

**Vaccine Law and Policy:
A Question of "Compulsory Safety"
Government Documents**

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INTRODUCTION

Vaccines have been used for hundreds of years. In 1796 Dr. Edward Jenner began experimenting with the concept of vaccination.¹ He observed that people who worked with cows afflicted with cowpox seemed to be immune to smallpox - a great scourge of the day. Jenner was able to show that injecting small amount of the virus from an infected person could be used to immunize another and the vaccine was established as a public health preventive measure. Over the next 200 years many other vaccines were to follow.

Vaccines are miraculous in their ability to prevent an epidemic of contagious disease. Our population of children does not have to worry about dying or being disabled from diseases that were once common and part of this is due to vaccination. Vaccines are unique in that they are the only class of drugs that the public is often compelled to accept them for themselves and for their children. They may be mandated as a condition of attendance to preschool, elementary school, or college and they may also be mandated as a condition of employment. It is considered to be a matter of public health, a demonstration of not only concern for personal health, but also concern for your community.

The issue of immunization is one that the general public does not often question. It has become somewhat of a national institution - taken for granted as something that is "good". But as the number of vaccines that a child is "required" to receive increases, there is an increase in the level of discomfort among some parents. They question the prudence of vaccinating their children against so many disease that do not appear to be a current threat, some they have never heard of.² In the United States, the Centers for Disease Control and Prevention now recommends 12 different types of vaccination including: Diphtheria (vaccine came on the market in 1923), Pertussis (introduced in the 1940s), Tetanus (also available in the 1940s), Polio (developed by Jonas Salk around 1954), Measles (live attenuated vaccine licensed in 1963), Mumps (vaccine licensed in 1967), Rubella (1969 licensure), Haemophilus influenza (marketed in late 1980s), Hepatitis A and B (1990s), and the Varicella vaccine for Chickenpox (available in 1995).³ Many of these vaccinations are given together, sometimes in one shot and each vaccine may require multiple boosters over time.

The increase in the number of vaccinations coming to the market and being required of citizens necessitates an understanding of the establishment of vaccination policy. There are entities in the Federal and State governments that determine the level of safety of vaccines and also which vaccines are "beneficial" to the public health. When there is controversy, it is important to know the role of the government in the process and who to approach for reliable

answers. An analysis of federal and state government documents from all levels - legislative, executive, and judicial - can provide powerful information.

This paper is divided in two parts. Within each topic I have present the governmental branches and important documents that each has produced for the determination of vaccine law and policy. The first part is "The Federal Government: Safety and 'More'." This provides a survey of the current issues that are causing concern for parents and others compelled to vaccinate children or themselves. The history of federal legislation dealing with vaccine safety is explained along with recent laws that compensate for vaccine injury. The role of the executive branch, specifically the National Institute of Health, the Food and Drug Administration, and the Center for Disease Control and Prevention, is outlined. Supreme Court cases that have been important in the safety of vaccines are also presented.

Once the federal government has developed, tested, evaluated, and regulated a vaccine, they make recommendations for the vaccination of particular populations of citizens: adults, children, or employees in certain professions. It is generally the role of the state governments to determine which vaccines will be required of their citizens. I will focus on a survey of the state laws that make vaccinations compulsory, specifically in the State of New Jersey. An exception to the state control of compulsory vaccination is the case of United States military personnel. Recommendations still come from the federal government but requirements for vaccination come from the Department of Defense.⁴ This has resulted in a great deal of controversy, particularly in the case of the anthrax vaccine program. I will not cover this topic, as it alone has generated numerous government documents.

FEDERAL GOVERNMENT: SAFETY AND "MORE"

Current Issues of Vaccine Safety

The safety of vaccines is of great concern because vaccines are usually given to healthy people to prevent illness over a long period of time, ideally a lifetime. This is not the case with other classes of drugs and this has implications for the testing and clinical trials of new vaccines. They need to be tested on people who are well and it may be difficult to get people to participate in studies. Also, for financial and practical reasons, it is not feasible to test them for any great length of time before they become available on the market. This has implications for the efficacy and safety of vaccines. Long term side effects for the vulnerable population of children cannot always be determined before marketing.

There have been many concerns about vaccine safety over the years, times when risk from the vaccine outweighs its benefit. Occasionally, it results in a vaccine being taken from the market. This was the case with the oral polio vaccine (OPV)⁵, a potent live-virus vaccine, that carried a risk of actually causing polio. By the mid-1990s, about 10 of the 4 million American children who were given the polio vaccine each year came down with the disease. Parents objected to this risk, and now a polio shot (IPV) that eliminates that threat is used instead.

