



# Mandatory Vaccination: Why We Still Got to Get Folks to Take Their Shots

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**MANDATORY VACCINATION: WHY WE *STILL* GOT TO GET FOLKS TO TAKE THEIR SHOTS**

**Ben Balding**

**Class of 2006**

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## **ABSTRACT**

Vaccination is widely considered one of the greatest medical achievements of modern civilization. Childhood diseases that were commonplace less than a generation ago are now increasingly rare because of vaccines. In order to be effective at eliminating communicable diseases, vaccines must be administered to sufficient levels of persons in the community. Because of this, public health officials have mandated vaccination for certain diseases as a condition to school attendance. The overwhelming effectiveness of vaccination programs may lead individuals to ignore the benefits of vaccination and focus more on the risk of side effects. Moreover, some have criticized the coercive nature of these programs. These objections may lead to an unacceptably high number of exemptions, which can compromise vaccination programs and leave the population susceptible to outbreaks.

This paper explores vaccination programs with an eye toward greater public safety without ignoring the reality of a small but committed group of vaccine critics. The paper begins with a discussion of the historical development of mandatory vaccination policies and the issues posed by exemptions. It then addresses some of these issues in the context of vaccine safety. It also seeks solution by framing the discussion in economic terms. It concludes by recommending stricter enforcement of mandatory requirements for most vaccines and greater dissemination of information on the continued importance of vaccination.

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## **INTRODUCTION**

Vaccination is widely considered one of the greatest medical achievements of modern civilization. Childhood diseases that were commonplace less than a generation ago are now increasingly rare because of vaccines. The smallpox vaccine has eradicated a disease that was responsible for centuries of outbreaks and had a 30% fatality rate.<sup>[1]</sup> Physical handicaps resulting from polio can still be observed on some of those who were

children before Jonas Salk developed a vaccine in 1955. Formerly common childhood diseases are now rarely observed. Even ear infections may soon be prevented by vaccination.<sup>[2]</sup> The widespread success of vaccinations has led one medical report to comment that “[n]ext to clean water, no single intervention has had so profound an effect on reducing mortality from childhood diseases as has the widespread introduction of vaccines.”<sup>[3]</sup>

The story of modern vaccination begins with Edward Jenner's development of the vaccine for smallpox, one of the most feared diseases in recent history. At first, vaccination was optional and not everyone chose to vaccinate.<sup>[4]</sup> In time, states would allow municipalities to mandate vaccination in time of outbreak in order to protect the public from epidemics.<sup>[5]</sup> A further step was taken when states imposed smallpox vaccination as a prerequisite for attending public schools.<sup>[6]</sup> These requirements were amended in time as new vaccines were developed.<sup>[7]</sup> At some point actual outbreaks and epidemics ceased to be the trigger for mandatory vaccination, and prevention became the overriding justification.<sup>[8]</sup> Most states today require vaccination for a multitude of childhood diseases, including measles, diphtheria, pertussis, polio, and now even chickenpox.<sup>[9]</sup>

Because of the success and the mandatory nature of vaccination, most people would probably not consider vaccination an optional method of medical treatment. For most parents, the “decision” to vaccinate is equivalent to the “decision” to feed one's child.<sup>[10]</sup> Typically, a doctor informs parents of the school vaccination schedule and the parents consent to having their child vaccinated. Since the vaccination schedule usually corresponds to the scheduled doctor visits for infants, full compliance with mandatory vaccination schedules is typically not a problem and can usually be substantially accomplished by age two.<sup>[11]</sup>

For some parents, however, vaccination is no routine matter.<sup>[12]</sup> From the time of Jenner's smallpox vaccine, vaccination has had its critics.<sup>[13]</sup> In the two centuries since that time, many different types of objections have been raised. Some have questioned the scientific qualifications of mass immunization.<sup>[14]</sup> Others have focused on the personal liberty interests at stake and have objected to the paternalistic nature of government imposition of what is viewed as a personal medical choice.<sup>[15]</sup> Still others have opposed vaccination for personal or religious reasons.<sup>[16]</sup>

Today, some parents raise similar objections. The idea that a potentially harmful substance is being placed directly into the bloodstream raises a red flag for some. Additionally, the decline of many diseases for which vaccination is still mandated may make some parents skeptical of the continued wisdom of subjecting a child to a vaccine, even if the vaccine is considered extremely safe. This skepticism grows when some point to the correlation between vaccinations and conditions such as SIDS and autism. Whether or not such a correlation is scientifically significant, many parents simply wonder if it is wise to vaccinate against a disease unlikely to afflict their child if any chance exists that the vaccine will cause autism, SIDS, or any other side effect.<sup>[17]</sup>

Since the efficacy of a particular vaccine corresponds directly with the percentage of a given population that has been vaccinated, proponents of mandatory vaccination have sought to convince those with reservations about vaccines that vaccination is the right choice. The Center for Disease Control has attempted to allay possible reservations parents may have with vaccinations by rebutting some of the commonly held fears about vaccines.<sup>[18]</sup> The CDC has pointed out, for example, that most adverse effects from vaccines are “minor and temporary, such as a sore arm or mild fever.”<sup>[19]</sup> Because vaccination often involves the introduction of a harmful live (although seriously weakened) organism into the patient, vaccination can never be 100% safe. Serious side effects usually occur only between one per thousands to one per millions of doses, while some serious reactions and death occur so rarely that accurate risk assessment is difficult.<sup>[20]</sup> The CDC has also responded to many of the other concerns raised about the need for vaccination, and the FDA continually works to ensure vaccine safety and efficacy, but many still harbor reservations toward vaccination.

This paper will endeavor to discuss some of the most common objections to vaccination programs in general while trying to shed light on the veracity and tenability of these objections. Part I will discuss the nature of mandatory vaccination programs in this country; both scientific and historical issues will play a key part in this discussion. Part II will describe the role of the FDA and other governmental bodies in the overall

vaccination picture. Part III will attempt to utilize multiple analytical tools in search of possible solutions to the dangers posed by those who may attempt to opt out of vaccination programs. It will first examine vaccination through the lens of an old television show episode. It will then adopt an economic analytical framework to discuss the balance between individual and general welfare in the context of vaccination. Part IV will conclude with some observations on how the goal of greater public health might be achieved without completely neglecting the concerns of many in the community regarding the prudence of using a medical technique that by definition relies on a degree of coercion.

# I. MANDATORY VACCINATION

## Historical Background

Jenner's smallpox vaccine led to the research and development of vaccines for other widespread and epidemic diseases. The twentieth century saw the development of vaccines for such diseases as polio, diphtheria, tetanus, pertussis, measles, and others.<sup>[21]</sup> As with the smallpox vaccine, many of these vaccines soon found their way into vaccination programs mandated by the government, albeit through a somewhat different pathway.

Mandatory smallpox vaccination programs typically arose through state police power legislation authorizing municipalities to deal with outbreaks.<sup>[22]</sup> Typically, when a local municipality decided that the threat of outbreak was sufficient to exercise this authority it would require vaccination of everyone in the community (with a possible exception for individuals who could demonstrate uncommonly high health risks from receiving the vaccine, although this exception sometimes applied only to children) and fine and/or quarantine those who refused to be vaccinated.<sup>[23]</sup> When other diseases became preventable by vaccination, outbreak ceased to be the trigger for mandatory vaccination. Rather, because of their cost-efficiency and their ability to reduce and ultimately eliminate disease, vaccination programs became an important part of general public health policy.<sup>[24]</sup>

Most of the time, vaccination programs are accomplished through the dual efforts of national entities (which tend to develop and recommend vaccines) and state legislatures and local boards of health (which usually implement these recommended vaccines through vaccination programs).<sup>[25]</sup> It is not entirely accurate to refer to this as "mandatory vaccination," as typically individual states will not criminally punish parents for not vaccinating their children or forcefully subject individuals to vaccination.<sup>[26]</sup> Instead, states typically condition school enrollment on proof of vaccination.<sup>[27]</sup> Though it may be a high price to pay, home schooling is usually an available means parents have if they wish to bypass these vaccination requirements. Moreover, most states grant exemptions to vaccination requirements for religious reasons and some even grant exemptions for philosophical reasons (in addition, every state exempts from school vaccination requirements individuals who cannot be vaccinated for medical reasons).<sup>[28]</sup>

The connection between school enrollment and vaccination programs may now seem obvious. Public health officials, faced with a means of protecting the general population from the harmful disease smallpox, realized that mass vaccination could lead to a sufficient level of immunity to eliminate the risk of outbreak, even for those in the community unable to vaccinate (because of medical reasons, for instance).<sup>[29]</sup> Because of the concept of herd immunity, public health officials considering the proper utilization of vaccines were dealing with a medical procedure quite out of the ordinary. Since vaccination itself does not typically provide 100% immunity to a disease, vaccinated individuals can still contract the disease.<sup>[30]</sup> Yet because of herd immunity, if a sufficient level of vaccination within a population is attained, the entire population will no longer be susceptible to the disease. In this way, vaccination came to be viewed not only as a personal

medical choice but also as a step taken to improve the overall health of the population.

With the rise of public schooling in the mid- to late-nineteenth century, cities decided to condition public school attendance on smallpox vaccination.<sup>[31]</sup> By the latter part of the century, many states had adopted this practice.<sup>[32]</sup> Such a policy makes sense when one considers the increased risk of infectious disease in public areas like cities in general and schools in particular. By mandating vaccination for school attendance, of course, the state would eventually have ensured the vaccination of the entire population by the time the initially vaccinated generation became the oldest living one.

These vaccination schemes have faced challenges, both legal and social, throughout their existence.<sup>[33]</sup> The reasons for such challenges have ranged from personal liberty interests to doubts about the efficacy of vaccines.<sup>[34]</sup> State courts in the nineteenth century typically upheld both the enactment of mandatory vaccination programs and the delegation of power to local authorities.<sup>[35]</sup> More importantly for the future of mandatory vaccination policy, two important Supreme Court decisions in the early part of the twentieth century affirmed the power of state governments both to mandate vaccination and to delegate a broad degree of authority to local municipalities and health boards to carry out particular vaccination programs.

## Judicial Approval

In 1905 the Court held in *Jacobson v. Massachusetts* <sup>[36]</sup> that the general police power of states is broad enough to overcome a Due Process claim brought by an individual who claimed his personal liberty interests were unconstitutionally invaded by the mandatory smallpox vaccination program in question.<sup>[37]</sup> In an opinion by Justice Harlan, the Court ruled that the constitutional guarantee of liberty “does not import an absolute right in each person, to be, at all times and in all circumstances wholly free from restraint.”<sup>[38]</sup>

This case still represents the initial constitutional basis of most mandatory vaccination legislation. Many states still provide for the governor or a public health official to mandate vaccination for all in the event of an outbreak.<sup>[39]</sup> Individuals who cannot vaccinate for health reasons or who refuse to vaccinate may be quarantined in order to protect the population in some states.<sup>[40]</sup> These laws gained greater relevance following the terrorist attacks of 9/11 and the increased public concerns regarding bioterrorism. For the most part, however, mandatory vaccination laws in the name of outbreak control have given way to vaccination requirements as a prerequisite for school attendance.

The issue of school vaccination came before the Court nearly two decades after *Jacobson* . In *Zucht v. King* <sup>[41]</sup> , the plaintiff challenged a general grant of authority from Texas to local boards of health to condition school entry on proof of vaccination.<sup>[42]</sup> To differentiate the case from *Jacobson* , the plaintiff noted that the San Antonio ordinances mandated vaccination even in the absence of evidence of outbreak.<sup>[43]</sup> The Court, speaking this time through Justice Brandeis, upheld the validity of the ordinances as well as the broad grant of authority to local health boards.<sup>[44]</sup> On the issue of the state's power to mandate vaccination, he merely cited *Jacobson* : “[l]ong before this suit was instituted, *Jacobson v. Massachusetts*...had settled that it is within the police power of a state to provide for compulsory vaccination.”<sup>[45]</sup> As for entrusting a broad degree of authority on local health officials, he noted that *Jacobson* and other cases had affirmed that a state may “delegate to a municipality authority to determine under what conditions health regulations shall become operative.”<sup>[46]</sup> This delegation includes the permission to vest municipal officials with “broad discretion in matters affecting the application and enforcement of a health law.”<sup>[47]</sup> In summary, the Court found that these ordinances were valid assignments of “that broad discretion required for the protection of the public health.”<sup>[48]</sup> The language of the opinion emphasizes the importance of the public health as the key justification for mandatory vaccination.

