The Case for Pneumococcal Immunization Requirements in Long-Term Care Facilities

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B.A. in Philosophy and Religion, January 2010, Boston University

A Thesis submitted to

The Faculty of
The Columbian College of Arts and Sciences
of The George Washington University
in partial fulfillment of the requirements
for the degree of Master of Arts

May 18, 2014

Thesis directed by

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I. Introduction

In both the past and the present, infectious diseases have been a primary topic of medicine.[1] Few other events, natural or human-made, have rivaled the massive loss of life caused by disease outbreaks such as the Black Death that swept through Eurasia in the fourteenth century, the Influenza Pandemic of the early twentieth century, or the introduction of smallpox to the Americas in the sixteenth century.[2] Just as infectious diseases have resulted in a great number of deaths over the course of human history, vaccines have been a hallmark of the modern era and have been responsible for saving millions of lives. In the developed world, however, many diseases that once ravaged communities have become a distant memory. It is within this context that one of the most contentious debates of the 21st century occurs: the public health use of immunization requirements.

In the United States, immunization requirements are primarily used for children.[3] Most states require children to receive at least the diphtheria-pertussis-tetanus (DPT) and measles-mumps-rubella (MMR) vaccines before entering schools or daycare centers.[4] While once commonly accepted as a necessary public health action, questions surrounding the safety of these vaccines have brought the issue of immunization requirements to the forefront of media and public attention.[5]

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[1] Michael J. Selgelid, "Ethics and Infectious Disease," *Bioethics* 19 (2005): 273.
[2] Daniel A. Salmon, Jason W. Sapsin, Stephen Teret, Richard F. Jacobs, Joseph W. Thompson, Kevin Ryan, and Neal A. Halsey, "Public Health and the Politics of School Immunization Requirements," *American Journal of Public Health* 95 (2005): 778.
[3] Salmon et al., 778
[4] Centers for Disease Control and Prevention, "Childcare and School Vaccination Requirements 2007-2008," 3. Accessed November 22, 2013. http://www2a.cdc.gov/nip/schoolsurv/CombinedLaws2007.pdf.
[5] Jason L. Schwartz, Arthur L. Caplan, Ruth R. Faden, and Jeremy Sugarman. "Lessons from the Failure of Human Papillomavirus Vaccine State Requirements." *Nature* 82 (2007): 760-763.

A memorable example of this so-called "vaccine controversy" was the introduction of the Human Papillomavirus (HPV) vaccine into school immunization requirements. In 2006, the HPV vaccine was recommended for use in 11- and 12-year-old girls by the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).[6] Since the federal government does not require states to codify ACIP recommendations as legal requirements, policymakers were placed at the center of this heated debate over the appropriate use of immunization requirements.[7]

This debate caught the attention of many prominent bioethicists. Since then several arguments have emerged regarding the ethical use of vaccine requirements, often incorrectly referred to as "mandates."[8] Historically, immunization requirements have been directed at young children, the primary bearers of infectious disease burdens. Yet due to emerging threats of new infectious diseases, as well as advances in vaccine technology, some of the discussion has shifted focus within the last few years to whether or not the possibility of adult immunization requirements has been unduly overlooked.

As new technology develops, in combination with other predicted demographic changes including an aging population, the question of whether adult immunization requirements are justified will become of greater societal and political significance. In what follows, I will base my argument on the presumption that, given the current state of scientific knowledge, the technology for at least one vaccine, the pneumococcal vaccine, can be expected to develop rapidly. As this occurs, it will raise the question of whether

[6] Schwartz et al.,760.
[7] Ibid.
[8] For examples see: Schwartz et al. (2007), Field and Caplan (2008), Walter (2013), Intlekofer et al. (2012), Tomljenovic and Shaw (2012), and Zimmerman (2006).

this vaccine should be required for use in specific populations. In particular, it should be expected that adults residing in long-term care facilities may become the focus of this debate.

Pneumococcal disease is a major cause of morbidity and mortality in the United States. Since pneumococcal vaccination campaigns have had enormous success in reducing morbidity and mortality from pneumococcal disease in children, elderly persons (those 65 years and older) and chronically-ill adults now suffer the greatest burdens of these infections in this country. Moreover, the CDC reports that "adults in long-term care facilities are at an increased risk of pneumococcal disease due to their advanced age, the frequent presence of chronic illnesses, and residence in a setting that might increase the risk for bacterial transmission."[9] Unfortunately, the effectiveness of the CDC recommended pneumococcal vaccine is being questioned.[10] As a result, researchers have begun to explore a next generation of vaccines that would confer greater immunity and longer protection in long-term care facility populations.

It can be reasonably expected that these vaccines will be developed and made available within the near future as several vaccines of this kind are already at late-stage clinical development or early-stage clinical trials.[11] At the same time, the elderly population in the United States is expected to grow significantly in the next 20 years, likely resulting in an increased number of adults residing in long-term care facilities.[12]

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[9] E. Bresnitz, C. Grant, S. Otrawski, C. Morris, J. Calabria, B. Reetz, and S. Clugston, "Outbreak of Pneumococal Pneumonia Among Unvaccinated Residents of a Nursing Home --- New Jersey, April 2001," *Morbidity and Mortality Weekly Report* 50 (2001): 707-710.

[10] Centers for Disease Control and Prevention, "Pneumococcal Disease: Prevention," Accessed April 1, 2014. http://www.cdc.gov/pneumococcal/about/prevention.html.

[11] Kristin L. Moffat and Richard Malley. "Next generation pneumococcal vaccines." *Current Opinion in Immunology* 23 (2011): 413.

[12] Administration on Aging, "Aging Statistics," Accessed April 6, 2014. http://www.aoa.gov/AoARoot/Aging_Statistics/.

Therefore, with the development of next generation vaccines and a burgeoning elderly population, the nature of vaccine policy can be expected to radically change in the coming years. In preparation for this imminent future, this paper addresses the bioethical implications of immunization requirements for adults residing in long-term care facilities and will hopefully initiate the conversation on whether such a possibility might be an ethically justifiable policy option.

To fulfill this aim, this paper will first provide background information on the threat of vaccine-preventable infectious diseases, pneumococcal disease and associated vaccines, and the possibility of immunization requirements in long-term care facilities in the United States. I will then evaluate three leading ethical positions for justifying public health measures, namely consequentialism, appeal to the harm principle, and Nancy Kass's ethics framework for public health. After careful analysis and reflection, I will conclude that if a pneumococcal vaccine is developed that instills broader and more effective protection among vulnerable long-term care facility populations, then an immunization requirement in these settings will be ethically justified on the basis of the three presented frameworks.

II: Background: Infectious Diseases, Pneumococcal Disease, and Residents of Long-Term Care Facilities

A. The Threat of Vaccine-Preventable Infectious Diseases

Vaccines play an important role in protecting United States citizens from the harms of vaccine-preventable infectious diseases. Though often considered a thing of the past, vaccine-preventable diseases remain a threat to the United States. Air travel alone can transmit any disease from anywhere in the world to the United States within 24

hours.[13] Without a sustained public health effort, any area of the United States is at risk of outbreaks and epidemics of vaccine-preventable illnesses. Due to the outstanding work of public health professionals and vaccination campaigns, diseases, such as measles and polio, once common in the United States have virtually vanished. Unfortunately, the rarity of many vaccine-preventable diseases has paradoxically shifted the American public's perception of the potential risks posed by these very diseases vaccinations have effectively eliminated over the past century. While once focused on the risks of these diseases, the public's attention now focuses on the risks of the vaccines, resulting in decreasing immunization rates.[14]

As vaccination rates have declined in recent years, communities have been put at risk of outbreaks and epidemics not seen in the United States in decades. In California, a 2010 outbreak of pertussis, commonly known as whooping cough, caused 9,120 cases and 10 deaths, a 60-year high.[15] Similarly, a 2013 epidemic of whooping cough in Texas resulted in at least 187 cases, the greatest number of cases in Texas since the 1950s.[16] Overall, 16 states saw increases in cases of pertussis in the first 30 weeks of 2013, compared with the first 30 weeks of 2012.[17] Additionally, in the spring of 2013, a

[13] Peter J. Lachmann, "Public Health and Bioethics," *Journal of Medicine and Philosophy* 23 (1998): 299.
[14] Salmon et al., 778.
[15] Michelle Healy, "Vaccine Refusal Linked to California Pertussis Outbreak," *USA Today,* September 30, 2013. http://www.usatoday.com/story/news/nation/2013/09/30/whooping-cough-california/2877343/.
[16] Bradford Pearson, "Texas Whooping Cough Epidemic – Centered in Tarrant County—Nears Record Levels," *D Magazine Healthcare Daily,* November 21, 2013. http://healthcare.dmagazine.com/2013/11/21/texas-whooping-cough-epidemic-centered-in-tarrant-county-nears-record-levels/.
[17] Centers for Disease Control and Prevention, "Changes in Pertussis Reporting by State from 2012 to 2013," Accessed November 23, 2013. http://www.cdc.gov/pertussis/images/pertussis-graph-2013-lg.gif.