In the case of the pertussis vaccine⁶, unforeseen complications from the vaccine came to light after it was introduced to the general public. In 1996, the National Vaccine Information Center (NVIC) called for the United States Food and Drug Administration (FDA) to remove the older pertussis vaccine formulations from the market when the new acellular vaccine had been approved. The older formulations had been associated with some severe reactions. In the late 1970's, one FDA funded study conducted at the University of California at Los Angeles discovered that one in 875 DPT shots is followed by a convulsion or collapse/shock. A large British study in 1981 found that one in 110,000 diphtheria/pertussis/tetanus (DPT) shots results in a brain inflammation and one in 310,000 DPT shots causes permanent brain damage. An Institute of Medicine review in 1994 concluded that the British study's finding that the DPT vaccine can cause permanent brain damage was scientifically valid.⁷ The new virus was substituted for the older vaccine.⁸

A vaccine for rotavirus--the most common cause of severe childhood diarrhea--was added to the immunization schedule of children in 1998, then withdrawn from the market in 1999 after it was found, in some cases, to cause intussusception, a type of bowel obstruction. The vast majority of children in the United States do not stand at risk of serious complication from this disease, in any case.⁹

Oversight of vaccines is the responsibility of the Government Reform Committee and the Committee has focused on the issue of potential problems with a vaccine preservative called thimerosal.¹⁰ This mercury-based preservative has been in multi-dose vials of many vaccines since the 1930s when the number of vaccines administered to infants was small. With the increase in the number of vaccines, there is currently much concern about what this mercury may have done to a generation of children,^{11,12} some who received levels of mercury exceeding standards set by the Environmental Protection Agency.¹³

Indiana Representative Dan Burton has repeatedly called for Government investigations into the safety of vaccines containing thimerosal and for the FDA to remove these vaccines from the market.¹⁴ As chairman of the Government Reform Committee, he has been in a position to confront the FDA on this issue, believing that these vaccines are not safe and may have caused the autism of his grandson and many other children as well.¹⁵

Current issues of vaccine safety also have revolved around anthrax and smallpox and the potential need for a bio-defense. The safety and efficacy of the anthrax vaccine adsorbed (AVA), which is used to vaccinate United States Armed Forces against inhalational anthrax has been a source of study.¹⁶ The Government Reform Committee has also examined this issue repeatedly over recent years, in the oversight of the Defense Department's Anthrax Vaccine Program. With biological weapons such as anthrax and small pox being in the news there is a high level of concern about these agents. Full Committee Hearings in the past few years include the topics of Anthrax safety.^{17,18,19}

There are obviously many issues associated with the vaccination of children and adults that must be monitored. Which vaccines become public health policy? How can we be sure that they are safe? Who is responsible for making these decisions for the public good and who is responsible when things go wrong with a vaccine? All of these questions begin with the federal government. The federal government has been involved with vaccination issues since the early 19th century, working to determine the appropriate role for themselves and for the various agencies of the executive branch. When all else fails, the judicial system has been called upon to interpret the laws that have been enacted.

United States Legislative Branch

The history of legislation concerning vaccines began at the Federal level of the United States government early in the 19th century, with the enactment of the Vaccine Act of 1813.²⁰ This act authorized the President to appoint a federal agent to "preserve the genuine vaccine matter and furnish it to any citizen of the United States, whenever it may be applied for, through the medium of the post office." In other words, the agent was to provide citizens with free smallpox vaccine. The law does not explicitly discuss the question of ensuring purity but it does state that it is referring to the "genuine vaccine matter", implying purity and efficacy.

This law was subsequently reconsidered when a contaminated vaccine caused smallpox in a North Carolina community.²¹ A letter from the appointed federal agent, Dr. James Smith to the Speaker of the House of Representatives explains how Smith accidentally mailed live smallpox to a physician in Tarboro, North Carolina; about ten deaths resulted.²² A Select Committee determined that a federal agent had accidentally provided a contaminated vaccine²³ and the law should stand as is.²⁴ Following debate²⁵ and the appointment of a new Select Committee, it was decided that the regulation of vaccine should be the realm of local authorities²⁶ and the Vaccine Act of 1813 was repealed.²⁷ Rather than work to ensure the safety of the vaccine matter, the federal government decided that the question of vaccines should be the responsibility of local authorities. Part of the local control allowing for compulsory vaccination laws remained with the states hereafter.

The Import Drug Act of 1848²⁸ was the first Federal statute to insure the quality of drugs. It provided for the inspection of imported drugs and the detention, destruction, or return of drugs that did not meet standards. It was passed when quinine, used by American troops in Mexico to treat malaria, was found to be contaminated.²⁹

In the Biologics Control Act of 1902,³⁰ biologics were defined to include "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives, applicable to the prevention, treatment, or cure of diseases or injuries to man." The bill introduced to Congress provided for federal regulation of substances of animal origin.^{31,32} Also known as the Virus Act, it provided for the licensing and regulation of interstate sale of serums or vaccines, used to prevent or treat diseases in humans. It was passed when a diphtheria epidemic in the St. Louis, Missouri area resulted in the death of ten children.^{33,34,35} A tetanus-infected diphtheria antitoxin was found to be the cause and Federal legislation was recommended that would require licensing and inspection of biological laboratories producing vaccines. President Theodore Roosevelt signed this act into

law on July 1, 1902. This was the first act that addressed the safety or purity of any class of drugs and it would be four years before other classes of drugs would be addressed by legislation.

