14 days after a person is infected. Symptoms usually consist of high fever, cough, runny nose, and red/watery eyes. Two to three days after the onset of symptoms, small white spots may appear inside the mouth; a rash typically follows three to five days after symptoms begin.

The most common complications from measles include inflammation of the middle ear, pneumonia, and diarrhea. Measles can cause serious illness resulting in hospitalization, and 1 in every 1,000 measles cases may develop acute encephalitis (inflammation of the brain), which could lead to permanent brain damage. Between 1 and 2 of every 1,000 children with measles will die from respiratory and neurologic complications.

Those who are most at risk for severe illness and complications from the measles include infants and children younger than 5 years old, adults older than 20 years old, pregnant women, and people with compromised immune systems (e.g., HIV infection, cancer patients).

The Measles Vaccine and Vaccination Rates2

Diagnosed cases of measles were first required to be reported by health care officials in the United States approximately 100 years ago; about 6,000 measles-related deaths were reported

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2 Much of the information from this section was taken from the Centers for Disease Control and Prevention’s website dedicated to the measles outbreak, including the history of the development and introduction of the measles vaccine, http://www.cdc.gov/measles/about/history.html.
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Each year for the first decade of reporting. In the decade prior to the introduction of the first
measles vaccine in 1963, most children got measles while growing up. Each year, approximately
3-4 million people in the United States caught the infection, an estimated 400 to 500 people died,and 48,000 were hospitalized. As recently as 2013, the World Health Organization estimated
145,700 deaths globally from measles.3

In 1954, John F. Enders and Dr. Thomas C. Peebles collected blood samples from several ill
students during a measles outbreak in Boston, MA, in an attempt to create a measles vaccine. By
1963, Enders and colleagues had successfully created a measles vaccine and licensed it in the
United States. Today, the measles vaccine is combined with mumps and rubella (MMR) or with
mumps, rubella and varicella (MMRV).

The Advisory Committee on Immunization Practices (ACIP)4 and CDC recommend that all
children receive two doses of MMR vaccine, the first dose at 12 to 15 months of age, and the
second at 4 to 6 years of age. Adults who do not have evidence of immunity5 (e.g., written
documentation of vaccination, laboratory confirmation of measles) are recommended to receive at
least one dose of the measles vaccine. Those who should not get the vaccine include

- anyone who has ever had a life-threatening allergic reaction (e.g., anaphylactic
  shock) to the antibiotic neomycin or to prior doses of the MMR or MMRV
  vaccine,

- pregnant women, and

- individuals with any type of cancer, HIV/AIDS, or other immune system
disease.6

According to the CDC, the risks associated with the MMR vaccine “causing serious harm, or
death, is extremely small” and receiving the vaccine “is much safer than getting measles, mumps,
or rubella.” However, as is the case with every medication, the MMR/MMRV vaccine is not
100% safe. It can result in what CDC characterizes as “mild problems,” such as fever (1 out of 6
people) or mild rash (1 out of 20 people); “moderate problems,” such as seizure caused by fever
(1 out of 3,000 doses) or temporary joint stiffness or pain, mostly in teenage or adult women (up
to 1 out of 4); and “severe problems,” such as serious allergic reaction (less than 1 out a million
doses) or deafness. The rarity of these severe problems makes it difficult to ascertain whether
they are caused by the vaccine.8

It should be noted that among the issues that has resulted in pockets of lower rates of
MMR/MMRV vaccination have been concerns over the safety of the measles vaccine itself, in
particular concerns that the vaccine may cause autism. While the perception is real and may be

3 World Health Organization, Measles Fact Sheet, Updated November 2014,
5 Centers for Disease Control and Prevention, Evidence of Immunity,
6 Centers for Disease Control and Prevention, Who Should Not Get Vaccinated with these Vaccines?
http://www.cdc.gov/vaccines/vpd-vac/should-not-vacc.htm#mmr.
7 Centers for Disease Control and Prevention, Vaccine Information Statements (VIS) for Patients, MMR (Measles,
Mumps, & Rubella) Vaccine, http://m.cdc.gov/en/HealthSafetyTopics/HealthyLiving/Vaccines/VIS/MMR.
8 Ibid.
influencing some parent’s decisions to vaccinate their children, the scientific link between autism and the MMR vaccine has been studied extensively and has overwhelmingly been found to be unsubstantiated.9