measles outbreak among an orthodox Jewish community in Brooklyn, New York resulted in 58 cases, all occurring in individuals who had not been vaccinated.[18]

Sadly, the threat vaccine-preventable infectious diseases pose to the United States does not stop there. A recent article written by Dr. Tom Frieden, Director of the CDC, highlighted the increasing threat of antibiotic-resistant bacteria to the United States. Antibiotic- and multi-drug-resistant strains of common and often vaccine-preventable bacteria that are immune to standard courses of antibiotics, and in some cases all antibiotics, make them particularly lethal. The CDC estimated that in the United States 2 million people are infected by and 23,000 people die from antibiotic-resistant bacteria each year.[19]

Over-prescription, self-medication, and other improper uses of antibiotics have been major contributors to the rise of antibiotic-resistant bacteria,[20] as has the United States' massive agribusiness industry. In many farms across the country, animals are kept in small, tight enclosures to maximize production. As with humans, when animals are forced to remain in close quarters for long periods of time, and even entire lifespans, disease spreads quickly. To mitigate this problem, farms add antibiotics to animal feed in an effort to keep livestock healthy enough for slaughter and human consumption. These

[18] Robert J. Aricuolo, Tamara R. Brantley, Mekete M. Asfaw, Rachel R. Jablonski, Jie Fu, Francesca R. Giancotti, Jennifer B. Rosen, and Jane R. Zucker. "Notes from the Field: Measles Outbreak Among Members of a Religious Community – Brooklyn, New York, March-June 2013," *Morbidity and Mortality Weekly Report* 62 (2013): 752-753.
[19] Tom Frieden, "A nightmare health scenario we can stop," *CNN*, November 20, 2013. http://globalpublicsquare.blogs.cnn.com/2013/11/20/a-nightmare-health-scenario-we-can-stop/.
[20] Freiden.

intensive farming practices as well as the misuse of antibiotics in humans have led to the rise in antibiotic-resistant bacteria in both animals and humans.[21]

Presently, antibiotic-resistant bacteria are primarily found in hospital settings, but the accreting threat of these types of bacteria becoming more commonplace is real and potentially disastrous for the state of our public health.[22] Fortunately, many antibiotic-resistant infections can be prevented through the use of vaccines. However, left unaddressed, the incidence of infection by antibiotic-resistant bacteria, and the associated fatalities, can be expected to increase.[23]

B. Pneumococcal Disease

Pneumococcal disease presents a unique threat to the health of the United States' population. Pneumococcal disease causes more deaths in the United States every year than all other vaccine-preventable diseases combined and more than 95% of pneumococcal deaths are in adults.[24] *Streptococcus pneumoniae*, or pneumococci, bacteria cause several different types of infections, including pneumonia (lung), bacteremia (blood), meningitis (tissues or fluid surrounding the brain and/or spinal cord), otitis (ear), and sinusitis (sinus) infections.[25] There are over 90 known serotypes of pneumococcal disease, most causing disease.[26] All infections caused by *Streptococcus*

[21] Richard Knox, "How Using Antibiotics In Animal Feed Creates Superbugs," *National Public Radio,* February 21, 2012. http://www.npr.org/blogs/thesalt/2012/02/21/147190101/how-using-antibiotics-in-animal-feed-creates-superbugs.
[22] Frieden.
[23] Ibid.
[24] Immunization Action Coalition, "Pneumococcal Vaccines --- CDC answers your questions," Accessed April 1, 2014. http://www.immunize.org/catg.d/p2015.pdf; Centers for Disease Control and Prevention. "Pneumococcal Disease: Types of Infection." Accessed April 1, 2014. http://www.cdc.gov/pneumococcal/about/infection-types.html.
[25] CDC, "Pneumococcal Disease: Types of Infection."
[26] Centers for Disease Control and Prevention, "Pneumococcal Disease: *Streptococcus pneumoniae*," Accessed April 4, 2014. http://www.cdc.gov/pneumococcal/clinicians/streptococcus-pneumoniae.html.

pneumoniae bacteria can collectively be referred to as pneumococcal disease. Every year in the United States, there are approximately 900,000 cases resulting in 400,000 hospitalizations from pneumococcal pneumonia.[27] Approximately 6% of these cases result in death.[28] Together pneumonia and influenza are the 8th leading cause of death in the United States resulting in 56,000 deaths annually.[29]

Invasive pneumococcal disease occurs when the bacteria infect normally sterile parts of the body.[30] Invasive pneumococcal disease, usually bacteremia or meningitis, can occur independently or as a result of pneumococcal pneumonia.[31] In either case, invasive pneumococcal disease disproportionately affects adults (over 90% of cases occur in adults).[32] Bacteremia has an estimated fatality rate of approximately 20%, though the fatality rate is thought to be around 60% for the elderly.[33] Meningitis has a mortality rate between 10% and 30%.[34] Every year, there are approximately 50,000 cases of bacteremia[35] and 3,000 cases of meningitis in the United States.[36] Of those who recover from meningitis, many are often left with physical disabilities such as hearing loss or brain damage.[37]

Streptococcus pneumoniae has also seen an increase in antibiotic-resistant strains. For all incidences of pneumococcal disease, the increasing presence of drug-resistant

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[27] Ibid.
[28] Ibid.
[29] U.S. Department of Health and Human Services, "Immunization and Infectious Diseases," Accessed April 1, 2014. http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23.
[30] CDC, "Pneumococcal Disease: Types of Infection."
[31] Ibid.
[32] Centers for Disease Control and Prevention, "Pneumococcal Disease: Fast Facts," Accessed November 22, 2013. http://www.cdc.gov/pneumococcal/about/facts.html.
[33] Centers for Disease Control and Prevention, "Pneumococcal Disease," 234. Accessed April 1, 2014. http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf.
[34] CDC, "Pneumococcal Disease: Fast Facts."
[35] CDC, "Pneumococcal Disease," 235.
[36] Ibid.
[37] Ibid.

bacteria has resulted in increasingly complex cases that require lengthier hospital stays and have increased fatality rates.[38] Further threatened is the growing number of residents in long-term care facilities.[39] Long-term care facility residents have a higher incidence of pneumococcal disease primarily due to their close proximity to others, advanced age, and likely presence of chronic conditions.[40] Several outbreaks of pneumococcal disease have occurred in these settings, including events involving drug-resistant and multidrug-resistant bacteria.[41]

C. The Use of Pneumococcal Vaccines in the United States

Due to the severity of pneumococcal disease, developing an effective pneumococcal vaccine has been a goal of health researchers for over 100 years. The first pneumococcal vaccine was developed by British physician Sir Almroth E. Wright and tested on gold miners in Johannesburg, South Africa in 1911.[42] At the time, the case-fatality rate for pneumococcal disease was about 35%.[43] In comparison, smallpox, a frightening and now eradicated disease, had a case fatality rate of approximately 30%.[44]

[38] L.M. Hampton, M.M. Farley, W. Schaffner, A. Thomas, A. Reingold, L.H. Harrison, R. Lynfield, N.M. Bennett, S. Petit, K. Gershman, J. Baumbach, B. Beall, J. Jorgensen, A. Glennen, E.R. Zell, and M. Moore. "Prevention of antibiotic-nonsuspectible Streptococus pneumoniae with conjugate vaccines." *Journal of Infectious Disease* 205 (2012): 401-411.
[39] Cynthia G. Whitney, William Schaffner, and Jay C. Butler, "Rethinking Recommendations for Use of Pneumococcal Vaccines in Adults," *Clinical Infectious Diseases* 33 (2001): 664.
[40] Whitney, Schaffner, and Butler, 664.
[41] Ibid.
[42] Grabenstein, J.D., and K.P. Klugman. "A century of pneumococcal vaccine research." *Clinical Microbiology and Infection* 18 (Suppl. 5) (2012): 15.
[43] Grabenstein and Klugman, 15.
[44] Centers for Disease Control and Prevention, "Smallpox Disease Overview," Accessed April 1, 2014. http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp.