*Zucht* , along with *Jacobson* , thus became the legal foundation for the mandatory vaccination laws of the twentieth century. Modern school vaccination laws and policies have grown from early mandatory smallpox vaccination laws:

The early successes of school vaccination laws against most political, legal, and social challenges helped lay the foundation for modern immunization statutes. Since the introduction of smallpox vaccination policies in the mid-to-late 1800s, states have amended them to include additional diseases as new vaccines become available.[\[49\]](#)

Though various amendments and additions have been made to mandatory vaccination laws throughout their history, the past half century has experienced the true culmination of mandatory vaccination policy. Public health officials have been able to institute a scheme for near-universal vaccination:

Many existing school vaccination laws were enacted in response to the transmission of measles in schools in the 1960s and 1970s. State legislatures at that time were influenced by the significantly lower incidence rates of measles among school children in states that strictly enforced vaccination requirements and school exclusions in outbreak situations without significant community opposition. Rather than having health departments require immunization in emergency conditions, legislatures acted to prevent disease by mandatory immunization as a condition of enrollment or attendance in schools or licensed day care facilities.[\[50\]](#)

Moreover, states have not been completely left to implement the recommended immunization schedule.[\[51\]](#) Though school requirements are still a state matter, national public health officials are typically able to enact their recommendations through federally funded immunization plans.[\[52\]](#) These plans require states to implement and enforce federally recommended immunization requirements before the states can receive federal funds.[\[53\]](#) The current recommended vaccination schedule appears below.

## Recommended Childhood and Adolescent Immunization Schedule[\[54\]](#)

Vaccine	Common Name or Symbol	Number of Doses	Age(s)
Hepatitis B	HepB	3	Birth, 1-2 months, after 24 weeks
Diphtheria and tetanus toxoids and acellular pertussis	DTaP	5+	2 months, 4 months, 6 months, 15-18 months, 4-6 years, Td booster at age 12 and every 10 years thereafter
<i>Haemophilus influenzae</i> type b conjugate	Hib	3	2 months, 4 months, 12-15 months
Inactivated Poliovirus	IPV	4	2 months, 4 months, 6-18 months, 4-6 years
Measles, mumps, and rubella	MMR	2	Two shots at least four weeks apart beginning at age 12

			months
Varicella	Chickenpox	1	Any time after age 12 months if the child has not had chickenpox
Meningococcal	MCV4	1	11-12 years
Pneumococcal	PCV	4	2 months, 4 months, 6 months, 12 months
Influenza	Influenza	Annual	6 months and annually thereafter for children with certain risk factors
Hepatitis A	HepA	2	First dose at 12 months, second dose at least 6 months thereafter

## Challenges and Concessions

While school vaccination requirements have been credited with bringing about the control and elimination of many devastating childhood diseases, critics have continued to voice concerns and raise legal and political challenges to the entire process of mandatory vaccination.

### Personal Liberty Concerns

One key argument against mandatory school vaccination has always focused on government intrusion into what is considered a personal medical choice.<sup>[55]</sup> Just as the government cannot force a person to have surgery to repair a torn ligament, for example, the government should not be able to force parents to vaccinate their children if the parents believe that vaccination is not the best medical decision. One prominent critic of mandatory vaccination has stated her organization's goal as simply providing parents with choices: "[w]e believe that health care consumers should have the right to choose the type of preventive health care that they want to use – including choosing whether to use one, ten, or no vaccines."<sup>[56]</sup> Other objections along similar bases argue that mandatory vaccination violates the medical ethic of informed consent or even that school district control over mandatory vaccination policies amounts to the unlawful practice of medicine without a license.<sup>[57]</sup>

The typical counterargument given by the public health officials is to point out that one's decision to vaccinate, unlike one's decision whether to undergo surgery, affects the health of others in the community.<sup>[58]</sup> To allow parents the right to choose not to vaccinate is to infringe on the ability of other parents to raise their children in a society free of certain deadly diseases. From a legal standpoint, *Jacobson* still seems to have settled the issue that at least under some circumstances, the government may force an individual to receive a vaccination.

Although public health officials have the legal authority to mandate vaccination for the public health under Jacobson, they should be very mindful of the personal liberty concerns just stated. Those with such views often cling to them vigorously.<sup>[59]</sup> As certain vaccine-preventable diseases decline, such concerns become even stronger. For this reason, it is important for public health officials to support their mandatory vaccination programs with justifiable arguments rather than simply citing legal precedent or historical tradition in support of their exercise of power. Fortunately for public health officials, the benefits provided by vaccination programs can be utilized to justify the existence of such programs.

## **Safety Accountability Concerns**

A variation on the consumer choice challenge to mandatory school vaccination requirements tends to accuse the public health community of conspiring with or at least willfully acquiescing to powerful vaccine manufacturers at the expense of citizens.<sup>[60]</sup> Mandatory programs, the argument goes, eliminate any accountability from vaccine manufacturers that the free market might otherwise provide.<sup>[61]</sup> Both the safety and efficacy of vaccines fail to improve because manufacturers do not have to respond to consumer concerns.<sup>[62]</sup> Mandatory programs thus prevent better vaccines. A prominent critic of these programs has stated that if mandatory vaccination programs are ended, “we will have the ability to put economic pressure on the drug companies and on the health agencies to do a better job with vaccine safety and efficacy.”<sup>[63]</sup>

The strength of this argument lies in its apparent lack of hostility toward vaccines per se. Given the historical success of vaccination in eradicating smallpox and in reducing or eliminating the risk of other childhood diseases, any critique of mandatory vaccination programs that focuses on the use of vaccines generally is likely to be dismissed by those in the field of public health. By focusing on the economic drawbacks inherent in a mandatory vaccination program and how those drawbacks can negatively affect the quality of vaccines, this argument may gain more traction. Indeed, all sides of this debate claim to desire both safer and more effective vaccines.

The response to this argument, I would imagine, would be to emphasize the drawbacks of opening up the “market” in this case. Because vaccination programs depend on a sufficient percentage of the community being vaccinated, complete consumer choice carries with it problems that might be absent in a standard market. As for vaccine quality, FDA regulation is in place to ensure a sufficient level of safety and efficacy to accomplish the goals of vaccination.<sup>[64]</sup> The pressure faced by vaccine manufacturers to obtain and maintain FDA approval should provide a check sufficient to guarantee proper vaccine quality. If not, the answer should be to raise FDA standards, rather than to jettison the entire mandatory vaccination process and with it the likelihood of maintaining a sufficient level of immunity among the population.

This response might be unacceptable to those concerned. If the connection between public health officials entrusted with implementing the mandatory vaccination schedule and FDA regulators entrusted with ensuring the safety and efficacy of vaccines is seen as too close, proposing higher FDA standards as a solution may not allay concerns. The independence and integrity of FDA is therefore critical in this arena, just as it is in other areas of public health.

## **Concern of Unknown Risks**

In what may be a combination of the two challenges previously discussed, many individuals challenge vaccine programs because of a lack of information about vaccines.<sup>[65]</sup> Many people, for example, legitimately question the wisdom of forced vaccination before long-term effects of a vaccine are studied. One website that purports “to provide a wide range of news and views on vaccination and vaccination policy” has summarized this challenge to vaccines simply as opposing the idea of “a parent, any parent, being forced to do something that has even a remote chance of harming their child.”<sup>[66]</sup> Since long-term (ten or more years down the road) and low-risk (on the order of one-per-million or less, for example) side effects may truly be unknown, this concern does present a challenge for public health officials.<sup>[67]</sup>

Unfortunately, even the best studies are unable to fully determine all long-term consequences of vaccination. In addition, “[t]here is no such thing as a ‘perfect’ vaccine which protects everyone who receives it AND is entirely safe for everyone.”[\[68\]](#) Therefore, it is true that mandatory vaccination probably forces some parents to inject their children with a substance that will cause some unknown harm.

As with the other objections to mandatory vaccination, however, this objection suffers from a critical flaw. Mandatory school vaccination requirements are not justified solely on the benefit they provide to the recipient. Instead, it is the benefit they provide to the community as a whole by ensuring a sufficient level of vaccination to prevent outbreak that justifies their intrusive nature on individual medical decision-making.[\[69\]](#) For this reason, if public health officials did not enact the mandatory vaccination program, they would be forcing on parents a system that had at least a “remote chance of harming their child.”[\[70\]](#) Because the decision to enact a community-wide vaccination program must be made at the general level if it is to be made at all, and because some children will undoubtedly suffer some health consequences regardless of which policy is chosen, individuals will always be able to raise this argument against mandatory vaccination programs.

A better critique of these programs would focus on whether mandatory vaccination causes more overall harm than a voluntary system; that is, is it better when viewed at the general, rather than the individual, level? Ironically, the very success of vaccination programs in reducing the incidence of once-prominent diseases has led some to ignore the overall and continuing benefit of community vaccination (herd immunity).[\[71\]](#) But for parents to decry the “remote chance” of harm from vaccination while ignoring the very real chance of outbreak in an under-vaccinated population is to reframe the issue entirely.

## Other Concerns

Other challenges to vaccination laws have cited strongly held religious or philosophical positions against vaccination in general. Such challenges require a different type of response from public health officials; often the options are limited to overriding such objections and excluding children of parents adhering to such positions from public schools (which is constitutionally permissible under *Jacobson* and its progeny) or creating exemptions to vaccination requirements (which is detrimental to the overall goals of mandatory vaccination if a sufficient number of exemptors exist). Reactions to such religious and philosophical concerns vary from state to state, with a general trend toward greater accommodation of objectors.

## Exemptions

In response to these and other challenges to mandatory vaccination laws, states have enacted various exemptions to vaccination requirements for school entry. Actual enforcement varies by state.

### Medical

All states provide exemptions for those with medical risks associated with vaccines.[\[72\]](#) If certain contraindications indicate a likelihood of harm from a particular vaccine, the exemption will be allowed.[\[73\]](#) Because such cases are rare and exemptions relatively easy to enforce, there usually is very little risk of compromising the efficacy of the overall vaccination program by granting these exemptions.[\[74\]](#) The ability to grant medical exemptions while still maintaining sufficient levels of vaccination to provide community-wide immunity is one of the great accomplishments of the vaccination system.[\[75\]](#)

### Religious

In addition to medical exemptions, almost every state grants religious exemptions for those with sincere religious beliefs opposing vaccination.<sup>[76]</sup> Individual states tend to vary with regard to the level of religious conviction necessary to obtain a religious exemption. Such exemptions reflect the sometimes uneasy balance between mandatory vaccination programs and First Amendment Free Exercise rights, even though the Supreme Court has validated the right of states to mandate vaccination without providing for such exemptions.<sup>[77]</sup> West Virginia, for example, does not provide religious exemptions.<sup>[78]</sup>

Some religious exemption statutes have spurred challenges on Establishment Clause grounds by those who claim they favor organized or recognized religions over the sincerely held religious views of others.<sup>[79]</sup> These challenges, if successful, would lead to the invalidation of many religious exemption statutes. Rather than decrease the number of religious excluders, however, this may actually lead to more religious excluders. The political climate of our day, along with the experience of a few states already (such as Arkansas), suggests that legislatures may respond to invalidation of religious exemption statutes that require adherence to an organized religion by drafting more general and expansive religious exemption statutes.<sup>[80]</sup> By subjugating religion to compulsory vaccination, courts may actually be helping to bring about a system with even more religious excluders, thereby harming the very vaccination programs to which religious objections had been subordinated.<sup>[81]</sup>

## Philosophical

The possibility that some parents who strongly oppose vaccination for other than religious reasons has led to other means of exempting from mandatory vaccination programs. In some states, people may avoid vaccination requirements by way of philosophical exemptions.<sup>[82]</sup> In California, for example, a parent need only “submit a letter or affidavit stating that the immunization is contrary to his or her beliefs” to exempt their child from vaccination requirements.<sup>[83]</sup> “Where available, parents are taking advantage of such exemptions with growing regularity; and in states offering both exemptions, the number of philosophical exemptions far exceeds the number of religious and medical exemptions.”<sup>[84]</sup>

States without philosophical exemptions, moreover, are often lax with their enforcement of religious exemptions.<sup>[85]</sup> Because of this, parents in these states can usually submit insincere affidavits purporting to object to vaccination for religious reasons and local health officials, unconcerned with delving into the sincerity of such affidavits, will widely grant exemptions.<sup>[86]</sup> In most states, therefore, persistent parents can usually find some way to exempt their children from vaccination requirements. If all else fails and vaccination is still regarded as unacceptable to the parent, the option of home schooling may provide a final avenue of evading these school vaccination requirements.