Dr. Harvey Wiley, Chief of the United States Department of Agriculture Division of Chemistry from 1883 till 1912, work tirelessly for pure food and drugs. In 1906, the Pure Food and Drugs Act³⁶ (Wiley Act) was passed, setting forth regulations for drug products manufactured in the United States. One year later, Dr. Wiley, as part of the Bureau of Chemistry began administering the Food and Drugs Act of 1906.³⁷ The definition of "drug" in this act included substances that would be used for the prevention of disease such as vaccines but it did not address how it was to work with the Biologics Control Act of 1902.

The Food, Drug, and Cosmetic Act of 1938³⁸ was the next significant legislation pertaining to the safety of vaccines. It also defined drug with prevention in mind and provided the basic foundation for the drug regulations to follow. It is interesting that this act did not require that traditional drugs be proven effective before marketing - unlike the earlier biologics legislation. Vaccines were by definition considered to be drug under this act and this was the beginning of a dual control of vaccines. This act applied to vaccines where necessary to protect the public, but "nothing in this act shall be construed as in any way affecting, modifying, repealing, or superceding the provisions of the Virus, Serum, and Toxin Act of July 1, 1902."³⁹

In 1944, the Virus Act was revised and became part of the larger Public Health Service Act (PHS Act). The portion of the Public Health Service Act was called the Virus, Serum, and Antitoxin Act (Biologics Act).⁴⁰ Its provisions affected biologics in that it gave the National Institute of Health (NIH) the authority to develop new biologics when these products were not available from establishments licensed under the Virus Act.⁴¹ This served to modify the role of the NIH to include commercial interests - it became aligned with industry that it was chartered to regulate. This situation was not corrected until the regulatory function was transferred to the Food and Drug Administration in 1972. This act also maintained the "difference" of biological products by stating as the Food, Drug, and Cosmetics Act of 1938 did, " nothing in *this* act shall be construed as in any way affecting, modifying, repealing, or superceding the provisions of the Food, Drug, and Cosmetics Act of 1938."⁴²

As a result of the NIH regulating *and* developing vaccines ineffective biologics were suspected to be on the market and The Food, Drug and Cosmetics Act was amended in 1962. The Kefauver-Harris Amendments required for the first time that drugs be proved safe *and* effective. Substantial evidence was required in the form of investigations by experts.⁴³

In the following years there were several laws passed regarding immunization but they were not directly dealing with the issue of regulating safety. In 1976, Congress passed the

National Swine Flu Immunization Program.⁴⁴ This program was an example of the Federal Government's sponsorship of a program of mass immunization against a swine flu epidemic that never materialized. An adverse effect of the vaccine was a form of paralysis known as Gullain-Barre Syndrome. For the first time a federal system was created to pay claims brought by those injured by vaccine inoculation. In this case, claims for injury due to the swine flu vaccine could only be brought against the United States. The government could then take action against a vaccine manufacturer if the manufacturer's negligence resulted in the injury.

The topic of vaccine safety became even more prominent during the mid 1970's with increases in lawsuits filed on behalf of those injured by the diphtheria, pertussis, tetanus (DPT) vaccine. In order to reduce liability and respond to public health concerns, Congress passed the National Childhood Vaccine Injury Act (NCVIA) in 1986.⁴⁵ This act had many important consequences. As a result of the NCVIA, the National Vaccine Program Office (NVPO) was established within the Department of Health and Human Services (DHHS). The responsibility of NVPO is to coordinate immunization-related activities between all DHHS agencies including the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA). A list of the office's publications can be found on their web site.⁴⁶

The NCVIA also requires that all health care providers who administer vaccines containing diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, Haemophilus influenzae and varicella must provide a Vaccine Information Statement (VIS) to the vaccine recipient, his parent or legal guardian prior to each dose.⁴⁷ Each VIS contains a brief description of the disease as well as the risks and benefits of the vaccine. VISs are developed by the CDC and distributed to state and local health departments as well as individual providers.

The NCVIA also mandates that all healthcare providers must report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)⁴⁸ and this reporting becomes part of a permanent record in the patient's file. VAERS was established by the FDA and the CDC in 1990. The system provides an early warning for safety problems relating to new vaccines. Guidelines for what is considered to be an adverse effect can be found in the vaccine injury table⁴⁹ or manufacturers contraindications. Manufactures are required to report to VAERS all adverse events made known to them as well.⁵⁰

Under the NCVIA, the National Vaccine Injury Compensation Program (NVICP) was also created. The NVICP went into effect in October 1988 and is a Federal "no-fault" system designed to compensate individuals, or families of individuals, who have been injured by childhood vaccines, whether administered in the private or public sector.

The systems set in place with this act has been revisited several times in the years since its enactment.⁵¹ There have been questions by the Federal Judicial Center about the use of expert testimony and specialized decision-makers in the National Vaccine Injury Compensation Program.⁵² The time that it takes to settle claims has also been questioned.⁵³ A Government Reform Committee hearing in 2000 questioned whether reforms might be needed⁵⁴ and another inquired if the program is working as it was intended.⁵⁵

The next significant legislation in food and drug safety was the Food and Drug Administration Modernization Act of 1997.^{56,57,58,59} It improved the Food and Drug Administration regulatory systems for the first time in 35 years, amending the Food, Drug, and Cosmetics Act and the Public Health Service Act. The portions dealing with the modernization of the regulation of biological products affected Section 351 of the Public Health Service Act. Section 118 allows for abbreviated study report for drugs and biologics and Section 123(f) focuses on minimizing the differences between FDA regulation of drugs and biologics.⁶⁰ The section with implications for vaccine safety is Section 413; it that provided for the Food and Drug Administration to study the use of mercury compounds in drugs and food. The subsequent "study" did not result in the removal of mercury from vaccines, as the FDA found no evidence of a problem - no studies had ever been done.