In the United States, the first pneumococcal vaccine was licensed in 1977 to protect against 14 strains of pneumococcal bacteria.[45] In 1983, a new vaccine was recommended that offered protection against 23 strains of pneumococci.[46] This vaccine, a polysaccharide vaccine developed by Merck & Co., Inc. under the drug name Pneumovax 23 (PPSV23), is still recommended for use today in some populations, including all adults 65 years of age or older.[47]

Unfortunately, the effectiveness of PPSV23 has been the subject of debate in recent years.[48] Though consistently shown to be effective in reducing invasive pneumococcal pneumonia in the elderly, its effectiveness in reducing non-bacteremic pneumococcal pneumonia has been contested.[49] Thus, while current evidence for PPSV23 strongly supports its use among long-term care facility residents to reduce invasive pneumococcal disease, scientists, researchers, and clinicians have been charged with developing a vaccine that would better protect against non-bacteremic pneumococcal pneumonia in these vulnerable populations.[50] Though a newer pneumococcal conjugate vaccine (PCV13) is available for use, it has not been ACIP-recommended for use in the elderly, making it unsuitable for an immunization requirement in long-term care facilities.[51]

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[45] Centers for Disease Control and Prevention, *Epidemiology and Prevention of Vaccine-Preventable Diseases,* W. Atkinson, S. Wolfe, and J. Hamborsky, eds., 12th ed., second printing, Washington DC: Public Health Foundation, 2012.
[46] CDC, *Epidemiology and Prevention of Vaccine-Preventable Diseases.*
[47] CDC, "Pneumococcal Disease: Prevention."
[48] Willbur H. Chen, Bernard F. Kozlovsky, Rita B. Effros, Beatrix Grubeck-Loebenstein, Robert Edelman, and Marcelo B. Sztein. "Vaccination in the elderly: an immunological perspective." *Trends in Immunology* 30 (2009): 353.
[49] Thomas Fekete, "Pneumococcal vaccine reduced pneumococcal pneumonia and associated mortality," *Annals of Internal Medicine* 152(12) (2010): JC6-5; Owen McCormack, James Meza, and Sandra Martin. "Is pneumococcal vaccine effective in nursing home patients?." *Journal of Family Practice* 52 (2003): 149-161.
[50] Chen et al., 354.
[51] Centers for Disease Control and Prevention, "Pneumococcal Disease: Prevention."

An additional problem with the current pneumococcal vaccines is that until recently it was generally accepted that vaccines for young, healthy adults would have similar effectiveness levels in older, sicker adults.[52] Yet recent studies of vaccine efficacy have shown much lower levels of effectiveness and sustained immunity in elderly adults compared with younger adult trial subjects.[53] While many vaccines have been specifically developed and tested for children, this same procedure and line of reasoning has not been applied to elderly populations.[54]

These recent findings have demonstrated the critical need for age-appropriate vaccines.[55] As the populations of both the United States and long-term care facilities increase, along with the proliferation of antibiotic-resistant strains of pneumococcal bacteria, the number of people in need of effective pneumococcal vaccines can be expected to rise dramatically.

D. Immunization Requirements: Why Focus on Residents in Long-Term Care Facilities?

In the United States, immunization requirements are state-level laws that define what vaccines must be obtained before an individual may enter a certain environment. Currently, the only requirements that are universal across the fifty states, the District of Columbia, and U.S. territories are requirements for entry into childcare and/or primary and secondary schools, although requirements for entry into colleges and universities for individuals seeking undergraduate degrees are becoming increasingly common.[56]

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[52] Chen et al., 351.
[53] Ibid.
[54] Ibid.
[55] Ibid.
[56] CDC, "Childcare and School Vaccination Requirements 2007-2008," 3.

While state-level immunization requirements only apply to children entering school or childcare, legal precedent makes it at least permissible to extend immunization requirements to any person residing within the United States.[57] However, it is often thought that many would regard such requirements for adults as overly paternalistic and of dubious enforceability.[58] Despite this tendency, based on the available scientific evidence, an effective vaccine to prevent pneumococcal disease among long-term care facility residents can be reasonably expected in the near future.[59] When such a vaccine is developed, promulgating an immunization requirement for populations residing in long-term facilities would likely be an attractive public health strategy.

Before continuing, we must understand exactly what is meant by the term "long-term care facilities." A long-term care facility will be defined as a privately or publicly funded facility, such as a nursing home, that provides residence and care to elderly and chronically ill adults who require at least minimal daily assistance. Minimal assistance includes the daily provision of meals or the general availability of medical staff. This definition includes "assisted living facilities," where individuals reside in apartment-style homes complete with kitchens, but are also typically offered shared meals and assistance with bathing, dressing, eating or toileting, as well as the proximal availability of emergency and primary care. Nursing homes, by contrast, feature more intensive care for

[57] Saad B. Omer, Daniel A. Salmon, Walter A. Orenstein, Patricia deHart, and Neal Halsey. "Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases." *The New England Journal of Medicine*, 360 (2009): 1982.
[58] John D. Lantos, Mary Anne Jackson and Christopher J. Harrison, "Why We Should Eliminate Personal Belief Exemptions to Vaccine Mandates," *Journal of Health Politics, Policy, and Law* 37 (2012): 136; Marcel Verweij, "Individual and Collective Considerations in Public Health: Influenza Vaccination in Nursing Homes," *Bioethics* 15 (2001): 537-8.
[59] Andres de Roux, B. Schmoele-Thoma, G. R. Siber, J. G. Hackell, A. Kuhnke, S. A. Baker, A. Razmpour, E. A. Emini, P. D. Fernsten, W. C. Gruber, S. Lockhart, O. Burkhardt, T. Welte, and H. M. Lode. "Comparison of Pneumococcal Conjugate Polysaccharide and Free Polysaccharide Vaccines in Elderly Adults: Conjugate Vaccine Elicits Improved Antibacterial Immune Responses and Immunological Memory." *Clinical Infectious Diseases* 46 (2008): 1015-1023.

residents, whose degree of disability is generally greater than that of residents of assisted living facilities.

Currently, in the United States there are no formal immunization requirements for nursing homes or other long-term care facilities. However, a study in 2000 highlighted the importance of standing orders, or pre-approved protocols allowing nurses and other trained medical professionals to vaccinate individuals without a doctor's order, in raising vaccination rates in long-term care facilities. As a result, the CDC recommended that standing orders be implemented in all long-term care facility settings.[60] At the same time, the Healthy People Program, a program initiated in 1990 by the Department of Health and Human Services that sets 10-year goals for improving the health and well-being of American citizens, set a goal of increasing pneumococcal immunization rates in long-term care facilities to 90% by 2010.[61] Unfortunately, even with the use of standing orders, this goal was not met.[62] As of 2010, only 66.4% of institutionalized persons aged 18 or older received the pneumococcal vaccine.[63] Thus, a requirement for pneumococcal vaccination in long-term care facilities may be necessary to raise immunization rates to the desired level.

However, requirements for vaccination in long-term care facilities pose serious ethical questions. Thus, in an effort to advance the discussion of adult vaccine requirements and prepare for this possible scenario, it will be helpful to examine three

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[60] Advisory Committee on Immunization Practices, "Use of Standing Orders Programs to Increase Adult Vaccination Rates," *Morbidity and Mortality Weekly* 49(RR01) (2000): 15-26.
[61] Centers for Disease Control and Prevention, "Healthy People: Healthy People 2000," Accessed April 1, 2014. http://www.cdc.gov/nchs/healthy_people/hp2000.htm.
[62] Centers for Disease Control and Prevention, "Healthy People: Healthy People 2010," Accessed April 1, 2014. http://www.cdc.gov/nchs/healthy_people/hp2010.htm.
[63] U.S. Department of Health and Human Services, "Immunization and Infectious Diseases: Objectives," Accessed April 1, 2014.
http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23.

prominent ethical positions that are often used in support of immunization requirements and assess whether these positions would also support the use of pneumococcal immunization requirements in long-term care facilities.

III. Three Arguments for Immunization Requirements

Immunizations are an easy and straightforward solution to many of the recent outbreaks seen within the United States.[64] For example, pertussis and measles are diseases with readily available vaccines.[65] Moreover, immunization can successfully stymie the spread of antibiotic-resistant forms of common bacterial diseases.[66] Consequently, it is important to consider prominent moral justifications for immunization requirements to determine whether implementing such a policy might be an acceptable public health action.

In justifying immunization requirements, consequentialist arguments point to the large benefits of herd immunity achieved through immunization requirements, as well as the low incidences of adverse reactions to vaccines, to support their claims.[67] Others have argued that immunization requirements may instead be justified by appealing to the harm principle.[68] The harm principle states that constraints on individual liberties may be acceptable in instances in which such constraints prevent harm to others. Although consistent with consequentialism, the harm principle is widely accepted by

[64] Omer et al.
[65] Centers for Disease Control and Prevention, "Vaccines and Immunizations: Lists of Vaccines Used in the United States." Accessed April 1, 2014. http://www.cdc.gov/vaccines/vpd-vac/vaccines-list.htm.
[66] Frieden.
[67] See: Field and Caplan (2008), Lantos, Jackson, and Harrison (2012).
[68] See: van den Hoven (2012), Krom (2011), Francis et al. (2005), and Millar (2012).

nonconsequentialists as well; indeed, it seems consistent with well-informed common sense and therefore has few detractors.