## Dangers of Widespread Exemptions

The ease with which non-medical exemptions can typically be obtained has raised concerns among many that the benefits of widespread immunization are being compromised.<sup>[87]</sup> Because of the nature of medical exemptions, unvaccinated persons in a community with only medical exemptions would be expected to be few and dispersed. Herd immunity can be attained, and protection is ensured for both the vaccinated majority and the unvaccinated few.<sup>[88]</sup> Broadly granted philosophical and religious exemptions make herd immunity more difficult to attain and increase the risk to the community. This risk is exacerbated by the fact that many of those who apply for such exemptions “will cluster together in one geographic area.”<sup>[89]</sup> This cluster effect tends to increase the likelihood of serious outbreaks:

Recent studies have shown that clusters of excluders, who are significantly more susceptible to contracting vaccine preventable illnesses, pose an increased risk of spread of diseases not only to their unimmunized peers, but also to the surrounding, largely vaccinated population.<sup>[90]</sup>

Given that many childhood diseases seem to be in decline, exemptors may fail to realize the continued value of vaccination. As the mumps outbreak in Iowa makes clear, however, vaccination programs take time and are at risk if vaccination rates fall. Other diseases are still prevalent in other parts of the world, and outbreaks can still occur in this country due to the prevalence of international travel. Even though measles is rarely observed in the US, for example, the World Health Organization has reported that nearly 900,000 measles-related deaths occurred in developing countries in 1999.[\[91\]](#) Until diseases are eradicated globally, it may be necessary to continue vaccination.

Because many of the aforementioned risks are frequently underappreciated by those who seek exemptions, some have suggested a combination of stricter enforcement of exemption requirements and increased public knowledge of the reasons underlying childhood vaccination requirements.[\[92\]](#) Knowledge is indeed essential to the resolution of this problem. The easier it is to obtain an exemption, the less likely individuals are to understand and appreciate the importance of widespread participation to the success of a vaccination program. Greater public appreciation of the need for such participation (even for diseases that seem to be in retreat), along with greater information on the safety of vaccines can go a long way toward increasing public health in this area.[\[93\]](#)

## **Partial Exemptors – A Modern Phenomenon**

The availability of exemptions has led to other interesting developments in the vaccination debate. Recently, for example, challenges have been raised against the need for mandatory chickenpox and hepatitis B vaccines. Diseases such as these, which are either not greatly feared (chickenpox) or transmitted primarily through voluntary rather than involuntary contact (hepatitis B), do not fit neatly into the typical justification for mandatory vaccination.[\[94\]](#) Nevertheless, public health officials have decided that recently-developed vaccines for these diseases should be placed on the recommended schedule. This has given rise to a significant number of partial exemptors – those who are not opposed to vaccination requirements per se, but who oppose particular vaccines on the schedule. Such a position may not have been comprehended by those who drafted the religious and philosophical exemptions, which seem to assume that a parent's opposition is to vaccination generally, rather than to a specific vaccine.[\[95\]](#)

Because the religious exemption is usually constructed to apply to those who oppose vaccination generally because of sincere religious beliefs, would-be partial exemptors have difficulty fulfilling their optimal desires. In states without a philosophical objection, parents must choose either to accept the entirety of the recommended schedule of vaccines or to obtain a religious exemption for all vaccinations.[\[96\]](#) Parents who live in states with a philosophical exemption are much more able to tailor their objection to those vaccines with which they disagree.[\[97\]](#)

From the standpoint of a public health official, this presents two possible worlds. In the world with traditional religious exemptors but no philosophical exemptors, overall percentages of vaccinations would be relatively equal from vaccine to vaccine, and higher vaccination rates would be obtained for diseases associated with more objectionable vaccines at the expense of lower vaccination rates for diseases associated with less objectionable vaccines.[\[98\]](#) By contrast, in the world with philosophical exemptors, the public health official would observe higher vaccination rates for the less objectionable vaccines and lower vaccination rates for the more objectionable vaccines.[\[99\]](#)

The difference between these two worlds can have far-reaching implications. If parents are forced to make the all-or-nothing choice, a significant enough number could choose to forego vaccines (including some which they would otherwise accept) that herd immunity is lost, even for less objectionable vaccinations. On the other hand, a significant enough number could accept the more objectionable vaccinations to bring about herd immunity for those diseases. Though the public health official might prefer a world in which neither religious nor philosophical exemptions exist, such a world may not be possible. Therefore, the official should determine which of the two possible worlds provides a greater overall level of safety for the society. In addition, potential public reaction to a vaccine should cause the public health official to consider the

ramifications the addition of a vaccine to the schedule will have on those vaccines already on the schedule.

Because partial exemptors have the potential to sway the balance between herd immunity and vulnerability, public health officials must take account of their concerns. Unlike in years past, today the development of a new vaccine presents public health officials with a choice that can affect other vaccines on the recommended schedule. Though the possibility for a chickenpox- and Hepatitis-B-free nation may seem tempting, officials should now consider the possible consequences of mandating such "borderline" vaccines. Parents who might otherwise vaccinate according to the old schedule might have second thoughts about the new vaccines on the schedule and seek means of avoiding the new requirements. If no means exist for avoiding the new vaccines other than complete exemption on religious grounds, parents who would subsequently pursue such exemptions would bring about a lower level of immunization for older diseases.

Studies may be necessary in the above situation to determine whether herd immunity status could be in jeopardy for those diseases for which vaccines are already on the schedule. While one solution might be to provide parents with greater ability to tailor their individual vaccination desires, such a solution would undermine the efficacy of newly scheduled vaccines. In addition, greater levels of flexibility in vaccination choice would undermine public understanding of the community-based nature of vaccination. I think it might be worth sacrificing the efficacy of the newer vaccines in order to maintain that of the more established ones. The public might be willing to suffer the possibility of chickenpox outbreaks, for example, in order to prevent an even minor epidemic of diphtheria or the measles.

Again, information should play a key role in the resolution of this issue. Many of the websites urging parents to carefully consider the vaccination decision do not inform parents that their decision to vaccinate may affect the overall health of the community.<sup>[100]</sup> The CDC, for its part, does urge parents to take note of this concern.<sup>[101]</sup> The very persons who most need to know of this concern (those seeking exemptions), however, are often those most likely to distrust CDC publications. For supposed citizen-oriented websites to urge individuals to make vaccination choices without considering how such decisions affect the community is irresponsible, especially given the scientific stability of the concept of herd immunity.

## II. THE ROLE OF THE FEDERAL GOVERNMENT

Some of the problems posed to vaccination programs by exemptors and others could be partially solved through greater public awareness of the stringent safety and efficacy testing done on vaccines before they may enter the market. This section summarizes the role of FDA in the context of vaccination programs. In addition, this section will discuss other ways in which the federal government gets involved in the vaccination issue, concluding with a brief synopsis of the no-fault compensation scheme enacted pursuant to the National Childhood Vaccine Injury Act of 1986.<sup>[102]</sup>

### FDA Regulation

Though state governments determine which vaccinations are mandatory for school attendance, the federal government plays a key role in vaccination. Perhaps most importantly, the federal government regulates the safety and effectiveness of all vaccines. The FDA's Center for Biologics Evaluation and Research (CBER) is charged with this critical task.<sup>[103]</sup> The role of CBER ranges from pre-approval testing of potential vaccines to facility inspection to continued oversight and sampling after approval.<sup>[104]</sup> Regulation of vaccines can be more stringent than for other biologics or drugs.<sup>[105]</sup> Even after a vaccine is licensed, for example, FDA oversight is prevalent.<sup>[106]</sup> Since vaccines are derived from living organisms and are particularly susceptible

to contamination and other environmental factors, manufacturers usually must submit samples of each vaccine lot for testing before release.[\[107\]](#)

Before a vaccine can even be licensed for distribution and use, it must go through an extensive testing process relatively similar to that of drugs and other biologics.[\[108\]](#) First, a new vaccine must be tested for safety on animals.[\[109\]](#) The vaccine manufacturer next must file an Investigational New Drug application (IND) with the FDA.[\[110\]](#) Studies are then undertaken to ensure safety before any human testing takes place.[\[111\]](#) In addition, the IND must describe the studies intended for humans.[\[112\]](#)

Once these initial steps are completed, proposed vaccines must undergo three phases of clinical trials, in which the vaccine is tested on humans.[\[113\]](#) Phase 1 testing looks only for very serious or very common problems.[\[114\]](#) A small number of subjects (usually less than 100) are closely monitored, usually for only a few months.[\[115\]](#) Testing expands in Phase 2 to begin evaluating efficacy, as well as to further test safety.[\[116\]](#) Phase 2 trials can last up to two years and typically include hundreds of subjects.[\[117\]](#) The final stage of testing, Phase 3, further studies safety and effectiveness.[\[118\]](#) Thousands of people may be involved in this stage of testing, and if successful it can lead to application for FDA licensing.[\[119\]](#)

Once the clinical trials are completed, the FDA can examine the results of the tests to determine whether the vaccine is safe and effective enough to be placed on the market.[\[120\]](#) At any point in the process, the FDA may halt ongoing studies if safety concerns require such action.[\[121\]](#) The FDA also reviews the data from the studies and inspects the manufacturing facility.[\[122\]](#) At this point the vaccine may be licensed.