A legislative role is also present in the form of Government Reform and Oversight Committee. The Government Reform Committee in the capacity of oversight of vaccines has had several hearings recently concerning safety issues with vaccines. One of the hearings focused on finding a balance between public safety and personal choice with regard to vaccination.⁶¹ Another was on the topic of conflict of interest and vaccine development.⁶²

United States Executive Branch

There are many Federal Agencies involved in immunization policy and safety and they fall under the United States Department of Health and Human Services.⁶³ Several organizations participate in the process of assuring the safety of the vaccines children and adults receive. These include the Public Health Service's National Institutes of Health, the Food and Drug Administration, and the Center for Disease Control and Prevention. The National Academy of Science, and specifically the Institutes of Medicine, is not a government agency but they are commissioned by Congress to advise Congress on matters of science. They have played a significant role in advising government agencies on the safety of vaccines and therefore are included in this section. Each group plays a role in ensuring vaccine safety and making recommendations to the Federal and State governments as to appropriate vaccine schedules.

-National Institutes of Health (NIH)

The NIH, comprised of 27 separate components, is one of eight health agencies of the Public Health Services which, in turn, is part of the U.S. Department of Health and Human Services. Its mission is to uncover new knowledge that will lead to better health for everyone. It does this by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helping in the training of research investigators; and fostering communication of medical information.⁶⁴

The NIH traces its roots to 1887, when a one-room laboratory was created within the Marine Hospital Service (MHS), on Staten Island, New York, predecessor agency to the U.S. Public Health Service (PHS).⁶⁵ At that time, the MHS had been charged by Congress with examining passengers arriving in New York by ship. They looked for clinical signs of infectious diseases to prevent epidemics. Joseph J. Kinyoun, MHS physician trained in the new bacteriological methods, to set up the laboratory. Kinyoun called this facility the "Hygienic Laboratory" and its purpose was to serve the public's health.

In 1891, the Hygienic Laboratory was moved to Washington, D.C. and in 1901, the laboratory was belatedly recognized in law when Congress authorized \$35,000 for construction of a new building in which the laboratory could investigate "infectious and contagious diseases and matters pertaining to the public health." The founding legislation for the NIH, therefore, resides in a routine supplemental appropriations act. If Congress did not find the NIH to be of use, it could eliminate their funding.

In 1902, the MHS was reorganized and renamed the Public Health and Marine Hospital Service (PH-MHS). In the same year The Biologics Control Act of 1902 had major consequences for the Hygienic Laboratory. It charged the laboratory with regulating the production of vaccines and antitoxins, thus making it a regulatory agency four years before passage of the better-known Pure Food and Drugs Act of 1906.

Between 1903 and 1907 standards were established and licenses issued to pharmaceutical firms for making smallpox and rabies vaccines, diphtheria and tetanus antitoxins, various other antibacterial antisera. The research required to set standards led investigators into new fields, such as immunology, in order to understand the sudden deaths that sometimes followed repeated injections of biologics. The NIH routinely published lists of products and establishments that it licensed under section 351 of the Public Health Service Act.⁶⁶

In 1912 another Public Service reorganization act shortened the name of the PH-MHS to Public Health Service (PHS). In 1930, the Ransdell Act changed the name of the Hygienic Laboratory to National Institute (singular) of Health (NIH) and authorized the establishment of fellowships for "use in ascertaining the cause, prevention, and cure of diseases affecting human beings".⁶⁷ In 1937, the Division of Biologics Control was established within the NIH.

The function of the National Institute of Health began as regulatory and evolved into both regulatory and developmental. With the Public Health Service Act of 1944, the NIH was given the authority to develop new biologics if they were needed and private industry had not done the development. This meant that the NIH had the power to approve its own products. This was controversial and in 1972, responsibility for regulation of biologics was transferred to the Food and Drug Administration.

-Food and Drug Administration (FDA)

The Food and Drug Administration evolved from the Chemistry Bureau, which was established in 1862 when President Lincoln appointed a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture.⁶⁸

As of 1927, The Bureau of Chemistry was reorganized into two separate entities. Regulatory functions were located in the Food, Drug, and Insecticide Administration, and non-regulatory research was located in the Bureau of Chemistry and Soils.

The name of the Food, Drug, and Insecticide Administration was shortened to the Food and Drug Administration (FDA) under an agricultural appropriations act. In 1972 regulation of biologics - including serums, vaccines, and blood products - was transferred from NIH to FDA.