A basis for defending immunization requirements that is less well-known than consequentialism and the harm principle is Nancy Kass's ethics framework for public health.[69] Kass's framework is a practical analytic tool that takes into consideration the competing bioethical principles of beneficence, respect for autonomy, and justice. The framework is used to determine whether a public health intervention is ethical, and if so, how it can be ethically implemented. Kass outlines six steps to follow; each step asks a question of which the response aids professionals and policymakers in considering the ethical implications of a proposed public health measure, intervention, or program. The types of questions asked are intended to produce public health programs that minimally compromise one principle comparable to the justifiable satisfaction of another, while discarding any unethical alternatives.

Apart from immunization requirements for healthcare workers and in the event of pandemics, there has been little consideration of whether these or other ethical frameworks might justify immunization requirements for a certain population of adults, specifically those adults residing in long-term care facilities. While the general assumption is that the threats of vaccine-preventable infectious diseases would not justify limits on autonomy and liberty for adults in everyday, non-emergency circumstances, adults in long-term care facilities are more vulnerable than most segments of the adult population and at an increased risk of morbidity and mortality from pneumococcal disease. Meanwhile, pneumococcal vaccinations in long-term care facility residents

[69] Armand H. Matheny Antommaria, "An Ethical Analysis of Mandatory Influenza Vaccination of Health Care Personnel: Implementing Fairly and Balancing Benefits and Burdens," *American Journal of Bioethics* 13(9) (2013): 30-37.

continue to remain well below the recommended levels set by the CDC and the Healthy People program.[70]

Nonetheless, the vaccines currently recommended by the CDC have not conclusively demonstrated their ability to significantly reduce pneumococcal disease. Fortunately, newly developed conjugate vaccines are exhibiting the qualities desired in robust vaccine replacements. And while these new vaccines do not offer protection from non-bacteremic pneumococcal pneumonia, they are an exciting indicator of future technological success. In response to these expected developments, in what follows, I will argue that at least these three ethical positions would support the use of pneumococcal immunization requirements in long-term care facilities.

A. Consequentialism

A consequentialist position judges the rightness or wrongness of an action (or public policy) according to the balance of its beneficial and harmful consequences.[71] Consequentialist reasoning is a common justification for both public health measures and public policies more generally.[72] Many in the scientific community support their positions for or against new policy measures with arguments founded in consequentialism.

Consequentialist reasoning has been used to justify immunization requirements in the United States for over a century. In 1905, the Supreme Court heard *Jacobson vs.*

[70] U.S. Department of Health and Human Services, "Immunization and Infectious Diseases: Objectives: IID-13.1 Increase the percentage of adults who are vaccinated against pneumococcal disease," Accessed April 1, 2014. http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23#569814.
[71] Beauchamp and Childress, 355.
[72] Tom L. Beauchamp and James F. Childress. *Principles of Biomedical Ethics*, 7th ed., New York: Oxford University Press, 2013, 354.

Massachusetts and upheld the ability of the state to implement immunization requirements to protect the health of the public.[73] In this landmark case, the court justified their ruling on the basis of a consequentialist calculation of harmful and beneficial outcomes. Today, when deciding whether or not to recommend a new vaccine, state immunization advisory boards, as well as the ACIP, examine data across an number of parameters including disease burden, efficacy, safety, and cost-effectiveness to determine which policy action is likely to produce the best outcome for the community.[74]

In weighing the benefits of a vaccine policy, defenders of immunization requirements often highlight a phenomenon known as herd, or community, immunity.[75] Herd immunity is defined as the state in which a large majority of a community is resilient, often through vaccination, to a particular disease, thereby limiting the ability of the pathogen to find a suitable host within the group.[76] In other words, by preventing incipient infection through herd immunity, a disease is unable to acquire the necessary foothold to effectively transmit throughout a population. Once vaccination rates attain this threshold level even unvaccinated individuals and those who have been immunized yet do not naturally produce the necessary levels of antibodies to allow for an adequate immunological defense are offered protection from the disease.[77] [78]

The level of vaccination needed in a community to achieve herd immunity is very specific; even a small decrease in the number of people immunized can have a serious

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[73] Lantos, Jackson, and Harrison, 134.
[74] Centers for Disease Control and Prevention, "Advisory Committee on Immunization Practices (ACIP): Evidence-Bases Recommendations---GRADE," Accessed April 1, 2014. http://www.cdc.gov/vaccines/acip/recs/GRADE/about-grade.html.
[75] Field and Caplan, 115.
[76] U.S. Department of Health and Human Services, "Community Immunity ("Herd Immunity")," Accessed April 1, 2014. http://www.vaccines.gov/basics/protection/index.html.
[77] HHS, "Community Immunity ("Herd Immunity")."
[78] Field and Caplan, 115.

and devastating impact on the entire community.[79] Population migration, extreme climate conditions, and even the oscillating effectiveness of immunizations are all examples of epidemiological factors that can interact to amplify the susceptibility of a community to a communicable disease.[80] Consequently, herd immunity may be continually in flux unless high levels of immunization are sustained. Along consequentialist reasoning, immunization requirements are often determined to be ethically justified in so much as the benefits received by the promotion of herd immunity in the form of good health and well-being among the entire populace far outweigh a vaccine requirement's impositions on the liberties of individuals.

For a proposal recommending a pneumococcal immunization requirement in long-term care facilities to succeed on consequentialist grounds, the policy must robustly satisfy several criteria. First, it must be demonstrated that pneumococcal bacteria cause severe disease associated with significant morbidity and mortality in long-term care facility residents. Second, the pneumococcal vaccine must be proven to bolster herd immunity within long-term care facility residents and effectively reduce disease transmission rates. And third, the potential harm incurred from the immunization requirement must be minimal. If an immunization requirement is favorable on all of these criteria, the policy will likely be justifiable from a consequentialist perspective.

The first point examines the severity of the disease in the population. Notably, over 95% of all pneumococcal deaths and 90% of the cases of invasive pneumococcal disease in the United States occur within the adult segment of the population.[81]

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[79] Ibid.
[80] Mark Fischetti, "Too Many Children Go Unvaccinated," *Scientific American,* May 14, 2013. http://www.scientificamerican.com/article/too-many-children-go-unvaccinated/.
[81] CDC, "Pneumococcal Disease: Fast Facts."

Approximately 900,000 cases of pneumococcal pneumonia occur annually in the U.S., with as many as 400,000 hospitalizations.[82] In 2011 alone, invasive pneumococcal disease resulted in 37,000 cases and 4,000 deaths.[83] Of the 37,000 cases in 2011, 31% of the cases were shown to be resistant to one or more antibiotics.[84] Moreover, the elderly, chronically ill, and others residing in long-term care facilities are at an increased risk for pneumococcal disease. Due to its high morbidity and mortality rates, pneumonia has been tellingly called "the most important of the common infections affecting nursing homes."[85]

Second, assuming we have clearly shown that pneumococcal disease is an adequately severe disease affecting long-term care facility residents, we must also show that pneumococcal disease is preventable through vaccination and herd immunity. Today, vaccines for pneumococcal disease are less than ideal, but it can be reasonably predicted that advances in biotechnology will greatly improve vaccines in the near future. With these new vaccines and sufficiently high levels of vaccination, herd immunity against pneumococcal disease is possible.[86] However, over 70% of adults asymptomatically carry pneumococcal bacteria in their throats or noses, thus high vaccination rates will need to be consistently sustained to maintain herd immunity.[87]

Third, from a consequentialist perspective, to justify a requirement, the potential harm from vaccination must be minimal. According to current policy, before a vaccine is

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[82] CDC, "Pneumococcal Disease: Fast Facts."; CDC, *Epidemiology and Prevention of Vaccine-Preventable Diseases.*; S.S. Huang, K.M. Johnson, G.T. Ray, P. Wroe, T.A. Lieu, M.R. Moore, E.R. Zell, J.A. Linder, C.G. Grijalva, J.P. Metlay, and J.A. Finkelstein. "Healthcare utilization and cost of pneumococcal disease in the United States." *Vaccine* 29 (2011): 3398-412.
[83] Centers for Disease Control and Prevention, "Pneumococcal Disease: Drug Resistance," Accessed November 24, 2013. http://www.cdc.gov/pneumococcal/drug-resistance.html.; CDC, "Pneumococcal Disease: Fast Facts."
[84] CDC, "Pneumococcal Disease: Drug Resistance."
[85] Krishnan Raghavendran, Joseph M. Mylotte, and Frank A. Scannapieco, "Nursing home-associated pneumonia, hospital-acquired pneumonia and ventilator-associated pneumonia: the contribution of dental biofilms and periodontal inflammation," *Periodontal* 44 (2000, 2007): 165.
[86] HHS, "Community Immunity ("Herd Immunity")."
[87] CDC, "Pneumococcal Disease: *Streptococcus pneumonia*."