As stated above, the FDA's role in protecting the safety and effectiveness of vaccines does not end at the licensing stage.[\[123\]](#) Before any vaccines from a particular lot can be released, the manufacturer must typically submit samples for potency, safety, and purity testing.[\[124\]](#) Periodic facility inspections also continue for the duration of the license.[\[125\]](#) Furthermore, formal post-market studies may be conducted in order to identify problems that would not show up in pre-market clinical testing.[\[126\]](#) These tests are referred to as Phase 4 tests and are not mandatory, but can help identify problems that may only occur very infrequently.[\[127\]](#) Post-marketing surveillance programs are important because manufacturers are "never going to be able to do studies big enough to detect risks that might happen at a level of one in 100,000 or one in 1 million."[\[128\]](#)

The Vaccine Adverse Event Reporting System (VAERS) is another valuable tool in identifying problems with a vaccine once it has been approved for the market.[\[129\]](#) VAERS was developed following Congress's enactment of the National Childhood Vaccine Injury Act of 1986 and has become a very useful tool for identifying possible adverse effects that would otherwise escape detection.[\[130\]](#) VAERS allows anyone to report a problem that may be associated with any vaccine.[\[131\]](#)

It is important to keep in mind that VAERS is simply a reporting system. Experts and others use the data in VAERS to attempt to determine whether a vaccine actually causes a particular adverse effect, but the events that VAERS documents are not all caused by vaccines. It is therefore easy to understand why VAERS encourages doctors and others to report any adverse event that may be related to a vaccine. "VAERS is designed to detect signals or warnings that there might be a problem rather than to answer questions about what caused the adverse event."[\[132\]](#) It is important to keep these facts in mind when looking at VAERS data, as many of the adverse effects may be completely unrelated to the vaccine in question. Often the effects are correlated with, but unrelated to, vaccination simply because many of the problems reported are those usually associated with events happening during the vaccination period (the first few years of life).[\[133\]](#)

Used correctly, VAERS can lead to useful studies and the discovery of potentially rare adverse effects.[\[134\]](#) VAERS can also be used to monitor individual lots of a vaccine.[\[135\]](#) Unfortunately, by encouraging individuals to report any adverse effect that may possibly have been caused by a vaccine, VAERS can provide ammunition for those claiming a definite link between a vaccine and a particular adverse effect, even if the data is silent on whether such a link exists.[\[136\]](#) While VAERS is in place to help identify actual risks associated with vaccines, these risks cannot be accurately assessed solely on the basis of reported incidents of

adverse effects.[\[137\]](#)

The real value of VAERS lies in the testing and hypotheses that are developed in response to the data that has been reported. Because of the serious adverse effects already occurring during the typical vaccination period, it will often be easy and convenient to point to the correlation between vaccines and reported adverse events. Lost in the picture is the foundational proposition that VAERS is, at its core, a data collection system. To forego scientific inquiry and point instead to simple correlation may be convenient, but it is unwise.[\[138\]](#)

## Thimerosal

The recent public discussion surrounding the use of thimerosal as a preservative in vaccines helps to illustrate the importance of the FDA and other factors in furthering the goals of vaccine safety and public confidence in the entire safety regulatory process. Thimerosal is a mercury-containing organic compound that for many years has been used as a preservative in vaccines to help prevent contamination with microbes that could potentially be fatal.[\[139\]](#) Recently, fears that mercury at very low levels may be toxic to the brain have raised concern among many in the public about allowing the use of thimerosal in vaccines.[\[140\]](#) Many began to fear a connection between thimerosal and autism.[\[141\]](#) Standard FDA testing of lots, as well as studies measuring the amount of mercury contained in the standard immunization schedule versus accepted safe amounts, did not lead to safety concerns sufficient to pull thimerosal from the market.[\[142\]](#) Though one committee (the Immunization Safety Review Committee, commissioned by the Institute of Medicine) concluded that a theoretical link between thimerosal and autism was biologically plausible, most health experts continue to assert that there simply is no scientific evidence of a link between the two.[\[143\]](#)

During this time period FDA performed additional tests to verify or refute the supposed link between thimerosal and autism.[\[144\]](#) In 1999, FDA performed a comprehensive study and review of thimerosal use in vaccines for children. This review revealed no risk from thimerosal use, other than "local hypersensitivity reactions."[\[145\]](#) Indeed, none of the standard safety protocols in place suggested or required that FDA pull thimerosal from the market. This is not to say, however, that no risk existed. As is clear from the foregoing summary of FDA vaccine approval, not all adverse effects will be known from clinical trials.[\[146\]](#) It may take years or longer to assess some of the risks of vaccines, including the risk of thimerosal as a preservative.[\[147\]](#)

Continued public concern over the safety of thimerosal caused FDA to begin to work with vaccine manufacturers in order to reduce or eliminate thimerosal from vaccines as a precautionary measure.[\[148\]](#) About this time, the American Academy of Pediatrics and the Public Health Service urged the removal of thimerosal from vaccines.[\[149\]](#) Today, with the exception of the inactivated influenza vaccine, all recommended childhood vaccines are either thimerosal free or contain only trace amounts of the compound.[\[150\]](#) Even though the risk may not have been as great as feared by the public or even existent at all, if the new vaccines are equally effective, the elimination of thimerosal from vaccines can probably be seen as a safety improvement, albeit at the expense of the added research and development needed to create the new thimerosal-free vaccines.

Rather than quell the existing safety concerns, this action led many of those who had decried the use of thimerosal to accuse FDA of participating in a cover-up to protect vaccine manufacturers.[\[151\]](#) Government agencies, for their part, continue to claim that vaccines with thimerosal are as safe as thimerosal-free vaccines, suggesting that the added development may have been superfluous.[\[152\]](#) While this may be so, the availability and now prevalence of thimerosal-free vaccines does provide the scientific and medical community with a new means of assessing the possible autism-causing effects of thimerosal. Namely, since thimerosal is suspected to cause autism within the first few years of life (the routine vaccination calendar), those who were vaccinated in the years since thimerosal-free vaccines have comprised the overwhelming majority of vaccines (that is, those born after 2001) would be expected to experience lower incidences of autism than the groups vaccinated with thimerosal-containing vaccines.[\[153\]](#)

In spite of the potentially costly decision to encourage the development of thimerosal-free vaccines when there is no sufficient safety concern to pull thimerosal from the market, FDA and other government officials have had little success in assuaging the fears and concerns of thimerosal critics.[\[154\]](#) Scientific arguments often fail to persuade, either because they are inconclusive or because of a perceived bias favoring vaccine manufacturers.[\[155\]](#) To back up their own arguments, thimerosal critics rarely point to scientific studies.[\[156\]](#) Instead, their reasoning seems to stem more from anecdotal evidence and comparison of thimerosal (which contains ethyl-mercury) to methyl-mercury-containing fish.[\[157\]](#) Representative Dan Burton (R-Indiana), a key supporter of the fight against thimerosal, explained that his belief in the toxicity of thimerosal stemmed from a personal episode: “[m]y grandson received nine shots in one day, seven of which contained thimerosal, which is 50 percent mercury as you know, and he became autistic a short time later.”[\[158\]](#) Others point to the rise in autism rates in the past twenty years and put the onus on the medical community to prove that this rise is not due to thimerosal.[\[159\]](#)

The response of health officials has been to ask why the burden should be placed on them to disprove a link between thimerosal and autism; cell phones, ultrasound, or diet soda could just as easily be the culprit.[\[160\]](#) Indeed, the typical response to those charging vaccination with causing many of the adverse effects occurring in life's first few years is to point out that usually such accusations are based on nothing more than the temporal proximity of the vaccine and the illness. Some have suggested that the rates of autism may be on the rise not because of thimerosal, but because of generally more accurate diagnosis of the affliction.[\[161\]](#) In the past, an autistic child may have been wrongfully diagnosed with other mental disorders.[\[162\]](#) Figures showing a correlation between the rise in autism and the drop in other diagnosed mental disorders bolster such assertions, and suggest that vaccination may simply be a convenient scapegoat.[\[163\]](#)

As the thimerosal issue makes clear, vaccines often provoke strong feelings amongst various segments of the population.[\[164\]](#) Proper consideration of public reaction to its actions is a delicate aspect of FDA regulation of vaccine safety. To complicate matters further, one can easily imagine an equally vehement response and similar claims of conspiracy had the FDA not worked to reduce thimerosal from vaccines as a precautionary measure. Indeed, public confidence in the safety of vaccines is often influenced by factors outside the typical FDA calculus. Though FDA must act in the interests of the general safety regardless of public opinion, it may sometimes be necessary for FDA to consider public opinion, at least when exercising discretionary oversight. After all, the entire VAERS system is to a large extent dependant on public cooperation. Nevertheless, when the choice is between FDA popularity and doing what is right for the safety of Americans, the FDA should not allow itself to be swayed by a misinformed public.

## Vaccine Injury Compensation Program

Congressional reaction to safety concerns goes beyond the adverse reporting system VAERS. The National Childhood Vaccine Injury Act of 1986, which created VAERS, also created a no-fault compensation scheme for people injured or killed by vaccines as an alternative to the traditional tort system.[\[165\]](#) This system was intended to efficiently and rapidly compensate those who are actually injured by vaccines while maintaining an environment in which further vaccine research and safety improvement could exist. The situation giving rise to this compensation program sounds remarkably similar to the more recent concerns surrounding thimerosal:

In the early 1980's, reports of harmful side effects following the DTP (diphtheria, tetanus, pertussis) vaccine posed major liability concerns for vaccine companies and health care providers, and caused many to question the safety of the DTP vaccine. Parents began filing many more lawsuits against vaccine companies and health care providers. Vaccination rates among children began to fall and many companies that develop and produce vaccines decided to leave the marketplace, creating significant vaccine shortages and a real threat to the Nation's health.[\[166\]](#)

Funding for the no-fault compensation scheme initially came from Congressional grants of federal tax dollars totaling \$110 million per year.[\[167\]](#) Since October 1, 1988, funding has proceeded from the Vaccine Injury

Compensation Trust Fund, which is funded by a \$0.75 excise tax on all doses of vaccines covered under the program.[\[168\]](#)

One may wonder what makes vaccines worthy of an alternative dispute resolution system. Perhaps it is the result of the power of the vaccine manufacturing lobby or simply an attempt by Congress to pass some legislation in the face of strong public sentiment. Although these reasons may appear plausible, it seems more likely to me that the Act created this no-fault compensation scheme because of the mandatory nature of vaccination. For those injured by other medical devices or drugs, the traditional tort system or medical insurance seem the proper means of addressing the issue. When people are told to undertake a medical procedure they may not agree with because it helps further a public goal, however, it may make sense to have a system in place whereby they can obtain relief quickly if harmed by the procedure. Moreover, because certain vaccines may be closely associated with particular adverse effects, the efficiency of a no-fault scheme may trump the standard fact-finding processes of the legal system. The government has chosen to enact such a no-fault scheme, and err on the side of compensation.

### III. ANALYTICAL MEANS OF ADDRESSING THE ISSUE

The concerns and problems raised in the context of mandatory vaccination programs do not readily suggest a simple answer. In examining the issue, I came across two particularly useful tools for analyzing the problem. The first comes from an old episode of *The Andy Griffith Show* in which a local farmer refused to accept a vaccination from the local nurse. In addition to providing substantial entertainment to the viewer, the characters can be viewed metaphorically to represent the various parties in the mandatory vaccination debate. The episode's solution, in turn, sheds some light on the current debate.

This section will also utilize the analytical framework of economic analysis. Though not as enjoyable a topic as *The Andy Griffith Show*, economic theory helps to reshape the vaccination discussion and greatly facilitates the process of assessing the various positions.

#### **“We got to get folks to take their shots” – Sheriff Andy Taylor[\[169\]](#)**

The *Andy Griffith Show* addressed the concept of popular resistance to universal vaccination over forty years ago. In “The County Nurse,” Sheriff Andy Taylor confronted a local nurse who was trying to bring everyone up to date on their tetanus shots. Not surprisingly, at least to Andy, many of the mountain farmers had not been inoculated. The naïve nurse would soon discover the reason for the low vaccination rate.

Rafe Hollister, one of the leading farmers in Mayberry, had little use for modern medicine or doctors in general. “We don’t need any nurse, nobody gets sick up here.”[\[170\]](#) Thermometers? “I know when I got a fever, I’m hot.”[\[171\]](#) Stethoscopes? “I know my heart’s beating, I’m alive ain’t I?”[\[172\]](#) But his strongest objection was saved for vaccinations: “I ain’t never been jabbed and I ain’t fixin’ to be.”[\[173\]](#) Such were the views that the nurse was up against in her attempt to achieve 100% vaccination rates.