According to data published in CDC’s Morbidity and Mortality Weekly Report (MMWR), in 2013 (the year for which most recent data are available) “the overall national coverage for MMR vaccine among children aged 19 - 35 months was 91.9%.”10 However, MMR vaccine coverage levels vary by state. According to the CDC, “in 10 states, 95% of the children aged 19–35 months in 2013 had received at least one dose of MMR vaccine, while in 17 other states, less than 90% of these children were vaccinated against measles.”11 The MMWR article also observes that “pockets of unvaccinated people can exist in states with high vaccination coverage, underscoring considerable measles susceptibility at some local levels.”12

CDC has noted that MMR vaccination rates among children 19 – 35 months have exceeded 90% since 1996. What has changed in recent years is the number of measles importations into the U.S. due to the continued high rates of measles in some parts of the world combined with pockets within the U.S. where vaccination rates are low. In tandem, despite an overall high rate of immunization, these trends continue to put individuals who cannot or will not get vaccinated at greater risk for the disease.

The President’s FY2016 budget request for the CDC reports that “from January 1 to November 29, 2014, CDC received reports of 610 measles cases from 24 states in the United States. This is the highest number of cases reported in the United States, including the largest single measles outbreak, since the Vaccines for Children (VFC) Program was established in 1994.”13 Thus far in 2015 (through January 30), CDC has received reports of 102 measles cases located in 14 states.14 Most of the 102 cases—81 people from California and 13 from six other states—are considered to be part of a large, ongoing outbreak linked to an amusement park in California, and about half the patients were unvaccinated or did not know their vaccination status.15

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11 Ibid.
12 Ibid.
15 Personal email communication from the Centers for Disease Control and Prevention’s Washington, DC Office dated February 5, 2014.
Who Makes the Measles Vaccine that Is Sold in the United States?

At present, only one company is licensed to sell measles vaccine in the United States: Merck & Co., Inc., based in Whitehouse Station, NJ. According to the U.S. Food and Drug Administration, Merck is licensed and approved to sell two vaccines that contain the measles vaccine—one is the Measles, Mumps and Rubella Virus Vaccine, Live (known as MMR II), and the second is Measles, Mumps, Rubella, and Varicella Virus Vaccine Live (known as ProQuad).16

According to Merck’s financial filings with the U.S. Securities and Exchange Commission, global revenue from the sale of ProQuad in 2013 (the most recent year for which annual sales data are available) was $314 million; revenue from the sale of MMR II was $307 million for the same year.17 For the first nine months of 2014, revenue from the sale of ProQuad was reported to be $278 million and revenue from the sale of MMR II was $249 million.18

What Is the Federal Role in Vaccine Policy?19

The role of the federal government in vaccine policy, particularly in the development of guidelines for when to administer specific vaccines (and when not to) and to what populations is extensive. The federal government also has a major role in the purchase and distribution of vaccines, particularly childhood vaccines. However, the role of the federal government is much more limited and constrained in its ability to mandate the use of specific vaccines by individuals—this responsibility rests primarily with state and local officials.

Guidelines and Surveillance

As mentioned earlier, the federal government’s role in making evidence-based recommendations and guidance on the use of vaccines by different population groups is significant. The CDC’s ACIP is the main group within the federal government charged with developing “recommendations on how to use vaccines to control diseases.”20 The federal government has a robust capacity for monitoring vaccine usage, particularly the potential for adverse events. The system in place for this task is the Vaccine Adverse Event Reporting System (VAERS), operated jointly by the CDC and the FDA. Both vaccine manufacturers and healthcare providers must

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16 U.S. Food and Drug Administration, Complete List of Vaccines Licensed for Immunization and Distribution in the US, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm. It should be noted that Merck has a third measles vaccine – Measles and Mumps Virus Vaccine, Live (MM Vax) - that is on FDA’s approved and licensed list but is listed as “not available.”


19 The legal discussion in this section is based on CRS Report RS21414, Mandatory Vaccinations: Precedent and Current Laws, by Jared P. Cole and Kathleen S. Swendiman.

report adverse events through the VAERS system, whereas others (e.g., consumers) may do so voluntarily.21