recommended for use in the United States, robust scientific data demonstrating a vaccine's safety must be thoroughly examined by both the U.S. Food and Drug Administration and the CDC.[88] While unforeseen adverse events may be inevitable in a large-scale vaccination campaign, any new vaccines considered for such a requirement can be presumed to be generally safe.[89]

In addition to the preceding arguments, a consequentialist public health ethicist might also consider the financial aspects of an immunization requirement as part of an overall cost-benefit evaluation. Much clinical research is aimed at developing more affordable vaccines. For example, newer conjugate vaccines are considerably less expensive than the older polysaccharide vaccines.[90] A 2013 study found that PCV13 would provide a total savings of $5 million per cohort of approximately 300,000 immunized individuals through the mitigation and reduction of pneumococcal disease.[91] Therefore, it can be reasonably expected that the cost-benefits from these next generation vaccines will be even greater.

Due to the significant morbidity and mortality caused by pneumococcal disease among long-term care facility residents, the expectation that next generation vaccines will successfully, safely, and affordably prevent the disease, and the additional benefits achieved by herd immunity as a result of high vaccination levels, a consequentialist analysis supports the implementation of pneumococcal immunization requirements in

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[88] Ibid.
[89] CDC, "Advisory Committee on Immunization Practices (ACIP): Evidence-Bases Recommendations---GRADE."
[90] Bo-Hyun Cho, Charles Stoecker, Ruth Link-Gelles, and Matthew R. Moore, "Cost-effectiveness of administering 13-valent pneumococcal conjugate vaccine in addition to 23-valent pneumococcal polysaccharide vaccine to adults with immunocompromising conditions," *Vaccine* 31 (2013): 6011.; Kenneth J. Smith, Mary Patricia Nowalk, Mahlon Raymund, and Richard K. Zimmerman. "Cost-effectiveness of pneumococcal conjugate vaccination in immunocompromised adults," *Vaccine* 31 (2013): 3950.
[91] Cho et al., 6011.

long-term care facilities. Before continuing, it will be important to consider under what circumstances a person could justifiably opt-out of the requirement according to this position.

In the United States, exemptions to school immunization requirements may be made in the event of medical contraindications, as well as in instances of religious or philosophical objection.[92] A consequentialist perspective would likely justify medical exemptions since the harm that could occur to individuals as a result of vaccination is significant and protection from the disease can be offered through herd immunity. Moreover, medical exemptions themselves are unlikely to threaten herd immunity due to the small percentage of the population that requires such exemptions. For example, in 2013, the CDC reported that the mean medical exemption level for kindergarteners per state was 0.3%, compared with 1.5% for non-medical exemptions.[93] However, a consequentialist position would likely not consider any non-medical exemptions justified, as these exemptions could potentially detract from the overall good that would be produced from the requirement.

Important to this claim is the degree of autonomy that can be afforded to persons in long-term care facilities. The autonomous state of long-term care facility residents may be less than those of younger, healthier adults due to a decline in mental abilities related to age or the presence of other mental handicaps. For these individuals, this type of immunization policy might not pose a serious issue.[94] However, not all long-term care

[92] Centers for Disease Control and Prevention. "Immunization Managers: Requirements & Laws." Accessed April 1, 2014. http://www.cdc.gov/vaccines/imz-managers/laws/index.html.
[93] Ranee Seither, Lauren Shaw, Cynthia L. Knighton, Stacie M. Gerby, and Shannon Stokley. "Vaccination Coverage Among Children in Kindergarten --- United States, 2012-2013 School Year." *Morbidity and Mortality Weekly Report* 62 (2013): 607-612.
[94] David DeGrazia, *Human Identity and Bioethics,* New York: Cambridge University Press, 2005, 5.

facility residents will fit into this category. Some enter long-term care facilities due to severe injuries or handicaps that do not affect their mental capacities. Others with declines in their mental capacities may have clearly expressed their autonomy in the past, such as through an advanced directive. In this way, the consequentialist position may be unacceptably strict for many people because it does not allow sufficient space for conscientious practice of religious or philosophical beliefs. This is an important and serious objection, but before we address it, it will be constructive to present our other two positions first and return to this objection after both have been comprehensively outlined.

B. Appeal to the Harm Principle

Immunization requirements have also been justified by appealing to the harm principle. The harm principle states: "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others."[95] In accordance with the harm principle, liberal democracies, such as the United States, generally accept that government intrusion into the lives of individuals is acceptable only in instances when such intrusion is reasonably related to the goal of preventing harm to others.[96] In other words, the prevention of harm can serve as a justification for government intrusion, even if other necessary conditions must be met for government intrusion to be considered justified.

The harm principle has two aspects that are worth distinguishing. One aspect speaks to the claim that liberty should not be restricted unless necessary—where

[95] John Stuart Mill, *On Liberty,* Harvard Classics (online edition), 1909, 29. http://www.constitution.org/jsm/liberty.htm.
[96] Marcel Verweij, "Individual and Collective Considerations in Public Health: Influenza Vaccination in Nursing Homes," *Bioethics* 15 (2001): 540.

necessity is cashed out in terms of harm prevention. This libertarian notion values the individual as the bearer of negative rights. From this stance, restrictions on liberty by a government must be necessary for them to be justified. The second aspect of the harm principle refers to the concept that a substantial threat of harm offers a *sufficient* reason to limit liberty. With this second aspect there may be other necessary conditions to limit liberty, such as minimizing restrictions on liberty consistent with the goal of preventing harm. Generally accepted on well-informed common sense grounds, this second position allows for a proactive government role in preventing harm. To this end, when a government identifies a substantial threat of harm, it may be acceptable for the government to place restrictions on an individual's liberty to prevent the occurrence of the harm.

In terms of public health and infectious diseases, government actions to prevent or reduce morbidity and mortality rates among the general public are often justified by this second aspect of the harm principle.[97] Before applying the harm principle to pneumococcal immunization requirements in long-term care facilities, it will be useful to examine whether or not the harm principle can serve as appropriate justification for immunization requirements in the first place.

Verweij has been one of the more prominent opponents of using the harm principle to justify immunization requirements. Verweij cites Feinberg when he defines a harm to be "when a setback to interests results from an action (or omission) that is *wrong*" (his emphasis).[98] Feinberg himself states that harm, as meant by the harm principle, refers to "only setbacks of interests that are wrongs, and wrongs that are set

[97] Madison Powers, Ruth Faden, and Yashar Saghai, "Liberty, Mill, and the Framework of Public Health Ethics," *Public Health Ethics* 5 (2012): 6.
[98] Ibid.

backs to interests."[99] It is clear that transmitting an infectious disease to a person results in a harm in so much as having the disease sets back the interests of the (newly) infected person, but it may not be a wrong. Verweij claims, "forgoing vaccination will only be considered morally wrong if such forgoing involved considerable risks to others, and if the vaccination of a person would significantly reduce these risks to others."[100] In the event of low vaccination rates, Verweij states that his vaccination would have little effect on your chances of contracting the disease.[101] However, it would contribute to your protection. But the contribution is only significant when "there is already a *strong protection within our whole group* (his emphasis)."[102]

In medicine, actions that result in "intentionally imposing unreasonable risks of harm" or "unintentionally but carelessly imposing risks of harm" are known as negligence.[103] In general, harming is wrongful when it is intentional or negligent (intentional harming is sometimes justified, however, such as in instances of justified punishment or self-defense). In other words, when one takes excessive risks, intentionally or unintentionally but carelessly, the action is usually negligent, and, for that reason, wrong. For example, it is wrong for me to drive my car 90 miles per hour in a residential neighborhood as I am exposing others to excessive risks without their consent; hence, the justified adoption of speed limits.[104]

In a long-term care facility setting, a resident (or their proxy decision-maker) who is aware of the harm caused by infection from pneumococcal bacteria and fails to

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[99] Joel Feinberg, *Harm to Others: The Moral Limits of Criminal Law,* New York: Oxford University Press, 1984, 36.
[100] Ibid.
[101] Ibid.
[102] Ibid.
[103] Beauchamp and Childress, 155.
[104] Ibid.

vaccinate may be intentionally imposing excessive risks on other residents without their consent. Individuals are vectors of disease transmission. Regardless of whether vaccination rates are high or low, vaccination prevents an individual from transmitting the disease. The possibility for transmission of pneumococcal disease is much higher in long-term care facilities given the age, health status, and community living situation of the residents. By intentionally imposing an excessive risk of significant harm (as a known vector for pneumococcal disease transmission in a setting extraordinarily conducive to disease transmission) on others in the long-term care facility without their consent, the individual, in forgoing vaccination, is committing an act of negligence. Thus, the action is morally wrong. In other words, because residents of long-term care facilities are at an increased risk for contracting (significantly harmful) pneumococcal disease beyond those normal risks of participating in everyday society, refusing vaccination and leaving oneself in a position to actively transmit the disease is negligent. Therefore, in at least this particular circumstance, it would seem that forgoing vaccination is a wrongful harm.