#### **Rafe Hollister**

Rafe Hollister’s reasons for opposing vaccination went beyond his desire to avoid getting “jabbed.” He was a farmer who lived off the land, and when he got sick he let his body fight the sickness naturally. His daddy had lived to the age of hundred and he aimed to do the same.[\[174\]](#) The concept of a vaccination was

certainly something foreign to him, as was the idea that a health official could force him to do anything. Even in the wake of the nurse's impassioned plea to accept a shot that could someday save his life, he retorted simply, "I done alright before you come around and I'm doing alright now." [175]

Although the county nurse was not acting pursuant to a mandatory vaccination program, under the circumstances her attempts to get Rafe inoculated were pretty forceful. The nurse was accompanied by the local sheriff to Rafe's farm to try to convince him to take the shot, and when he refused, the sheriff and nurse continued to attempt to make him acquiesce. When Deputy Barney Fife heard of Rafe's stubbornness, he insisted the nurse return to Rafe's farm with him to force Rafe to take the shot. After all, boasted the deputy, "Rafe Hollister's like a child and he's gotta be treated like one...I'll make him take his shot." [176] When the deputy arrived at Rafe's farm yelling that he was forcing Rafe to accept the vaccination, Rafe decided to fight the mandatory vaccination by drawing his rifle and forcing the deputy to leave the farm.

In a classic manifestation of the early spirit of the television series, Sheriff Andy Taylor finally convinced Rafe to take the shot through a little reverse psychology. Andy began by facetiously praising Rafe's refusal to take the shot as stemming from Rafe's desire for immortality. Namely, by refusing to take the shot, Rafe was sure to become the impetus for all the other townspeople not to neglect to take their shots. Unfortunately for Rafe, this heroic stature would only be achieved posthumously, as he will have succumbed to a violent and painful death from tetanus. As Andy explained to Rafe, someday, after getting cut by a rusty saw or bitten by an animal, without the shot he'll "be a cinch to go." [177] Eschewing the chance to be a dead hero, Rafe finally took the shot.

## Sheriff Andy Taylor

Vaccination has changed the modern world. Indeed, it has led to the elimination or significant decline of many diseases that once posed significant and potentially deadly health risks. Public health officials in the United States have managed to institute a program that, though subject to variations on a state by state basis, essentially mandates certain vaccinations as a requirement for school attendance. While these vaccination programs are touted by most public health officials, a significant number of people oppose mandatory vaccination. The County Nurse episode helps illuminate the perspectives of the various sides of the issue, as well as one possible solution.

The nurse herself represents the public health officials. Though she is not implementing a mandatory vaccination program, her stated goal is to inoculate 100% of the population. [178] As mentioned above, she has the assistance of local law enforcement and she is quite persistent. Rafe Hollister, the stubborn farmer, represents those within the community who oppose or resist mandatory vaccination programs. His reasons initially rest on a general reluctance to stray from natural medicine. In this way he represents the contingent of society that scientists and medical researchers will always find difficult to convince of any developments in the medical field. In many ways, he is comparable to the plaintiff in *Jacobson*. Andy and Barney can be seen as the arms of the state that are entrusted with carrying out the general vaccination plan. Their varying styles can be seen as varying state requirements and enforcement options for vaccination.

Though these comparisons may seem elementary and of little value, the character development that the characters undertake during the episode greatly increases the episode's usefulness as a surrogate for real world concerns and issues. Rafe resists the shot initially not only because he distrusts medicine in general, but also because he resents the idea that a county nurse can make him do anything. Many who resist mandatory vaccination schemes do so because of personal liberty concerns; they do not want the government to tell them what to do, especially in the context of personal medical decisions. Just as Rafe's stance becomes more vehement the harder the nurse attempts to convince him, many who oppose mandatory vaccination see the persistence of the medical community as evidence of blind adherence to a potentially dangerous system, or worse yet as an active promotion of the special interests of the vaccine manufacturers. [179] The episode does not paint the nurse in this way at all, however. Rather, after seeing how strongly Rafe opposes vaccination, the nurse passionately pleads with him to reconsider. Her stance truly seems to stem from a

genuine concern that he not suffer the potentially terrible effects of the disease.[\[180\]](#) As before, he refuses; this seems to illustrate that the stance of some may be so strong that they will never accept vaccination on the basis of arguments advanced by government officials.

Barney Fife's insistence that Rafe accept the shot demonstrates the lack of understanding among many in the government and in the general population as to the vehemence with which those opposing mandatory vaccination hold to their views. His paternalistic stand only serves to exacerbate the situation with Rafe. Indeed, Barney Fife helps to illustrate that there cannot be a one-way solution to the issue of mandatory vaccination.

Andy Taylor's method of convincing, which eventually carried the day, may not be very conducive to real-world implementation. After all, it is unrealistic to think that reverse psychology will convince those currently opposed to vaccination programs to change their minds. What I think is important to notice, however, is the role information can play in this issue. Andy finally convinces Rafe Hollister to take his shot after describing the horrible effects of the disease and how likely Rafe is to contract it. Similarly, any solution to the issue of mandatory vaccination holdouts must rely on increased information dissemination. That the information in the episode came from a trustworthy source may also have been crucial, which seems to imply that public health officials may need to work more closely with local personnel in order to obtain higher vaccination rates.

Because this episode deals with the vaccine for tetanus, a non-communicable disease, the usual community-based arguments in favor of vaccination do not enter the equation. Extra-personal consequences of Rafe's decision to vaccinate do exist, however. Most importantly, as the unofficial leader of the farming community, his decision will be followed by the other farmers. This is shown both in Andy's assurances to the nurse that Rafe is the most important of the farmers to convince on the issue and later, after Rafe has decided to get the shot, in his promise to the nurse that all she has to do is come with him and he'll get all the farmers to take their shots. Perhaps those parents who support vaccination can help bring about higher vaccination rates by being more vocal and persistent with their neighbors who oppose vaccination programs.

## **Economic Analysis**

Economic analysis[\[181\]](#) provides a useful theoretical basis for evaluating the competing sides of the vaccination debate. Arguments regarding the wisdom of the current vaccination policy can often be recast as economic questions involving a cost-benefit analysis.

When an epidemic breaks out, for example, the benefits of vaccination (protection from the disease both for the individual and for society through herd immunity) seem more clearly to outweigh the costs (potential side effects of the vaccine, decreased ability of the immune system to defend the body from variant strands of the disease, or personal or religious objection). Vaccination rates would, therefore, be expected to be highest during such epidemics. Consequently, those few who continue to oppose vaccination during such epidemics would be expected to do so for only the strongest reasons. This is due to the fact that in economic terms, the opponent of vaccination would have to believe that the benefits of vaccination still do not outweigh the costs, even during an epidemic. This might stem from a relative undervaluation of the benefits of vaccination (perhaps due to a belief that contracting the disease would not be so bad) or a relative overvaluation of the costs of vaccination (possibly due to the greater cost to the conscience of the personal or religious opponent of vaccination) or some combination of both. Medical exemptions directly illustrate this cost-benefit analysis: for a person likely to suffer serious side effects from a vaccine, the cost of vaccination is much greater than the cost to the average individual. Even in a time of epidemic, therefore, vaccination might not be rational for such an individual.

## **Jacobson**

This economic analysis of vaccination is well illustrated by the facts of *Jacobson v. Massachusetts* [182], the first Supreme Court case addressing the constitutionality of mandatory vaccination legislation. The case involved a Massachusetts statute allowing local authorities to mandate vaccination for smallpox if necessary for the public health and safety. [183] Subsequently, and upon a determination that smallpox was “prevalent to some extent” and “continues to increase,” the city of Cambridge passed a mandatory vaccination ordinance. [184] This ordinance represented the economic determination that the benefit of mandatory vaccination outweighed the cost of supplying vaccines, finding and prosecuting holdouts (such as Jacobson), and the decreased liberty of individuals to be permitted to decide whether to vaccinate.

Jacobson subsequently challenged his prosecution under the ordinance by claiming it to be an unconstitutional denial of his liberty under the 14th Amendment (as well as in violation of the Preamble and the “spirit” of the Constitution, arguments that were summarily dismissed). [185] In economic terms, this may simply indicate that he viewed the cost of accepting a forced vaccination (perhaps of any kind, in any circumstance) as greater than any possible benefit. A closer look at his arguments, however, suggests that he may have performed a more detailed cost-benefit analysis. One can easily convert the various arguments he attempted to advance into economic costs. Among these arguments were the likelihood of vaccination to bring about “serious and permanent injury” and occasional death, the inability of an individual to assess the risk of vaccination in a particular case, and the potential impurity of vaccines and inability to test such impurity, among others. [186] At the very least, it would appear that Jacobson attributed a greater than average cost to vaccination.

The statute also provided that ordinances mandating vaccination provide an exception for “children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination.” [187] This reflects the state's determination that the cost of forcing vaccination upon those more likely to suffer adverse side effects outweighed the benefit of completely universal vaccination. Given the determination that near-universal vaccination was required to provide the desired benefit, one would expect that the state expected to grant relatively few medical exemptions (or at least few enough not to seriously compromise the goal of providing protection against smallpox through vaccination).

In rejecting Jacobson's liberty challenge to the ordinance, the Court endorsed the concept that the State's cost-benefit analysis can supersede that of the individual, at least in the area of public health. The Court's decision, in fact, makes irrelevant any individual cost-benefit analysis in the face of a comprehensive mandatory vaccination program.

Various vaccination-related developments in the century since *Jacobson* can also be cast in an economic analytical framework. Certainly the benefit from vaccination disappears when a disease has been eradicated, which explains why the smallpox vaccine is no longer mandated. Any cost greater than zero (the likely benefit of smallpox vaccination at this point, barring of course a reintroduction of the disease using laboratory samples) will suffice to outweigh this benefit. [188] The success of vaccination policies, however, may lead to an undervaluation of the benefit of continuing to vaccinate due to the lack of visible instances of the disease. [189] This problem may be compounded when vaccines are mandated for diseases which are not associated with high mortality rates, such as chickenpox. A further complication to the cost-benefit analysis arises when assessing vaccination policy for diseases such as Hepatitis B, which is spread typically through voluntary contact. In such a case, an individual who feels highly unlikely to engage in the behavior giving rise to the risk of the disease might rationally see very minimal benefit from vaccination, while the state may view widespread vaccination as the most cost-effective method of dealing with the disease. [190]

## **Altruism and Free Riding**

Given the continuing policy of vaccinating for diseases that have become relatively rare in recent decades, one might expect individual cost-benefit analyses to increasingly come into conflict with the societal policy. Several factors, however, serve to counteract this possibility. Perhaps most significantly, it is likely that many parents defer on the question of vaccination and accept the cost-benefit analysis of the state (communicated

to the individual through the vaccination schedule and through doctor's recommendations) as their own. Along the same lines, many individuals might not strongly consider the pros and cons involved in vaccinating; if the possibility exists for contracting a disease, and a vaccination is available, the decision may already be made.[\[191\]](#) A third possibility implicates a factor that I have not yet mentioned in relation to the individual cost-benefit analysis: altruism.