Laws enforced by the FDA are numerous.⁶⁹ Those relating to vaccines include the Federal Food and Drug Act of 1906 (Wiley Act)⁷⁰ the Federal Food, Drug and Cosmetics Act of 1938, portions of the Public Health Service Act of 1944, and the Food and Drug Modernization Act of 1997,⁷¹ all outlined in the section on legislation. The FDA develops its plans of action in terms of these laws⁷² and publishes documents to educate the public about the laws they enforce.^{73,74}

Biological products, such as vaccines, that are regulated by the FDA are also considered to be drugs under 39 Fed. Reg. 18,614 (1974). This means that they are subject to the Food, Drug, and Cosmetics Act although they may be licensed under the Public Health Services Act. The Public Health Services Act does not supercede the FDCA.

The 600 series of the Code of Federal Regulations⁷⁵ determines whether there are general or specific regulations applicable to a vaccine. This code is also outlined in the FDA publication,

Preamble Compilation: Biological Products.⁷⁶ In addition to these regulations, some drug regulations⁷⁷ will also apply to vaccines. This can be difficult because the Center for Biologics Evaluation and Research (CBER) had been known to selectively acknowledge and apply those regulations. They also had a history of regulating by memoranda, issued as guidances, points to consider documents, or recommended procedures.⁷⁸

-Center for Biologics Evaluation and Research (CBER)

FDA's Center for Biologics Evaluation and Research is trusted to ensure the safety⁷⁹ and effectiveness of biological products for the prevention and treatment of human diseases.⁸⁰ They received this mandate from the Public Health Service Act in 1991.⁸¹ Their activities include monitoring pre-clinical and clinical testing of new biological products. They are required to evaluate their safety and effectiveness before marketing is possible. The next phase in the process is the licensing of the biological products and manufacturing establishments, including vaccines. In order for a biological product to be approved for marketing in the U.S., an applicant must submit a Biologics License Application (BLA). The BLA must include information on animal studies and human clinical trials performed, how the biologic is manufactured, processed, and packaged, including information on the quality control methods used during its manufacture and labeling that will be used with the product. After a biological product is approved, its identity (or make up) and manufacturing process cannot change without prior FDA approval.

Once the vaccine is on the market, CBER then is responsible for compliance monitoring, lot releasing, and post-market surveillance of the biologic product.

-Center for Disease Control and Prevention (CDC)

The Center for Disease Control and Prevention began in 1946 as the Communicable Diseases Center. Its name was changed to the Center for Disease Control in 1970 and the word Prevention was added in 1992. The mission of the Center for Disease Control and Prevention is stated as "to promote health and quality of life by preventing and controlling disease, injury, and disability."⁸²

National Immunization Program (NIP) is a major component of the CDC. It provides leadership for the planning, coordination, and conduct of immunization activities nationwide. In carrying out its mission, NIP provides consultation, training, statistical, promotional, educational, epidemiological, and technical services to assist health departments in planning, developing, and implementing immunization programs. It also helps in the establishment of vaccine supply contracts for vaccine distribution to state and local immunization programs.

The NIP assists health departments in developing vaccine information systems to help identify children who need vaccinations. They help parents and providers ensure that all children are immunized at the appropriate age and assess vaccination levels in state and local areas. In the area of vaccine safety, they monitor the safety and efficacy of vaccines by linking vaccine administration information with adverse event reporting and disease outbreak patterns.

A subgroup of the NIP is the Advisory Committee on Immunization Practices (ACIP). This committee is the link between the federal government and state governments with respect to vaccination policy. It works with the American Academy of Pediatrics (AAP) and the American Association of Family Practitioners (AAFP) to provide one written schedule of recommended childhood and adult immunizations. This serves to reduce the amount of confusion of those implementing policy. ACIP is the only entity in the federal government that makes such recommendations.

The authority for the ACIP comes from the Public Health Service Act,⁸³ as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act,⁸⁴ which sets forth standards for the formation and use of advisory committees. The Advisory Committee on Immunization Practices has been given a statutory role under Section 13631 of the Omnibus Budget Reconciliation Act of 1993.⁸⁵

Another part of the CDC deals with vaccination is the National Vaccine Program Office (NVPO), created by Congress with Public Law No. 99-660. The NVPO is designated to provide leadership and coordination among Federal agencies, as they work together to carry out the goals of the National Vaccine Plan. The National Vaccine Plan provides a framework, including goals, objectives, and strategies, for pursuing the prevention of infectious diseases through immunizations.

The National Vaccine Program is a collaborative effort that brings together all of the groups that have key roles in immunizations. Such groups are Federal agencies, the public, States, municipalities, health care providers, and private-sector entities such as vaccine manufacturers. Through the National Vaccine Program, these groups undertake their individual activities in a coordinated manner.

-National Academy of Science (NAS): Non-Governmental but Important

The National Academy of Sciences was established in 1863 at the height of the Civil War during the 37th Congress, 3rd Session. The Speaker of the House of Representatives was Galusha A. Grow and the President of the Senate pro tempore was Solomon Foote. Its cited purpose, as mandated in its Act of Incorporation,⁸⁶ was to "investigate, examine, and report on any subject of science or art" whenever called upon by any department of the Government.

The efforts of Massachusetts Senator Henry Wilson resulted in a bill to the Senate on February 20, 1863 where it was passed on March 3, 1863. It was passed by the House of Representatives later that day, and was signed into law by President Abraham Lincoln before the day was over. The National Academy of Sciences had officially come into being.