In keeping with the common sense aspect of the harm principle, Luyten et al. have argued that before the decision not to be vaccinated can be viewed as a threat to others, "(i) it has to be shown that an unimmunized individual is a serious health threat to others that goes beyond the normal risks of participating in society and (ii) those who are at risk are unable to take precautionary measures themselves."[105] Assuming an autonomous decision-maker, Luyten et al. present four questions that they argue must be answered favorably for an immunization requirement to be justified from a liberal perspective: "(i) Have voluntary measures failed? (ii) Are those unwilling to become vaccinated to be

[105] Jeroen Luyten, Antoon Vandevelde, Pierre Van Damme, and Philippe Beutels, "Vaccination Policy and Ethical Challenges Posed by Herd Immunity, Suboptimal Uptake and Subgroup Targeting," *Public Health Ethics* 4 (2011): 283.

considered as autonomous decision makers? If so, (iii) is the burden imposed on others by not being vaccinated to be considered a harm (directly through being a medical risk for others or indirectly through not contributing to a collective good like herd immunity)? And (iv) are those at risk unable to protect themselves?"[106]

The first question posed by Luyten et al. has already been addressed in the preceding sections of this paper. In short, voluntary vaccination campaigns have continuously failed to raise pneumococcal vaccination rates to levels that would confer herd immunity. In response to the second question, some residents of a long-term care facility may not be fully autonomous due to a reduced mental capacity or handicap, but this will certainly not be true for all residents. It will be better then to consider all residents as autonomous decision-makers in so much as those who are not fully autonomous would be required to have a proxy decision-maker before any medical intervention (vaccination or otherwise) could be carried out.[107]

The third question has also been addressed above, but an additional point is worth making. By offering protection from an infectious disease to the whole community, in this case the long-term care facility, herd immunity is a collective good. Therefore, non-participation in efforts to achieve herd immunity is a harm in that it fails to ensure the achievement of herd immunity.[108] Thus, forgoing vaccination is not only a harm because it is negligent, but also because by refusing to vaccinate one fails to contribute to a collective good.

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[106] Luyten et al., 284.
[107] Beauchamp and Childress, 188.
[108] Dawson, A. and Y. Paul, "Mass public health programmes and the obligations of sponsoring and participating organisations," *Journal of Medical Ethics* 32 (2006): 580-583.

Finally, the fourth question assesses whether or not the most vulnerable persons are able to protect themselves. As the community in this instance is well-defined, and some individuals within this well-defined community are likely to be unable to be vaccinated for some good reason, it is easy to identify who the vaccination is protecting from harm. With all four questions favorably answered, it seems a harm principle justification would support the use of an immunization requirement for pneumococcal vaccines in long-term care facilities.

As with the consequentialist argument, it is important to examine which, if any, exemptions would be justified under the harm principle. Medical exemptions are likely justifiable as they prevent individuals from direct harm. However, with or without herd immunity, the unvaccinated individual who refuses to vaccinate poses a significant threat of harm to other individuals. Therefore, religious or philosophical exemptions would likely not be justified.

Appealing to the harm principle, like our consequentialist argument, opens up an important objection; namely, immunization requirements under this justification do not allow adequate space for the practice of individual religious or philosophical beliefs. Liberals hold diversity in values and opinions in high regard, so a non-trivial restriction on the freedom to exercise those values could strike many as disrespecting autonomy. In fact, this freedom might be so essential to a liberal ideology that many may reject such a policy on these grounds alone. For this reason, it is important to evaluate a third argument for immunization requirements.

C. Kass's Ethics Framework for Public Health

A third approach that has garnered some prominence in the public health ethics literature defending immunization requirements is Kass's ethics framework for public health. The ethics framework for public health, henceforth referred to as the 'framework,' is a practical analytic tool focused on balancing the bioethical principles of beneficence, respect for autonomy, and justice.[109] To maintain the morality of any public health program, it is essential that each principle be satisfied to the greatest extent possible. However, as the promotion of one principle may conflict with the fulfillment of another, the framework offers us a means of comparatively weighing these principles to determine a morally justified policy option.[110]

Citing Beauchamp and Walters, Kass and Gielen argue that in evaluating a policy, beneficence calls for assessing the benefits and harms of a policy to evaluate if, when balanced, the policy is beneficial.[111] Respecting autonomy requires respecting persons as autonomous agents with decision-making capacities and privacy rights, including rights to discretion and confidentiality.[112] Justice compels us to treat people fairly; equitably-situated groups or individuals ought not to be subjected to inequitable treatment without adequate justification.[113] In relation to public policy, justice demands that policies are implemented fairly and any disproportionate impacts to certain groups, favorable or unfavorable, are satisfactorily justified.[114]

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[109] Nancy E. Kass and Andrea Carlson Gielen, "The Ethics of Contact Tracing Programs and Their Implications for Women," *Duke Journal of Gender Law and Policy* 5 (1998): 90.
[110] Ibid.
[111] Tom L. Beauchamp and LeRoy Walters, "Ethical Theory and Bioethics" in *Contemporary Issues in Bioethics,* 4th ed., Tom L. Beauchamp and LeRoy Walters, eds., Belmont: Wadsworth Publishing Company, 1994 cited by Nancy E. Kass and Andrea Carlson Gielen, "The Ethics of Contact Tracing Programs and Their Implications for Women," *Duke Journal of Gender Law and Policy* 5 (1998): 92.
[112] Kass and Gielen, 95.
[113] Ibid., 98.
[114] Ibid.

Overall, Kass devised her framework to assess whether a proposed public health intervention is ethically acceptable on the balance of these three principles and, if so, how best to enact the intervention.[115] Composed of questions and steps, each question of each step in the framework must be justifiably answered in order to arrive at an ethical policy proposal at the completion of the sixth step. We will now go through each of the six steps to determine whether a pneumococcal immunization requirement in long-term care facilities would be justified according to Kass's framework.

Step 1: What are the public health goals?

The first step of the framework is to identify the goals of the proposed intervention.[116] Kass argues that the goals of an ethically sound intervention should reflect some improvement in the public health status of a population, rather than, for example, attempting to achieve more intermediary goals of raising awareness about a particular disease or behavior.[117] To ensure they are properly defined, Kass suggests that goals are framed in terms of reductions in morbidity and mortality.[118]

Pneumococcal disease and influenza are the 8th leading cause of death in the United States. Adults, particularly the elderly and those in long-term care facilities, suffer the overwhelming majority of pneumococcal disease cases in the United States, and the associated burden of morbidity and mortality is considerable.[119] As a result, the goal of implementing an immunization requirement in long-term care facilities would be to

[115] Kass, 1777.
[116] Ibid.
[117] Ibid.
[118] Ibid.
[119] CDC, "Pneumococcal Disease: Fast Facts."

reduce morbidity and mortality caused by pneumococcal disease in long-term care facility populations.

Step 2: How effective is the program in achieving its goals?

The second step of the framework examines the assumptions made to support the use of the public health intervention.[120] As opposed to relying on instinctual or experiential presumptions, this step requires us to thoroughly analyze available quantitative and qualitative data to determine if the available evidence supports the use of our proposed intervention.[121] Accordingly, Kass states that empirical evidence supporting an intervention must be proportionate to the potential restrictions on liberty proposed by the intervention.[122] In other words, the more coercive the proposed measure, the stronger the evidence needed to support it. If the data is not sufficiently sound or the analysis acceptably supportive, then the intervention cannot be ethically implemented.[123]

For pneumococcal immunization requirements in long-term care facilities, this second step demands that we look beyond the effectiveness of a vaccine in reducing pneumococcal disease in long-term care facility populations. Instead, we must determine the effectiveness of immunization requirements generally in raising vaccination rates and encouraging herd immunity. It would be especially prudent to look at data on the effectiveness of immunization requirements in encouraging herd immunity among long-term care facility residents in settings similar to those found in the United States.