Some have proposed that altruism may bridge the gap between incompatible cost-benefit analyses of states and individuals.[\[192\]](#) Whereas typical medical decisions affect only the patient making the decision, it is pointed out, medical decisions regarding vaccine-preventable diseases usually implicate outside interests.[\[193\]](#) A patient thinking only of his own interests may forego vaccination if he feels the risk from vaccination outweighs the personal benefit. Altruism, it is argued, may present a separate benefit for such an individual.[\[194\]](#) Though the individual may not consider the risk of contracting the disease high enough by itself to justify vaccination, he may still vaccinate in order to help accomplish the public goal of eliminating the threat of an epidemic. Public health officials hope that comprehensive vaccination will produce herd immunity.[\[195\]](#) Thus the individual who may otherwise forego vaccination might undertake it in order to "do his part" for the community at large. Individuals who cannot vaccinate are particularly dependent on this sort of altruistic behavior, as they often have no other protection from the disease.[\[196\]](#)

Working against this altruistic behavior is the temptation of individuals to enjoy the benefit conferred on them by herd immunity without undertaking the cost of being vaccinated personally.[\[197\]](#) This is widely referred to as "free riding," and greatly undermines the goal of comprehensive vaccination. Since herd immunity is supposed to create a level of protection sufficient for even those few who are not vaccinated, a small number of free riders might not pose a significant problem. As described earlier in this paper, comprehensive vaccination programs are designed to work even though some members of society cannot be vaccinated.[\[198\]](#) The problem arises when the number of free riders becomes sufficiently high to compromise the ability of the society to achieve herd immunity. Since the average citizen (one with no greater reason to avoid vaccination than any other member of society) could always choose to free ride if immunization were voluntary, herd immunity might never be achieved. This is one of the key arguments advanced in support of government mandated vaccinations.[\[199\]](#)

## **Ex Ante Versus Ex Post**

The concepts of altruism and especially free riding emphasize the importance of ex ante (before the fact) versus ex post (after the fact) decision making in the context of vaccination. One of the main benefits of economic analysis is that it requires decisions to be justified ex ante. Public health officials, for example, are faced with the decision of whether to mandate vaccination for a particular disease at a time when all adverse effects cannot be known. They must weigh the possible consequences of allowing a disease to continue against the possible known and unknown adverse effects of a vaccine that may have just entered the market. When this decision is made properly, the benefit of the vaccination program will have outweighed the cost. The benefit is manifested in lower or no occurrences of the disease, while the cost is seen most directly in those children who have actually experienced adverse effects as a result of the vaccine. If the benefit is greater than the cost from an ex ante perspective, to the economist there should be no second-guessing of the vaccination program.[\[200\]](#)

The economist, of course, is not the parent. Parents who decry mandatory vaccination as the cause of their child's adverse reaction are typically viewing the situation ex post. That the program has been implemented assumes that the sum of these adverse reactions was an acceptable alternative to non-implementation, and should therefore not be allowed to undermine public confidence in the program. When one surveys the landscape of the vaccination issue, however, objections are usually of the ex post variety. Since it is harder to appreciate the absence of an epidemic than the presence of a child suffering a vaccine-related injury, it is easy to look at the issue solely ex post. In the interests of public safety, such reasoning should be avoided.

This is not to imply that all critics of mandatory vaccination are on unsound theoretical footing. In fact, those

whose objections are marked by a distrust of the government authorities in charge of implementing vaccination programs can be seen as questioning only the ex ante judgment of the officials. If this is so, they are actually on firmer ground than those who object to the programs because they feel their child was harmed by the vaccine. Ex ante critiques are valuable because they can bring about change in the system at a time when it can still prove useful.

The National Vaccine Injury Compensation Program represents a theoretically sound program under these criteria. Economically, it represents the idea that some of the costs of mandatory vaccination programs known only ex post will be compensated by all those who share the benefits ex ante. The excise tax, paid ex ante by all who receive the vaccine, is used to compensate anyone who experiences certain adverse effects ex post. This is simply an example of the government distributing the costs of the vaccination program across the spectrum of those who receive the benefit, rather than an ex post complaint by those on whom the costs have fallen.

## Other Issues

The modern trend toward more widely-granted exemptions represents government acquiescence toward a certain degree of free riding. Should such exemptions proliferate too widely, herd immunity may indeed be lost and a recalculation of the cost-benefit analysis of individuals will be necessary. In the face of a greater potential to contract disease, the benefit of vaccination grows significantly, while the cost of accepting the vaccine remains the same. Likewise, from the standpoint of the government, the cost of allowing widespread exemptions will eventually overtake the benefit of permitting such exemptions if that cost suddenly includes serious risk of epidemic.

The risks associated with non-vaccination can be illustrated through a rather simplified mathematical example.<sup>[201]</sup> Suppose a school with 1,000 students is exposed to a measles outbreak. 990 of the students have received all of their measles shots, and so are fully immunized. Suppose further that the measles vaccine is 99% effective; that is, it produces complete immunity in 99% of patients.<sup>[202]</sup> Therefore, 10 out of the 990 who have been fully immunized will be susceptible to the disease. In addition, all 10 of the 1,000 students who had not been fully immunized will be susceptible to measles. Therefore, 20 out of 1,000 students will get the disease. Although the number of infected students who were vaccinated is equal to the number who were not, this example demonstrates that vaccination can be very effective even if it sometimes does not produce immunity in an individual. If no one had been vaccinated, 980 more students would probably have caught the measles. It is also important to note that this example assumes an epidemic; in reality, herd immunity would probably be attained at this level of inoculation and none of the 1,000 students would have caught the disease.

## IV. CONCLUSION

Vaccines have immeasurably improved our quality of life. They have led to the eradication of deadly diseases like smallpox and the near elimination of diseases such as diphtheria, polio, and measles. Outbreaks of vaccine-preventable diseases, such as mumps, are infrequent and are also quite newsworthy on the rare occasion that they do occur. And people like Rafe Hollister can survive a run-in with a rusty saw or an animal bite.

The life-saving benefits of vaccination often overshadow the vast economic and personal benefits it has helped provide. Jonas Salk's cure for polio has spared generations from a life hindered by the devastating physical handicaps of that terrible affliction. Children no longer must miss vast stretches of school to overcome a debilitating battle with pertussis (although there is no doubt that some children lament this decline in excused absences from school). Parents no longer have to spend restless hours worrying as their

children suffer the body's natural response to disease. In economic terms, this translates directly into fewer missed hours of work and less administrative difficulty, leading to a generally more productive society.

### Jonas Salk

For all the benefits of vaccines, of course, it is important not to ignore the costs. The National Vaccine Injury Compensation Program is one way of dealing with the economic costs of vaccination, but this may provide little solace to the parent of a child who has been injured by a vaccine for a disease that is seemingly in decline. Side effects with very low probability will sometimes occur; though from a community-wide view this possibility is acceptable, for the individual who experiences the adverse effect the vaccination may not have been the best medical decision. Many who view natural immunity as a rite of passage for children might not desire a means of bypassing the disease entirely.

Some may accuse public health officials of dreaming for an unreachable day when all diseases are controlled by vaccination. Zeal on the part of public health officials, however, should not overshadow the actual benefits of vaccination generally. Soon may come the day when diphtheria, like smallpox, will be eradicated globally. At that point, it can be removed from the vaccination schedule and future generations will reap the benefits of vaccination while undertaking none of the costs.

This prospect, I think, sheds light on the ultimate solution to vaccination issues that have been discussed in this paper. Highly communicable and especially terrible diseases should continue on the vaccination schedule until they are virtually eliminated. The eventual elimination of these scourges will someday make vaccination unnecessary, and the costs of vaccination will drop to zero. Until that time, officials should seek stricter enforcement of the mandatory vaccination laws and should tighten down on non-medical exemptions. At the same time, information campaigns should be considered in the interest of reminding the public of the continued importance and relevance of vaccine programs. Though risks are unavoidable when dealing with vaccines, parents should constantly be reminded that immunity depends on a high level of cooperation. This will hopefully keep immunization rates high, at least for the most harmful diseases.

Meanwhile, public health officials may be wise to consider an alternate stance toward somewhat less-important vaccines such as Hepatitis B and varicella (chickenpox).<sup>[203]</sup> With such diseases it may be worthwhile to wait longer before placing the vaccines on the recommended schedule. This will undoubtedly make herd immunity more difficult if not impossible to attain, while simultaneously announcing to parents that undertaking the vaccine in question is a personal medical decision. Most of those who choose to vaccinate (and accept the risk of adverse effects from these newer vaccines) will still acquire immunity. Without a mandatory program in place, however, one would still expect to see regular occurrences of the disease. Given the relatively high likelihood of outbreak under these circumstances, a percentage of those who vaccinate will probably get the disease. They will likely turn to those who did not vaccinate at all and see them as the cause of the outbreak. In time, social pressures may lead to greater vaccination rates, and the time may be ripe for greater acceptance of mandatory vaccination for the disease.

One significant benefit to this approach lies in its natural tendency to point out to parents the importance of receiving the more important vaccines. When some vaccines are mandatory and others are not, the distinction between the two types of vaccines is impossible to neglect. It would hopefully make parents think more carefully before attempting to gain an insincere exemption. This approach would fail to satisfy those who want parents to have the option to choose "one, ten, or no vaccines,"<sup>[204]</sup> but it would at least allow an element of choice for some vaccines while hopefully maintaining a sufficient level of immunization for the more important vaccines. It is also important to remember that parents with serious reservations about any vaccines will usually have the option of home schooling. Overall, this approach might have the advantage of winning over those who only partially object to the vaccination schedule, thus helping bring about a greater chance of herd immunity for diseases associated with less objectionable vaccines.

Vaccination certainly is unique among medical treatments, both for its incredible potential and its coercive

nature. It is unfortunate that questionable evidence has led many concerned parents to question the wisdom of vaccination programs that still serve important goals. Given the importance of public support for the achievement of these goals, however, public health officials must account for sometimes questionable concerns in determining vaccination policy. Greater information dissemination, combined with more sharply drawn (and potentially vaccine-specific) guidelines, can hopefully further the important goals of vaccination policy.

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[1] Center for Disease Control, "Smallpox Disease Overview," at <http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp> (last visited April 27, 2006).

[2] GlaxoSmithKline is currently developing an ear infection vaccine and plans to seek regulatory approval shortly. Jessica Said, "Vaccine Could End Children's Ear Infections," CNN online article, March 3, 2006 (on file with author).

[3] Institute of Medicine. CP Howson, et al. eds. *Adverse Effects of Pertussis and Rubella Vaccines*. Washington, DC: National Academy Press; 1991, at 1.

[4] James G. Hodge, Jr. and Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L. J. 831, 867 (2001).

[5] See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

[6] Hodge and Gostin, *supra* note 4, at 867.

[7] *Id.* at 868.

[8] "Rather than having health departments require immunization in emergency conditions, legislatures acted to prevent disease by mandatory immunization as a condition of enrollment or attendance in schools or licensed day care facilities." *Id.*

[9] *See id.*; *see also infra* Part I (chart describing the current recommended vaccination schedule).

[10] The Center for Disease Control has gone so far as to suggest that "to have a medical intervention as effective as vaccination in preventing disease not use it would be unconscionable." Center for Disease Control, National Immunization Program publication, "Six Common Misconceptions About Vaccination and How to Respond to Them," at <http://www.cdc.gov/nip/publications/6mishome.htm> (last visited April 27, 2006) (hereinafter "Six Common Misconceptions").

[11] Center for Disease Control, National Immunization Program publication, "Ten Things You Need to Know about Immunizations," at <http://www.cdc.gov/nip/publications/fs/gen/shouldknow.htm> (last visited April 27, 2006).

[12] This is not to imply that parents who vaccinate without carefully considering the pros and cons of vaccination are in the wrong. The health and safety of a child is of paramount importance to most parents, and every parent must make decisions that affect the welfare of the child. Most parents approach such decisions with a sincere desire to promote the child's best interests, and this desire is no different in the context of vaccination.

[13] "Despite its utility, vaccination has provoked popular resistance from the beginning." Hodge and Gostin, *supra* note 4, at 834.

[14] "Some opponents express valid scientific objections about effectiveness or need for mass vaccinations; some fear harmful effects arising from the introduction of foreign particles into the human body; and others worry that vaccination actually transmits, rather than prevents, disease, or weakens the immune system." *Id.*

[15] See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (constitutional challenge to government mandated smallpox vaccination); “Six Common Misconceptions,” *supra* note 10 (“[s]ome see mandatory vaccination as interference by the government into what they believe should be a personal choice”).

[16] “Six Common Misconceptions,” *supra* note 10.

[17] A more detailed explanation of this subject appears in Part I of this paper.

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] See, e.g., “Ten Things You Need to Know about Immunizations,” *supra* note 11.