**Purchasing Vaccines and Funding Research**

The President’s FY2016 budget request22 included $4.1 billion for the Vaccines for Children Program (VCP), which provides “vaccines to children whose parents or guardians may not be able to afford them,”23 including vaccination against the measles. Funding for the program is allocated through the Centers for Medicare & Medicaid Services to the CDC. In addition to the VCP is CDC’s Section 317 immunization program, which is funded by annual discretionary appropriations and provides grants to states, territories, commonwealth trusts, and several cities for vaccine purchase and programs (e.g., outreach and disease surveillance). The President’s FY2016 budget request includes a projected $560.5 million for the Section 317 program.24 According to CDC, in calendar year 2014, the VCP and Section 317 programs spent $38.3 million on the purchase of MMR vaccine for children.25 The National Institutes of Health reports that in FY2015, it plans to spend an estimated $1.65 billion on vaccine-related research, focusing on issues ranging from HIV/AID to biodefense.26

**Legal Issues**

**State and Local Authority**

The preservation of public health has traditionally been regarded as primarily the responsibility of state and local governments, and the authority to enact laws relevant to the protection of the public health derives from the states’ general police powers. With regard to communicable disease outbreaks, these powers may include the enactment of mandatory vaccination laws. The Supreme Court has upheld the power of states to institute a mandatory vaccination program as an exercise of its police powers.27 In *Jacobson v. Commonwealth of Massachusetts*, the Supreme Court upheld a state law that gave municipal boards of health the authority to require the vaccination of persons over the age of 21 against smallpox, and determined that the vaccination program had “a real and substantial relation to the protection of the public health and safety.”28 In

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25 Personal email communication from the Centers for Disease Control and Prevention’s Washington, DC, office dated February 5, 2014.
28 Id. at 31. The Massachusetts statute in question reads: “Boards of health, if in their opinion it is necessary for public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants of their towns, and shall provide them with the means of free vaccination. Whoever refuses or neglects to comply with such requirement shall forfeit five dollars.” M.G.L.A. c. 111, §181 (2014).
upholding the law, the Court noted that “the police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.”

Likewise, the Court has recognized state and local power to require students to be vaccinated. In *Zucht v. King*, the Supreme Court upheld a local ordinance requiring vaccinations for schoolchildren. The Court invoked *Jacobson* for the principle that states may use their police power to require vaccinations, and noted that the ordinance did not bestow “arbitrary power, but only that broad discretion required for the protection of the public health.” In turn, lower courts have given considerable deference to the use of the states’ police power to require immunizations to protect the public health. For example, West Virginia does not offer a religious exemption from school vaccination requirements, but the U.S. Court of Appeals for the Fourth Circuit has rejected free exercise, equal protection, and substantive due process challenges to the law. Similarly, New York permits religious exemptions only if a parent holds “genuine and sincere religious beliefs” against vaccination, and permits school districts to bar unvaccinated children from school during an outbreak. The U.S. Court of Appeals for the Second Circuit has upheld the law against substantive due process, free exercise, and equal protection claims.

Many states also have laws providing for mandatory vaccinations during a public health emergency or outbreak of a communicable disease. Generally, the power to order such actions rests with the governor of the state or with a state health officer. For example, a governor may have the power to supplement the state’s existing compulsory vaccination programs and institute additional programs in the event of a civil defense emergency period. Or, a state health officer may, upon declaration of a public health emergency, order an individual to be vaccinated “for communicable diseases that have significant morbidity or mortality and present a severe danger to public health.” In addition, exemptions may be provided for medical reasons or where objections are based on religion or conscience. However, if a person refuses to be vaccinated, he or she may be quarantined during the public health emergency giving rise to the vaccination

29 *Jacobson*, 197 U.S. at 25.
31 Id. at 177.
32 Id.
33 See, e.g., *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 887 (Ark. 1951) (mandatory school vaccination does not deprive individuals of liberty and property interests without due process of law); *McCartney v. Austin*, 293 N.Y.S. 2d 188, 200 (N.Y. 1968) (New York vaccination law does not interfere with freedom to worship since Roman Catholic faith does not proscribe vaccination).
37 Haw. Rev. Stat. §128-8 (2014). In Arizona, the Governor, during a state of emergency or state of war emergency in which there is an occurrence or the imminent threat of smallpox or other highly contagious and highly fatal disease, may “issue orders that... mandate treatment or vaccination of persons who are diagnosed with illness resulting from exposure or who are reasonably believed to have been exposed or who may reasonably be expected to be exposed.” *Ariz. Rev. Stat.* §36-787 (2014).
order. State statutes may also provide additional authority to permit specified groups of persons to be trained to administer vaccines during an emergency in the event insufficient health care professionals are available for vaccine administration.40