A minor amendment to the Act of Incorporation took place on July 14, 1870. The amendment removed the limitation of the number of ordinary members of the Academy as provided in the original act.⁸⁷ Further amendments to the Act of Incorporation allowed the Academy of Sciences to "receive and hold trust funds for the promotion of science, and for other purposes." There was also a provision to reserve the right to alter, amend, or repeal the act.^{88,89}

Scientific issues would become even more controversial and complex in the years following the war. To keep pace with the growing importance of science and technology, the institution expanded to include the National Research Council in 1916, the National Academy of Engineering in 1964, and the Institute of Medicine in 1970. Collectively, these organizations are called the National Academies.

The National Academies of Science and its associated organizations (such as the Institute of Medicine) are private, non-governmental, organizations and do not receive direct federal appropriations for their work. Studies undertaken for the government by the Academy are generally funded out of appropriations made available to federal agencies. Most of the studies carried out by the Academy complex are at the request of government agencies.

In 1991 and 1994, two committees were convened by the Institute of Medicine (IOM) to assess the causal relationship between vaccines and adverse health consequences.⁹⁰ These committees concluded that the evidence was inadequate to accept or reject a causal relation between a specific vaccine and a putative adverse effect approximately two-thirds of the time.⁹¹

Controversies about the safety of vaccines, particularly mandatory childhood vaccines, continue to concern some members of the public, health care professionals, the public health community, the media, Congress, vaccine manufacturers, and federal agencies. In response to these concerns, the Centers for Disease Control and Prevention and the National Institutes of

Health have asked the IOM to establish an independent expert committee to review hypotheses about existing and emerging immunization safety concerns.

The most recent reports of the committee dealt with the issues of vaccines, the Measles, Mumps and Rubella (MMR), contributing to the rise in the incidence in autism,⁹² the thimerosal containing vaccines and neurological problems in children that had them⁹³ and the safety and efficacy of the Anthrax vaccine.^{94,95}

Other vaccine safety issues have been addressed in reports over the years^{96,97} and the Institute has also issued reports on the topics of vaccine supply and innovation^{98,99} new vaccine development,¹⁰⁰ Food and Drug Administration Advisory Committees,¹⁰¹ and overcoming barriers to immunization.^{102,103}

The United States Supreme Court

The judicial branch of the Federal government has been instrumental in ensuring vaccine safety and efficacy by hearing cases that serve to clarify the laws that have been passed. For example, in 1911, the Supreme Court ruled that the 1906 Food and Drugs Act did not prohibit false therapeutic claims but only false and misleading statements about the ingredients or identity of a drug.¹⁰⁴ In one of the first challenges to drug regulation under the 1906 Act, "Johnson's Mild Combination Treatment for Cancer," was accused of being a worthless product that bore false therapeutic claims on its label. When the case came to trial, the judge determined that claims made for effectiveness were not within the scope of the Pure Food and Drugs Act, and ruled against the government. As a result of this decision Congress passed the Sherley Amendment,¹⁰⁵ written by Parke, Davis & Co. pharmaceutical lobbyists, in 1912. This amendment prohibits labeling medicines with false therapeutic claims intended to defraud the purchaser, a standard difficult to prove.

The volume of cases claiming damages from vaccines, increased as the number of vaccines increased. In *Reyes v. Wyeth Laboratories, Inc.*,¹⁰⁶ the Supreme Court noted that "Pharmaceutical companies, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician who acts as a 'learned intermediary' between manufacturer and consumer."

A major decision in the area of product liability occurred in 1988. Due to the unique regulatory scheme that governed biologics, the Supreme Court held that the federal government could be held liable for negligence in licensing and releasing a particular lot of a polio vaccine. The products liability laws associated with biologics were tested in *Berkovitz v. United States*¹⁰⁷. *Berkovitz* deals with the standards for holding the federal government liable under the Federal Torte Claims Act. The case arose from claims that the government had not properly certified a batch of polio vaccine, leading to a case of paralytic polio. The Court discusses the standards for the operation of agencies and how they impact the liability of the public health agency. In this case, the FDA was responsible for following its own regulations with regard to vaccine safety.

STATE GOVERNMENT: COMPULSORY VACCINATION

Introduction to Compulsory Vaccination

The question of which vaccines become public health policy began at the federal level of the government but is now a matter of state control. The states are the in control of who is required to have vaccines and when you can challenge the laws compelling vaccination.

The first country known to legislate vaccinations was Bavaria in 1807. In the United States, there was no Federal law making vaccination compulsory but there were states that made their own laws. The first state to have a compulsory vaccination law was Massachusetts in 1809.¹⁰⁸ It was a law making the smallpox vaccine compulsory. A school law followed in 1855; children were required to be vaccinated against smallpox as a condition of school attendance.

As previously stated, the United States agencies responsible for the regulation of vaccines are many. They serve a dual function - not only assuring vaccines are safe but investigating the risk - benefit question of vaccination. Once this assessment has been done recommendations are forth coming. Agencies such as the Food and Drug Administration, the Public Health Service, the National Institutes of Health and the National Academy of Science have a certain amount of input to the process.