[22] Angie A. Welborn, “Mandatory Vaccinations: Precedent and Current Laws,” CRS Report for Congress, at <http://www.fas.org/sgp/crs/RS21414.pdf> (last updated Jan. 18, 2005).

[23] For a typical scenario of public health response to outbreak, see the facts of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

[24] Hodge and Gostin, *supra* note 4, at 833-34.

[25] *Id.* at 867-68.

[26] *Id.* at 833.

[27] *Id.*

[28] *Id.*

[29] This level of immunity is often referred to as “herd immunity,” the concept that not everyone in a population must be vaccinated in order for the entire population to be protected. Abi Berger, “How Does Herd Immunity Work?” 319 *BMJ* 1466 (1999). “As long as a sufficient number of children are immunised against each disease for which there is a vaccine, protection against that disease will be conferred on everybody.” *Id.* Also, the level of vaccination necessary to attain herd immunity increases as the infectivity of the disease increases. *Id.* Highly infectious diseases, therefore, require higher levels of immunity for herd immunity to occur. *Id.* The concept of herd immunity will arise throughout this paper, with particular emphasis in Part III.

[30] This is evidenced by the fact that in time of outbreak, the vaccinated population can still be susceptible to the disease, although usually the vaccinated population is far less susceptible to the disease than the unvaccinated population. Vaccines typically produce the desired antibody in an individual around 90% of the time, with actual percentages varying from vaccine to vaccine. Some vaccines, moreover, lose their efficacy and require boosters. These concepts will be further developed throughout this paper.

[31] Hodge and Gostin, *supra* note 4, at 850-51.

[32] *Id.* at 851.

[33] *Id.* at 834.

[34] *Id.* at 834-35.

[35] See, e.g., *Duffield v. Sch. Dist.*, 29 A. 742 (Penn. 1894).

[36] 197 U.S. 11 (1905).

[37] *Id.*

[38] *Id.* at 26.

[39] Welborn, *supra* note 22.

[40] *Id.*

[41] 260 U.S. 174 (1922).

[42] *Id.* at 175.

[43] *Id.* (“[t]he bill charges that there was then no occasion for requiring vaccination” and that the ordinances “in effect, mak[e] vaccination compulsory”).

[44] *Id.*

[45] *Id.* at 176.

[46] *Id.*

[47] *Id.*

[48] *Id.* at 177.

[49] Hodge and Gostin, *supra* note 4, at 867-68.

[50] *Id.* at 868.

[51] The schedule of immunizations is published by the Center for Disease Control, and follows the recommendations of the Advisory Committee on Immunizations Practices, the American Academy of Pediatrics' Committee on Infectious Diseases, and the American Academy of Family Physicians. *Id.*

[52] *Id.* at 869.

[53] *Id.*

[54] Based on chart publicized by Center for Disease Control, approved by Advisory Committee on Immunization Practices, American Academy of Pediatrics, American Academy of Family Physicians, *available at* [http://www.cisimmunize.org/IZSchedule\\_2006.pdf](http://www.cisimmunize.org/IZSchedule_2006.pdf) (last visited April 27, 2006).

[55] Indeed, the law in *Jacobson* was challenged for this reason.

[56] Statement of Barbara Fisher, founder of National Vaccine Information Center, *quoted in* Neenyah Ostrom, “First Do No Harm,” *at* <http://www.chronicillnet.org/online/Fisher.html> (last visited April 27, 2006).

[57] K.N.O.W. Vaccines, Vaccine Awareness of Florida fact sheet, *at* [http://www.know-vaccines.org/vaccine\\_fact.html](http://www.know-vaccines.org/vaccine_fact.html) (last visited April 27, 2006).

[58] The most direct way in which this occurs surrounds the concept of herd immunity, as discussed elsewhere throughout this paper. If a sufficient number of persons in the community does not vaccinate, herd immunity may be unattainable and others may be put at risk.

[59] See, e.g., the discussion in Part III involving The Andy Griffith Show.

[60] See Statement of Barbara Fisher, *quoted in* Ostrom, *supra* note 56. See also "Autism and Vaccines: Activists Wage a Nasty Campaign to Silence Scientists," Wall Street Journal, February 16, 2004, at <http://www.opinionjournal.com/forms/printThis.html?id=110004700> (last visited April 27, 2006) (citing vaccination critics who had accused the vaccination-defending writers of "having an 'industry profit promoting agenda'").

[61] See Statement of Barbara Fisher, *quoted in* Ostrom, *supra* note 56.

[62] *Id.*

[63] *Id.*

[64] See the discussion in Part II regarding vaccine safety.

[65] See, e.g., "Six Common Misconceptions," *supra* note 10.

[66] Mission Statement of Vaccination News website, at <http://www.vaccinationnews.com> (last visited April 27, 2006).

[67] As the discussion in Part II on vaccine safety demonstrates, pre-licensing testing for very rare adverse effects cannot take place if vaccines are ever to reach the market. Phase 4 post-licensing testing does exist, but may take years to discover extremely rare adverse effects.

[68] World Health Organization Immunization Safety page, "Adverse Events Following Immunization," at [http://www.who.int/immunization\\_safety/aeafi/en/](http://www.who.int/immunization_safety/aeafi/en/) (last visited April 27, 2006).

[69] As the recent mumps outbreak in Iowa demonstrates, not everyone who receives a vaccine develops immunity to the disease. For this reason, the success of vaccination depends on a sufficient level of vaccination in the community. When a significant percentage of the population has not received the vaccine, an outbreak can occur and even threaten some of those who have been vaccinated. See David Pitt, "Iowa Mumps Epidemic Continues to Broaden," Associated Press, April 13, 2006, at <http://www.breitbart.com/news/2006/04/13/D8GVGL600.html> (last visited April 27, 2006). See also the above discussion of the history of vaccination.

[70] Mission Statement of Vaccination News website, *supra* note 66.

[71] See, e.g., Ross D. Silverman, "No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure Public Health Protection," 12 *Annals Health L.* 277, 278-79 (2003).

[A]s risks of contracting many deadly and crippling diseases continue to decline to near negligible levels, and rates of childhood immunization continue to reach record levels, the public today places greater attention on the relative weaknesses and dangers of immunizations, and the systems through which they are administered.

*Id.*

[72] Hodge and Gostin, *supra* note 4, at 874.

[73] Usually this requires physician certification. *Id.*

[74] Indeed, the CDC itself presupposes the existence of medical exemptors in any broad mandatory vaccination program. See "Six Common Misconceptions," *supra* note 10 (noting that the mandatory vaccination program can work to protect even those few who cannot vaccinate because of the possibility of adverse medical reactions).

[75] *Id.*

[76] Hodge and Gostin, *supra* note 4, at 874.

[77] *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). *See also Employment Division v. Smith*, 494 U.S. 872 (1990) (permitting neutral laws of general applicability that incidentally affect religion); *Boone v. Boozman*, 217 F.Supp.2d 938 (E.D. Ark. 2002) (“constitutionally-protected free exercise of religion does not excuse an individual from compulsory immunization...the right to free exercise of religion and parental rights are subordinated to society’s interest in protecting against the spread of disease”).

[78] W. Va. Code Sec. 16-3-4 (2004).

[79] *See, e.g., Boone v. Boozman*, 217 F.Supp.2d 938 (E.D. Ark. 2002). The challenged Arkansas immunization statute exempted “individuals for whom ‘immunization conflicts with the religious tenets and practices of a recognized church or religious denomination of which [they are] an adherent or member.’” The statute was struck down under the Establishment Clause using the test laid out in *Lemon v. Kurtzman*, 403 U.S. 602 (1971). 217 F.Supp.2d at 950. The Arkansas legislature subsequently amended the exemption generally to allow for religious or philosophical objections without regard to recognized churches. Ark. Code Sec. 6-18-702(d).

[80] *See Silverman, supra* note 71, at 290-93.

[81] *See id.*

[82] Hodge and Gostin, *supra* note 4, at 874.

[83] Cal. Health and Safety Code Sec. 120365 (2003).

[84] Silverman, *supra* note 71, at 284.

[85] *Id.* at 285.

[86] *Id.*

[87] *See id.*

[88] Recall that for those unable to vaccinate for medical reasons, herd immunity provides the only protection from the disease. *See* “Six Common Misconceptions,” *supra* note 10.

[89] Silverman, *supra* note 71, at 285.

[90] *Id.* The recent mumps outbreak may directly demonstrate this. Officials have pointed out that vaccination only confers immunity on 95% of patients, and of those affected in the recent outbreak, 25% have been vaccinated. *See Pitt, supra* note 69. The strong implication is that the 75% of those inflicted who were not vaccinated have put the entire community at risk.

[91] Center for Disease Control, National Immunization Program publication, “What Would Happen If We Stopped Vaccinations?” at <http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm> (last visited April 27, 2006).

[92] Silverman, *supra* note 71, at 293.

[93] Silverman suggests that eliminating philosophical and religious exemptions would do more harm than good. This approach, he believes, “would exacerbate feelings of animosity and skepticism toward vaccination and the public health system in general.” *Id.* at 293. On this score he is probably correct, and I agree that wider knowledge, at the very least, is a better initial response to this problem.

[94] Incidentally, it is worth mentioning that of the more longstanding vaccines, the tetanus vaccine stands out as unique. Tetanus is a very harmful disease with about a 20% fatality rate. "What Would Happen If We Stopped Vaccinations?" *supra* note 91. What makes it unique in the vaccine schedule is that tetanus is not contagious. That is, herd immunity is not attainable and cannot be used to justify mandatory tetanus vaccination. The reason for the general acceptance of the tetanus vaccine seems to stem both from the high risk of the disease and the fact that tetanus can only be prevented by immunization. In addition, the tetanus vaccine for infants has been combined with the vaccines for diphtheria and pertussis. On strictly public health grounds, however, the status of the tetanus shot on the compulsory vaccination schedule comes closest to government fiat of individual health decisions.

[95] Because medical risks may vary from vaccine to vaccine, and thus the justification for such exemptions remains even if the risk is to some but not all vaccines, medical exemptions are somewhat outside the scope of this discussion.

[96] Sean Coletti, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 Conn. L. Rev. 1341, 1344 (2004).

[97] *Id.*

[98] This follows directly from the all-or-nothing nature of the vaccination decision in this world.

[99] Again, this follows directly from the nature of the decision.

[100] *See, e.g.*, National Vaccine Information Center, at <http://www.nvic.org> (last visited April 27, 2006) (urging parents to consider eight questions before vaccinating, none of which inform parents of the effect their decision may have on others).

[101] *See* "Six Common Misconceptions," *supra* note 10.

[102] 42 U.S.C. §§ 300aa-1 to 300aa-34.

[103] U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, "Vaccine Product Approval Process," updated July 27, 2002, at <http://www.fda.gov/cber/vaccine/vacappr.htm> (last visited April 27, 2006) (hereinafter "Vaccine Product Approval Process").

[104] *See id.*

[105] *See, e.g.*, Isadora Stehlin, "How FDA Works to Ensure Vaccine Safety," FDA Consumer magazine (December 1995), at [http://www.fda.gov/fdac/features/095\\_vacc.html](http://www.fda.gov/fdac/features/095_vacc.html) (last visited April 27, 2006).

[106] "Licensing of a vaccine is only the beginning of FDA's oversight." *Id.*

[107] *Id.*

[108] *Id.*

[109] "Vaccine Product Approval Process," *supra* note 103.

[110] *Id.*

[111] *Id.*

[112] Stehlin, *supra* note 105.

[113] *Id.*

[114] *Id.*

[115] *Id.* ; “Vaccine Product Approval Process,” *supra* note 103.

[116] Stehlin, *supra* note 105.

[117] *Id.*

[118] “Vaccine Product Approval Process,” *supra* note 103.

[119] *Id.*

[120] *Id.*

[121] *Id.* ; Stehlin, *supra* note 105.