[120] Ibid.
[121] Ibid.
[122] Ibid.
[123] Ibid, 1779.

Vaccine uptake for adults in long-term care facilities has been consistently low[124] resulting in frequent outbreaks of pneumococcal disease in these settings.[125] Efforts have been made by states to improve vaccination coverage among residents by implementing standing orders to vaccinate individuals upon entering a long-term care facility.[126] Unfortunately, this strategy has been inefficiently or inconsistently implemented or enforced, keeping pneumococcal vaccination rates considerably lower than levels needed to induce and sustain herd immunity within these communities.[127]

In comparison, school immunization requirements, when sufficiently enforced, have been extremely effective in increasing childhood vaccination rates in the United States.[128] Plausibly, similar vaccination requirements for long-term care facilities could be effective in increasing immunization rates among these communities. Additionally, a recent study in the United Kingdom found that introducing immunization requirements to nursing homes was effective in increasing the vaccination rates of the residents and reducing the morbidity and mortality caused by vaccine-preventable diseases, further supporting our assertion that introducing an immunization requirement into long-term care facilities in the United States would reduce the effects of pneumococcal disease.[129]

Thus, it can be reasonably assumed that a pneumococcal vaccination requirement for long-term care facility residents would be effective in achieving the intended goal of the proposed intervention as the available evidence indicates that immunization requirements in long-term care facilities would likely increase the vaccination rates of

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[124] HHS, "Immunization and Infectious Diseases: Objectives."
[125] Bresnitz et al.
[126] Advisory Committee on Immunization Practices.
[127] Bresnitz et al.; HHS, "Immunization and Infectious Diseases: Objectives."
[128] CDC, *Epidemiology and Prevention of Vaccine-Preventable Diseases.*
[129] Amir Shroufi, Joanna Copping, Roberto Vivancos and Richard CB Slack, "Influenza and pneumococcal vaccine uptake among nursing home residents in Nottingham, England: a postal questionnaire survey," *BMC Geriatrics* 8(11) (2008): 4.

residents and, assuming the effectiveness of next generation vaccines, greatly reduce the morbidity and mortality from pneumococcal disease in this population.

Step 3: What are the known or potential burdens of the program?

Kass's third step instructs us to pinpoint the burdens and/or harms associated with the proposed public health intervention.[130] With a public health intervention, it is thoroughly understood that unequal burdens may be unavoidable if its goals are to be achieved.[131] Regardless, any public health intervention seeking ethical justification must demonstrate that any resulting unequal burdens are, in fact, unavoidable and necessary to achieve the specified public health goal.[132] Once the burdens and/or harms have been carefully and thoughtfully identified, all subsequent steps (steps 4-6) will be focused on minimizing, fairly implementing, and balancing the identified burdens and/or harms. According to Kass, we can categorize the most ethically serious burdens and/or harms into three broad groups, or 'risks': risks to privacy and confidentiality; risks to liberty and self-determination; and risks to justice.[133]

First, it is reasonable to claim that immunization requirements do not pose significant risks to privacy or confidentiality. While doctors and some administrators of long-term care facilities would require access to a patient's vaccination status and other medically necessary information, requiring the disclosure of this information to long-term care facility medical staff would not pose an excessive risk to privacy or confidentiality as long-term care facilities can be reasonably expected to (necessarily) obtain medical

[130] Kass, 1779.
[131] Ibid.
[132] Ibid.
[133] Ibid., 1779.

records before admitting a new resident. Moreover, there would be no need to disclose immunization status in connection with any identifying details to any other party.

Justice is also unlikely to be threatened by an immunization requirement for long-term care facilities. An immunization requirement could raise issues of justice if families of individuals needing long-term care (or the individuals themselves) oppose vaccination, but the family does not have the ability or resources to care for the would-be resident at home. In this way requiring a vaccination to enter a long-term care facility could place unfair burdens on these individuals and their families. On the other hand, all health care institutions need some rules. If a rule for an immunization requirement is independently reasonable, it may not be unjust to refuse care to someone who refuses to follow that rule.

A second concern related to justice is that immunization requirements could unfairly burden less affluent families because of the costs associated with receiving a vaccine. Fortunately, for many long-term care facility residents, Medicare will cover the expense of pneumococcal vaccines at no cost to the patient.[134] For those not insured by Medicare, under the 2010 Patient Protection and Affordable Care Act (ACA), private insurance plans must cover all vaccines recommended by the ACIP at no cost to the patient in the next plan year that falls one year after a recommendation is made, when the vaccine is administered by network providers.[135] This scenario creates a potential loophole for individuals with private insurance and no Medicare coverage in the (up to 24) months that fall between when the next generation pneumococcal vaccine is

[134] Centers for Medicare & Medicaid Services, "Immunizations," Accessed April 1, 2014. http://www.cms.gov/Medicare/Prevention/Immunizations/index.html?redirect=/immunizations/.
[135]U.S. Department of Health and Human Services, "The Affordable Care Act and Immunization," Accessed April 1, 2014. http://www.hhs.gov/healthcare/facts/factsheets/2010/09/The-Affordable-Care-Act-and-Immunization.html.

recommended by the ACIP and the next plan year that begins one year after the recommendation is made.[136]

Furthermore, immunization requirements pose significant risks to liberty and self-determination. Notably, with the implementation of an immunization requirement in long-term care facility settings, a simple refusal to vaccinate would no longer be sufficient to avoid vaccination and, in fact, could result in an individual being prohibited from entering a long-term care facility. In such cases, an immunization requirement could cause serious internal dilemmas for individuals and/or their families.

Finally, outside of the three risk categories described by Kass, immunization requirements pose risks of physical harm to long-term care facility residents as a result of adverse reactions to vaccines. Though incidences of severe adverse reactions to vaccines are very low, the potential still exists and thus must be identified as an important potential harm to long-term care facility residents.

Step 4: Can the burdens be minimized? Or are there other approaches?

Step four calls for us to explore the ways (if any) to minimize the burdens and/or harms identified in step three. According to Kass, we are morally required to select the public health program that poses the fewest threats to other moral claims, such as liberty, opportunity, justice, and privacy to name a few.[137] For example, it would be unethical to implement a mandatory program if a voluntary program demonstrated near equal effectiveness.[138] Respectively, we must consider if there are other approaches to raising vaccination rates in long-term care facilities that might reduce the burdens and/or harms

[136] HHS, "The Affordable Care Act and Immunizations."
[137] Kass, 1780.
[138] Ibid.

associated with an immunization requirement while still achieving similar results, or at least not substantially reducing the likelihood of achieving our goal of reducing morbidity and mortality associated with pneumococcal disease in long-term care facilities.[139]

As previously discussed, pneumococcal vaccination rates in long-term care facilities have failed to reach the 90% goal established by the United States' Healthy People program. While the use of standing orders has been shown to be effective at increasing vaccination rates in long-term care facility settings, vaccination rates remain well below target levels. On the other hand, school and childcare immunization requirements have been extremely effective in raising immunization rates among children.[140] Therefore, the failure of standing orders to raise vaccination rates to target levels coupled with the success of school vaccination requirements indicates that an immunization requirement for pneumococcal vaccines is likely a necessary approach to achieve our goal. Without viable alternatives to increase vaccination rates, this analysis will only consider how the burdens and potential harms of an immunization requirement can be minimized.

One way to minimize the burdens of an immunization requirement program, without greatly reducing the efficacy of the program, is to allow for medical, religious, and philosophical exemptions. These exemptions would allow patients the option to refuse vaccination while still allowing them to reside in a long-term care facility. However, to ensure herd immunity would not be threatened by these exemptions, vaccine requirements would need to be consistently enforced with strict parameters for obtaining exemptions.

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[139] Ibid.

[140] CDC, "Vaccines and Immunizations: What Would Happen If We Stopped Vaccinations?"

To address the vaccine coverage loophole, it would be in states' best interests to offer funding to long-term care facilities to cover the costs of vaccination for patients with private insurance unable to cover vaccination costs during the relatively short window between the ACIP recommendation and the (up to) 24 months before private insurers would be required to cover the cost of receiving the vaccine. Such an investment would be beneficial for states as, by offering vaccinations to residents, it would likely reduce costs associated with pneumococcal outbreaks in long-term care facilities. Moreover, as most long-term care facility residents will be covered by Medicare or have the financial means to cover the cost of vaccination themselves, very few long-term care facility residents would be in need of vaccination coverage funding.