The Center for Disease Control and Prevention provides the link between these federal agencies and laws that make vaccination compulsory - the state laws. Within the CDC is the Advisory Committee on Vaccination Policy. As previously stated this committee is responsible for determining which vaccine will be recommended as part of the childhood immunization schedule and policy concerning adult vaccination as well.

State Laws

Enacting and enforcing immunization laws and regulations are the responsibility of state governments. The CDC supports states' decisions to require certain immunizations as recommended on the Childhood Immunization Schedule for children entering school and childcare facilities. Almost all State immunization mandates pertain to entrance into school and childcare facilities. These laws are often called "school" laws. Many states also have college immunization requirements as well, or requirements for certain employees.

States have varying approaches to exemptions for immunization requirements. All states allow medical exemptions for immunization. Forty-eight states permit exemptions for religious reasons and fifteen states permit parents to claim exemptions on philosophical grounds. Implementation of religious and philosophical exemptions also varies among states. In some

states, immunization program staff review written applications for exemption before granting or denying religious or philosophical exemptions. In other states, parents can obtain exemptions by simply signing a form, which is accepted without review.¹⁰⁹

State public health laws and regulations are enacted pursuant to the provisions of individual State constitutions. CDC guidelines are voluntary rather than regulatory. CDC works with States who are ultimately responsible for the development and enforcement of school laws.

The Supreme Court Upholds the States Rights

The Supreme Court has upheld the rights of the states to make their own laws about which vaccines will be required of their citizens and when they will be required.

In 1904, the case of *Jacobson v. Massachusetts* came before the court.¹¹⁰ At that time compulsory vaccination existed in eleven States with thirteen States providing for the exclusion of unvaccinated children from the public schools. Mr. Jacobson believed that the scientific basis for vaccination was unsound and that he would suffer if he were vaccinated. The Massachusetts Supreme Court found the statute consistent with the Massachusetts State constitution, and Jacobson appealed to the United States Supreme Court. The Supreme Court examined the issue of whether involuntary vaccination violated Jacobson's "inherent right of every freeman to care for his own body and health in such way as seems to him best . . .".

The Court ruled that it is within the police power of a state to enact a compulsory vaccination law. It is for the legislature, and not for the courts, to determine whether vaccination is or is not the best mode for the prevention of smallpox and the protection of the public health. The Court ruled that the State could encroach upon individual privacy and even invade the individual's body when the health of the public is threatened. The Court stated that the Massachusetts vaccination statute was a "reasonable regulation" for the elimination of the public health threat of smallpox.

In *Zucht v. King* (1922),¹¹¹ the Supreme Court upheld a San Antonio law that required all school children within the city to be vaccinated for a number of diseases before matriculating at public schools. Ordinances of the City of San Antonio, Texas provide that no child or other person shall attend a public school or other place of education without having first presented a certificate of vaccination. Acting under these ordinances, public officials excluded Rosalyn Zucht from a public school because she did not have the required certificate and refused to submit to vaccination. They also caused her to be excluded from a private school.

The city of San Antonio, the Court agreed, has the authority to make vaccination laws, if the State delegates such power to municipalities. The Court in *Zucht* stated that the states and

cities have a great degree of legal discretion if the issue the proposed law seeks to resolve is "highly dangerous to the health of the community." Only "an affirmative showing that the power (of the state or city) has been exerted in an arbitrary and oppressive manner" makes a public health law unconstitutional. However, what constitutes "arbitrary and oppressive" was left undefined by the Court.

New Jersey State Laws

The New Jersey Legislature is responsible for making the laws regarding vaccination within the state. These laws become part of the New Jersey Sanitation Code. Currently New Jersey has vaccination laws that apply to children entering school and college students.

The latest legislation of New Jersey can be investigated on their Web-site: "Welcome to the New Jersey State Legislature Bills".¹¹² At this cite bills submitted for consideration from 1996 to the present can be examined. Some of the legislation on the site demonstrates the process that takes place to include a new vaccine into the requirements for the state's citizens. An example is the assembly bill A2821, sponsored by John A. Rocco and Carmine DeSopo. The bill "Requires hepatitis B immunization for admission to kindergarten or first grade and sixth grade at a public or private school". The steps to law are outlined as follows:

Mar-20-1997	Introduced And Referred To Assembly Education Committee
May-5-1997	Reported 2nd Reading
Jun-5-1997	Assembly Floor Amendments Passed (Rocco)
Jun-23-1997	Passed Assembly (74-1-2)
Jun-23-1997	Received In Senate Referred To Senate Education Committee
Dec-1-1997	Reported 2nd Reading
Dec-15-1997	Senate Floor Amendments Passed (31-2) (Ewing)
Dec-18-1997	Passed Senate (37-0)
Dec-18-1997	Received In Assembly 2nd Reading On Concurrence
Jan-12-1998	Passed Assembly (77-0-0)

-New Jersey Sanitation Code

Laws making vaccination compulsory in New Jersey are part of the state Sanitation Code. The code states the role of the Public Health Council in establishing the Sanitation Code:

"The Public Health Council shall have power, by the affirmative vote of a majority of all its members, to establish, and from time to time amend and repeal, such reasonable sanitary regulations not inconsistent with the provisions of this act or the provisions of any other law of this State as may be necessary properly to preserve and improve the

public health in this State. The regulations so established shall be called the State Sanitary Code.¹¹³

The force of the Sanitation Code and the role of the board of education are outlined in section 9:

The provisions of the State Sanitary Code shall have the force and effect of law. Such code shall be observed throughout the State and shall be enforced by each local board of health, the local police authorities and other enforcement agencies. Every person organization or board of education having control of any public or private school in this State shall insure compliance with the State Sanitary Code as it pertains to the immunization against disease of children attending or having the right to attend such school, including any provision of the code which prohibits attendance by a child who has not been immunized.¹¹⁴

The laws specifically outlining the vaccinations required of students entering school, preschool, or child-care centers are presented in detail, when vaccine should be administer and when exemptions are accepted.¹¹⁵

Students at institutions of higher education are also subject to compulsory vaccination law, specifically for measles, mumps, and rubella. Immunity must be proven or exemptions claimed as outlined in the New Jersey State Code.¹¹⁶ Beginning with the 2000-2001 school year, there is also a provision for providing four-year college students with information regarding meningitis and include with that information notice of the availability and benefits of a meningitis vaccination.¹¹⁷

New Jersey's State power to enact legislation requiring compulsory vaccination for school children, smallpox and diphtheria at that time, was upheld in *Board of Education of Mountain Lakes V. Maas* (1959).¹¹⁸

Final Impressions

Examination of government documents can provide enlightening information about how the government works and the evolution of law and policy. In this case it showed that the role of the government in determining vaccine laws and policy is by no means straightforward. The federal role is predominantly in the area of vaccine safety. The Food and Drug Administration works to ensure that vaccines are properly tested before they are used on the general public but the process can be vague because biologics are considered to be "different". The distinction between drugs and biologics began very early in drug law history. This is because vaccines were developed rather early compared to other drugs and the fear of epidemic motivated the government into legislation dealing with vaccine beginning in 1813. Problems with quality and purity soon became evident and the federal government decided to remove itself from the role of vaccine provider. The purity issue did not go away and the Federal government stepped into the picture once more in 1902 with the Biologics Control Act.

The regulation of other drugs and food purity did not occur until four years later. The Food and Drug Act of 1906 included vaccines in the definition of "drug", but no clarification was made as to what part of this act applied to vaccines, what part of the law superceded the Biologics Act, if any.

With the passage of the Food, Drugs and Cosmetics Act of 1938 and the Public Health Services Act of 1944, the dual role of these legislative acts with regard to vaccines was acknowledged. Both stated that they did not supercede the other but both did cover vaccines in some way. The role of the NIH as drug developer and regulator until 1972 is somewhat disconcerting as well. The transfer of regulatory authority to the FDA put the FDA in a position of double checking what the NIH had approved in the way of new vaccines.

The Food, Drug and Modernization Act of 1997 attempts to address some of the concerns that vaccines have been treated differently than drugs, working to close the gap in regulations between the two. It also acknowledged a concern about mercury in food and drugs, although it is unclear as to the outcome of this concern.

Documents highlight concerns with the vaccination policy of today. These concerns include the fact that vaccines are a matter of risk versus benefit. Unfortunately, the risk of the disease and the benefit of the vaccine are usually emphasized. The cost for long term testing of new vaccines is prohibitive for those developing and manufacturing vaccines and, therefore, there are risks with vaccine safety. Children are the population that assumes these risks. With the number of new vaccines coming on the market ever-increasing, it is understandable that parents are concerned. Advertisements from drug companies are telling parents that their child may die

from chickenpox when less than 40 children died last year - out of over four million cases. Before the diphtheria vaccine became available there were ten to twenty *thousand* deaths in 1923.

The House Government Reform Committee is instrumental in bringing forth topics of concern to the public and holding hearings. They have held hearings on the controversial Hepatitis B vaccine and the question of mercury in medicines but government documents may not answer many questions. Why do non-Hepatitis B exposed infants need to be inoculated against a sexually transmitted disease? Why did the FDA did not study the consequences of injecting mercury into babies? It is also unclear if the Committee hearings have an impact in changing existing policy.

The role of the state governments in vaccine policy is in legislating what vaccines their citizens need to maintain the public health. The documents from the state were much more difficult to find, the state agencies are less prolific than the federal, so some of the steps in the process of legislating vaccination are difficult to define. The state legislators look to the CDC for vaccine recommendations, introduce legislation, pass the legislation, and laws are in place. If you do not agree with the law, and do not have a legitimate exemption, your child cannot go to school, but there are laws that say your child must go to school.

After researching this topic from the perspective of government documents, explaining the laws and responsibilities of the state and federal agencies, it is important to point out that it is only one perspective. There will be pieces of the vaccination policy picture that might be missing, such as the role that vaccine manufacturer's lobbyists have in the process, where they exert their influence in vaccine policy. Government documents are an invaluable source of information concerning vaccination law and policy but will not provide a complete understanding of the topic.

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