[122] *Id.*

[123] Indeed, the National Immunization Program has confidently pointed to the FDA's role in continued oversight of vaccines:

FDA would recall a lot of vaccine at the first sign of problems. There is no benefit to either the FDA or the manufacturer in allowing unsafe vaccine to remain on the market. The American public would not tolerate vaccines if they did not have to conform to the most rigorous safety standards. The mere fact that a vaccine lot [is] still in distribution says that the FDA considers it safe.

“Six Common Misconceptions,” *supra* note 10.

[124] “Vaccine Product Approval Process,” *supra* note 103.

[125] *Id.*

[126] *Id.*

[127] Stehlin, *supra* note 105.

[128] So states Susan Ellenberg, Ph.D., director of CBER's division of biostatistics and epidemiology. *Id.*

[129] “Vaccine Product Approval Process,” *supra* note 103.

[130] Stehlin, *supra* note 105.

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *See, e.g.* , “Six Common Misconceptions,” *supra* note 10 (“[o]nly some of the reported health conditions are side effects related to vaccines. A certain number of VAERS reports of serious illnesses or death do occur by chance alone among persons who have been recently vaccinated”).

[137] “VAERS reports have many limitations since they often lack important information, such as laboratory results, used to establish a true association with the vaccine.” *Id.*

[138] “In summary, scientists are not able to identify a problem...based on VAERS reports alone without scientific analysis of other factors and data.” *Id.*

[139] U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, “Thimerosal in Vaccines,” at <http://www.fda.gov/Cber/vaccine/thimerosal.htm> (last updated Sept. 6, 2005).

[140] *Id.*

[141] *See, e.g.*, Gardiner Harris and Anahad O'Connor, “On Autism's Cause, It's Parents vs. Research,” *New York Times*, June 25, 2005, at <http://www.nytimes.com/2005/06/25/science/25autism.html> (last visited April 27, 2006) (reporting the ongoing tension between parents of autistic children and the medical community over the use of thimerosal in vaccines).

[142] *See, e.g.*, Center for Disease Control, National Immunization Program publication, “Mercury and Vaccines (Thimerosal),” at <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/default.htm> (last visited April 27, 2006) (studies have failed to find any association between exposure to thimerosal in vaccines and autism); “On Autism's Cause, It's Parents vs. Research,” *supra* (noting that the amount of ethyl mercury in each childhood vaccine was once about the same as the amount of methyl mercury, a more toxic compound, found in an average tuna sandwich).

[143] “Thimerosal in Vaccines,” *supra* note 139.

[144] *Id.*

[145] *Id.*

[146] Stehlin, *supra* note 105.

[147] *Id.*

[148] *Id.*

[149] “On Autism's Cause, It's Parents vs. Research,” *supra* note 141.

[150] “Thimerosal in Vaccines,” *supra* note 139; *see also* “On Autism's Cause, It's Parents vs. Research,” *supra* note 141 (“[b]y 2001, no vaccine routinely administered to children in the United States had more than half a microgram of mercury – about what is found in an infant's daily supply of breast milk”).

[151] “Autism and Vaccines: Activists Wage a Nasty Campaign to Silence Scientists,” *Wall Street Journal* editorial, February 16, 2004, at <http://www.opinionjournal.com/forms/printThis.html?id=110004700> (last visited April 27, 2006).

[152] “On Autism's Cause, It's Parents vs. Research,” *supra* note 141.

[153] Indeed, one recent study has suggested that neurological disorders have decreased with the removal of thimerosal from most vaccines. *See* David A. Geier and Mark R. Geier, “Early Downward Trends in Neurodevelopmental Disorders Following Removal of Thimerosal-Containing Vaccines,” 11 *J. Am. Physicians and Surgeons* 8 (2006). This study should be taken with a grain of salt, however, as the Geiers are widely known thimerosal critics. Years before this study, Dr. Mark Geier called thimerosal use in vaccines the world's “greatest catastrophe that's ever happened, regardless of cause.” “On Autism's Cause, It's Parents vs. Research,” *supra* note 141. A witness in many vaccine cases, a judge once ruled that he was “a professional witness in areas for which he has no training, expertise and experience.” *Id.* Scientists have

criticized his prior studies and even called his methods “voodoo science.” *Id.*

[154] *Id.*

[155] *See id.*

[156] *See* “The Politics of Autism: Lawsuits and Emotion vs. Science and Childhood Vaccines,” Wall Street Journal editorial, Dec. 29, 2003, at <http://www.opinionjournal.com/forms/printThis.html?id=110004487> (last visited April 27, 2006) (characterizing the position of thimerosal critics as “scientifically untenable”).

[157] *See generally* “On Autism’s Cause, It’s Parents vs. Research,” *supra* note 141.

[158] *Id.*

[159] *Id.*

[160] *Id.*

[161] “The Politics of Autism,” *supra* note 156.

[162] *Id.* ; “Study: Autism Rise from Labeling, Not Epidemic,” April 3, 2006, at <http://www.cnn.com/2006/EDUCATION/04/03/health.autism.reut/index.html> (last visited April 27, 2006) (noting rise in diagnosed cases of autism since 1994 is correlated with fall in diagnosed cases of mental retardation and learning disabilities).

[163] “The Politics of Autism,” *supra* note 156.

[164] *See, e.g.* , “Six Common Misconceptions,” *supra* note 10 (noting that many anti-vaccine publications claim vaccines are unsafe on the basis of sheer numbers of reports to VAERS without noting that many of them may not represent actual vaccine side-effects).

[165] National Vaccine Information Center, “The Vaccine Injury Compensation Program,” at [http://www.909shot.com/Issues/Comp\\_Summary.htm](http://www.909shot.com/Issues/Comp_Summary.htm) (last visited April 27, 2006).

[166] Center for Disease Control, National Vaccine Program Office, Vaccine Fact Sheets, “National Vaccine Injury Compensation Program,” at [http://www.hhs.gov/nvpo/factsheets/fs\\_tableIV\\_doc1.htm](http://www.hhs.gov/nvpo/factsheets/fs_tableIV_doc1.htm) (last visited April 27, 2006).

[167] *See* National Vaccine Injury Compensation Program, at <http://www.hrsa.gov/vaccinecompensation/> (last visited April 27, 2006).

[168] *Id.*

[169] *The Andy Griffith Show: The County Nurse* (CBS television broadcast, March 19, 1962).

[170] *Id.*

[171] *Id.*

[172] *Id.*

[173] *Id.*

[174] *Id.*

[175] *Id.*

[176] *Id.*

[177] *Id.* That is, there will be a high probability of death.

[178] *Id.*

[179] *See* the discussion above in Part I of this paper.

[180] For example, she begs Rafe to consider his family and what his decision could mean to them. She literally appears to be on the verge of tears as he refuses.

[181] In utilizing the theoretical framework of economic analysis, it is useful to keep in mind a few foundational concepts. First, a policy or program (in this case mandatory vaccination) is desirable if the overall benefit to society as a whole outweighs the cost of the program, where benefits and costs include both monetary and non-monetary factors. Second, individuals making rational choices regarding vaccination will vaccinate when the benefits of vaccination outweigh the risks or costs of non-vaccination to the individual. This decision-making process can be skewed by externalities, such as an unforeseeable decrease in the effectiveness of a vaccine due to a reduction in vaccination by others unknown to the individual at the time of the decision.

[182] 197 U.S. 11 (1905).

[183] *Id.* at 12.

[184] *Id.*

[185] *Id.* at 13, 22.

[186] *Id.* at 36.

[187] *Id.* at 12.

[188] As the CDC itself explains, “[e]ven one serious adverse effect in a million doses of vaccine cannot be justified if there is no benefit from the vaccination.” “Six Common Misconceptions,” *supra* note 10.

[189] In Japan in the 1970s, for instance, pertussis vaccination coverage fell from 80% to 20%, leading to an outbreak in 1979 resulting in 13,000 cases and 41 deaths. “What Would Happen If We Stopped Vaccinations?” *supra* note 91.

[190] Judge Richard Posner has suggested that this difference between sexually transmitted diseases and air- and water-borne diseases may imply a lesser imperative to eliminate sexually transmitted diseases:

[T]he externality created by sexually transmitted diseases is smaller than in the case of other contagious diseases. Sexually transmitted disease is spread primarily by *voluntary* contact, implying (to the economist) that a person is compensated...for assuming the risk of contracting the disease. Hence the number of cases of sexually transmitted diseases may be closer to the optimum than in the usual air-borne or water-borne or insect-borne epidemics.

Posner, *Economic Analysis of Law* 162. (6th Ed. 2003).

[191] Additionally, if vaccination rates are high, these individuals may assume that those in society who have already made the choice to vaccinate have performed a similar cost-benefit analysis. These individuals choose to vaccinate based simply on vaccination rates in the community. *See* John C. Hershey et al., *The Roles of Altruism, Free Riding, and Bandwagoning in Vaccination Decisions*, 59 *Organizational Behavior and Human Processes* 177, 178 (1994).

[192] See, e.g., *id.* (behavioral survey studying various factors individuals use to make vaccination decisions).

[193] *Id.*

[194] See *id.* at 178 (“[i]f a patient believes vaccination is in his own best interests, then he has two reasons to vaccinate. One is selfish, in that he will improve his own well being. The other is altruistic, in that he can improve the health prospects of those around him who might otherwise become infected if he is not vaccinated himself”).

[195] The concept of herd immunity is discussed in Part I. Note that “[i]n economic terms, herd immunity is a positive externality of vaccination. Altruistic individuals who recognize and value this externality may undergo vaccination partly to help others in addition to themselves.” *Id.* See also Berger, *supra* note 29 (“[h]erd immunity’...is the concept that not everybody in a population has to be immunised to protect everyone in that population. As long as a sufficient number of children are immunised against each disease for which there is a vaccine, protection against that disease will be conferred on everybody”).

[196] The CDC has pointed to this as one of the two most important reasons to vaccinate:

There is a small number of people who cannot be vaccinated (because of severe allergies to vaccine components, for example), and a small percentage of people don’t respond to vaccines. These people are susceptible to disease, and their **only** hope of protection is that people around them are immune and cannot pass disease along to them. A successful vaccination program, like a successful society, depends on the cooperation of every individual to ensure the good of all.

“Six Common Misconceptions,” *supra* note 10.

[197] In economic terms, “[w]idening vaccine use decreases each individual’s benefit from being vaccinated, but leaves unchanged each individual’s risk from the vaccination itself.” Hershey, *supra* note 191, at 178.

[198] “Six Common Misconceptions, *supra* note 10.

[199] Hershey, *supra* note 191, at 178.

[200] Suppose, for sake of example, that a vaccination program, if implemented, would save ten lives out of a thousand that would otherwise have perished without the program. Unfortunately, the vaccine will randomly cause death to five persons out of a thousand. From an *ex ante* perspective, the vaccination program should be implemented as it will save five lives overall. Concerns or complaints from those five persons who die (or their estates) represent *ex post* objections, and, though unfortunate, should not affect evaluations of the soundness of the program.

[201] This mathematical explanation is a slight variation of that found at CDC, “Six Common Misconceptions,” *supra* note \_\_\_.

[202] Note that no vaccine is 100% effective, and vaccination efficacy rates for most childhood vaccinations range from 85 to 95%. *Id.* As stated in an earlier section, herd immunity is relied upon to protect those who do not develop full immunity from the vaccine.

[203] Given that these particular vaccines are already on the schedule, I think it would be unwise to remove them now. My analysis applies to comparable vaccines that may arise in the future – vaccines for those communicable diseases that do not pose relatively significant health risks. The definition of such diseases, of course, would be a matter of debate. Vaccines for noncommunicable diseases like ear infections would also fall within this rubric.

[204] Statement of Barbara Fisher, *quoted in* Ostrom, *supra* note 56.

Vaccination is widely considered one of civilization's greatest modern medical achievements