**Federal Authority**

Although states have traditionally exercised the bulk of authority in this area, the federal government does have jurisdiction over public health matters. The Commerce Clause states that Congress shall have the power “[t]o regulate Commerce with foreign Nations, and among the several States.”41 Accordingly, under the Public Health Service Act, the Secretary of the Department of Health and Human Services has authority to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”42 Regulations issued pursuant to this authority include quarantine and isolation measures to halt the spread of certain communicable diseases.43 However, no mandatory vaccination programs are specifically authorized, nor do there appear to be any regulations regarding the implementation of a mandatory vaccination program at the federal level during a public health emergency.44

With regard to foreign countries, the Secretary has the power to restrict the entry of groups of aliens for public health reasons.45 This power includes the authority to issue vaccination requirements for immigrants seeking entry into the United States. Currently, certain vaccines specified in statute, and other vaccines recommended by the ACIP for the general U.S. population, are required for immigrants who seek permanent residence in the United States, and for people currently living in the United States who seek to adjust their status to become permanent residents.46 CDC has determined that two diseases for which vaccines are


41 U.S. Const. Art. I, §8. Recognizing that vaccines occasionally cause adverse events, and to assure a supply of vaccines while still providing a financial remedy to those injured, Congress passed the National Vaccine Injury Compensation Act, which created the National Vaccine Injury Program. That program provides a no-fault compensation plan, with capped damages for pain and suffering. 42 U.S.C. §§300aa-1–300aa-34.

42 42 U.S.C. §264(a). Originally, the statute conferred this authority on the Surgeon General; however, pursuant to Reorganization Plan No. 3 of 1966, all statutory powers and functions of the Surgeon General were transferred to the Secretary.

43 See 42 C.F.R. Parts 70 (interstate matters) & 71 (foreign arrivals).


46 See the CDC Division of Global Migration and Quarantine website for information on vaccination requirements for (continued...)
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recommended for routine use by the ACIP—for human papillomavirus (HPV) and zoster (shingles)—do not have the potential to cause outbreaks, and are therefore not required for admission.\textsuperscript{47} Vaccination requirements may be waived when the foreign national receives the vaccination, if the civil surgeon or panel physician certifies that the vaccination would not be medically appropriate, or if the vaccination would be contrary to the foreign national’s religious or moral beliefs.\textsuperscript{48}

Likewise, the military has broad authority in dealing with its personnel, both military and civilian, including the protection of their health.\textsuperscript{49} Military regulations require U.S. troops to be immunized against a number of diseases, including tetanus, diphtheria, influenza, hepatitis A, measles, mumps, rubella, polio, and yellow fever.\textsuperscript{50} Inoculations begin upon entry into military service, and later vaccines depend upon troop specialties or assignments to different geographic areas of the world. Courts have upheld the legality of military mandatory vaccination orders.\textsuperscript{51}

**Additional Resources on Measles**

- **American Academy of Pediatrics/Measles Outbreak Update 2015:**
  http://www2.aap.org/immunization/illnesses/mmr/measles.html;

- **CDC/Epidemiology and Prevention of Vaccine-Preventable Diseases:**
  http://www.cdc.gov/vaccines/pubs/pinkbook/meas.html#vaccines

- **CDC/Measles Cases and Outbreaks:**
  http://www.cdc.gov/measles/cases-outbreaks.html

- **CDC/Advisory Committee on Immunization Practices:**
  http://www.cdc.gov/vaccines/acip/index.html;

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\textsuperscript{48} 8 U.S.C. §1182(g)(2).

\textsuperscript{49} Congress’s war powers include the power to “raise and support Armies,” to “provide and maintain a Navy,” and to “make Rules for the Government and Regulation of the land and naval Forces.” U.S. Const. Art. 1, §8, cls. 12-14. The Supreme Court has called these powers “broad and sweeping,” United States v. O’Brien, 391 U.S. 367 (1967), and the Court gives its highest level of deference to legislation made under Congress’s authority to raise and support armies and make rules and regulations for their governance. See Rostker v. Goldberg, 453 U.S. 47 (1981).


- **CDC/Ten Great Public Health Achievements in the 20th Century:**
  http://www.cdc.gov/about/history/tengpha.htm

- **Institute of Medicine/On the U.S. Measles Outbreak:**
  http://notes.nap.edu/2015/01/28/the-institute-of-medicine-on-the-us-measles-outbreak/#.VNEIIIC43m7M

- **World Health Organization/Measles Fact Sheet:**
  http://www.who.int/mediacentre/factsheets/fs286/en/

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