Finally, the potential of adverse reactions to the vaccine poses risks of harm to the residents. The risk of adverse events may be minimized by requiring that injections be given in the presence of a trained nurse or other medical care provider rather than a home health aide. Trained medical personnel would have access to health records allowing them to determine whether the potential recipient of the vaccination would be at risk for an adverse reaction. Requiring a trained medical professional's presence in the administration of immunizations would also help to identify serious adverse events more quickly and better ensure that appropriate medical action is taken as soon as possible.

Step 5: Is the program implemented fairly?

The fifth step of Kass's framework highlights concerns of distributive justice.[141] Kass argues that the proposed public health intervention must also be fairly implemented. To ensure compliance with the immunization requirements in all long-term care facilities,

[141] Kass, 1780.

resources to encourage long-term care facilities to comply with the new policy must be equally distributed among stakeholders. State offices responsible for overseeing licensures for long-term care facilities should incorporate compliance with state regulations for immunization requirements into their review protocol for certification, better ensuring that requirements are being fairly and consistently implemented across the state.

Punishments for failure to comply with immunization requirements, such as failing to ensure individuals are vaccinated prior to entering a long-term care facility or falsifying documents, ought to be clearly communicated to long-term care facility administrators and handed down evenly across facilities. Similarly, punishments should be proportionate to the severity of the noncompliance. It would certainly be undesirable to have a system in which long-term care facilities drastically reduced the rate at which they accepted new residents simply because they could not risk receiving a noncompliance penalty as a result of an unintentional mistake or clerical error.

Step 6: How can the benefits and burdens of a program be fairly balanced?

In step six, Kass recommends the use of an open, democratic process in an effort to further identify as well as fairly balance the benefits and burdens of an intervention.[142] In alignment with our democratic principles, before an intervention is implemented, we are likely obligated to hold hearings and open forums to allow minority and underrepresented voices to be heard before final policy decisions are made.[143] Dissent for the intervention should be anticipated at these open forums, and may even be encouraged,

[142] Ibid., 1781.
[143] Ibid.

but dissent in and of itself is not enough to prevent the intervention's implementation.[144] Instead, the forum's purpose is to highlight the perceived and actual benefits and burdens of an intervention. Those benefits and burdens can then be evaluated and, if necessary, actions should be taken to fairly balance them.[145]

However, even before a forum is held, public health professionals ought to try to fairly balance any anticipated burdens and benefits of an intervention. In the case of an immunization requirement, many of those who are burdened by the requirement also stand to benefit. Vaccination does not only protect the individual, but also those who cannot be vaccinated. This logically entails an imbalance between the burdens of those who can be vaccinated and the benefits of those who cannot. Unfortunately, this imbalance of burdens and benefits is unavoidable for persons who cannot receive the vaccination due to medical contraindications. The situation becomes more complicated when considering persons who claim religious or philosophical objections to vaccination. In one regard, the elimination of non-medical exemptions would likely unfairly burden those who would have claimed them. On the other hand, if exemptions are relatively easy to obtain, it seems that the burden would then rest solely on those who can and will be vaccinated voluntarily. In an effort to balance the scales, religious and philosophical exemptions might be more strictly regulated and involve more than minimal effort to obtain. A practical policy proposal of this sort will be discussed in Section V.

According to Kass, in addition to fairly balancing the benefits and burdens of an intervention, a successful public health department will also maintain the public's trust.[146] This is particularly relevant for immunization requirements. In recent years, more parents

[144] Ibid.
[145] Ibid.
[146] Kass, 1781.

have been taking advantage of school vaccination requirement exemptions than ever before, most of them claiming philosophical exemptions.[147] In states where philosophical exemptions are especially common, parents cite a variety of reasons for not vaccinating or delaying the vaccination of their children from simply forgetting a vaccination was required to a belief that all vaccinations are poisonous.[148] Many fears of vaccination have no scientific backing, but do point to a larger problem: a general distrust in the government may in some way be contributing to an increase in school immunization requirement exemptions.[149]

Increases in philosophical exemptions coupled with the outspokenness of those opposed to childhood vaccination and the prominence of libertarian ideologies in many mass media outlets could lead one to plausibly conclude that resistance to adult immunization requirements would be strong in the United States. However, in reality, the idea of immunization requirements for adults may not be so unpopular. A study of school district employees in Utah on their opinions of vaccine requirements for school administrators found that over 45% of employees agreed with vaccine requirements, while only 24.4% were in opposition.[150] Therefore, it is possible that the active distribution of information on the benefits and risks associated with vaccines and immunization requirements might be an advantageous advocacy tactic. An educational campaign of this sort would serve to improve the public's knowledge of immunization

[147] Omer et al., 1984.
[148] Omer et al., 1985.; Cindy Hadish, "Preventable diseases on the rise as more parents defer, refuse vaccines," *The Gazette*, October 25, 2011. http://thegazette.com/2011/10/25/preventable-diseases-on-the-rise-as-more-parents-defer-refuse-vaccines/.
[149] Hadish.; Omer et al., 1985.
[150] Karlen E. Luthy, Eli Thornton, Renea L. Beckstrand, Janelle Macintosh, and Richard G. Larkin, "Rural School Employees' Status, Awareness, and Perceptions of Adult Vaccinations," *The Journal of School Nursing* 29 (2013): 298.

policymaking while also bolstering the public's trust in the government to make decisions regarding public health issues.

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After a thorough examination of the consequentialist argument, appeal to the harm principle, and Kass's ethics framework for public health, we can conclude that at least some kind of immunization requirement would likely be ethically justifiable (once next generation pneumococcal vaccines have been developed, tested, licensed, and recommended). While this analysis is not intended to override any future arguments for less coercive measures that may in time prove to be equally as effective at increasing vaccination rates as vaccination requirements, currently, an immunization requirement for long-term care facility residents would be a beneficial and ethical approach to increasing pneumococcal vaccination rates pending the development of an improved, next generation vaccine.

There are notable and serious objections that have not yet been adequately addressed in the preceding presentation of the three positions. The following section will give these objections their appropriate consideration.

IV. Objections

There may be good reason to accept immunization requirements in long-term care facilities, but this type of public health intervention still raises serious concerns. In what follows, I will address what I see to be the most important objections to a proposal for an immunization requirement.

First, some opponents of immunization requirements claim that these requirements violate a person's right to bodily integrity or rights of informed consent.[151] While rights of informed consent justify significant constraints on medical practice and policymaking, they generally do not permit an individual to impose a significant risk of harm on others.[152] Flanigan states this point well, "Just as patients' rights do not entitle a person to willfully contract a contagious disease and expose others to the risks of transmission, informed consent does not entitle patients to expose others to risks of transmission with their refusal choices."[153]

Second, others object to consequentialist and harm principle-based arguments claiming that neither position allows adequate space for individual religious or philosophical practice. Though an infectious disease may present a considerable threat, these objectors assert a value of philosophical and religious liberty over liberty-limiting public health aims.[154] This is a very serious objection that is likely to trouble many people.

One response to this objection is to make a plea to fairness. It is clear that all scientific evidence concludes that pneumococcal disease is an infectious disease that causes substantial morbidity and mortality. It is also clear that while immunization laws impose a constraint on individual liberty, failure to immunize (and subsequent disease transmission) can also be constraining to individual liberty. What is less clear is the incremental contributive value of one additional immunized individual to the overall

[151] Jessica Flanigan, "A Defense of Compulsory Vaccination," *HEC Forum* 26(5) (2013): 17.
[152] Onora O'Neill, "Accountability, trust and informed consent in medical practice and research," *Clinical Medicine* 4 (2004): 269-76.
[153] Flanigan, 17-8.
[154] Violetta Igneski, "Defending Limits on the Sacrifices We Ought to Make For Others." *Utilitas* 20 (2008): 425.; Lantos, Jackson, and Harrison, 134.

reduction in the spread of disease.[155] Lantos and Jackson argue that it is impossible to quantify the effect each individual's decision will have on another individual's liberty. Instead, they maintain that the fairest way to equalize the burden of protecting long-term care facility residents from pneumococcal disease is through an equal, and relatively minor, infringement on each person's liberty in the form of immunization requirements.[156] Importantly, in order for the infringements on liberty to be fair, they must be equally applied. Thus, in the interest of fairness, exemptions to vaccine requirements would not be justified.[157]

Lantos and Jackson's account, however, is problematic in that it would seem to eliminate the possibility for medical exemptions. But it is counterintuitive to even think of requiring people with allergies or other contraindications to vaccines to be vaccinated. Alternatively, Flanigan defends vaccination requirements with only the possibility for medical exemptions by comparing non-vaccination to random gunfire. Just as bans on random gunfire are justified in that they prevent harm to others, even if the harms are low-probability, even if the actor had no intention of harming the victim, even if the victim is likely unable to identify the actor, and even if the avid gun lover may not see any reason to accept these bans as cohesive to their internal doctrine, in a similar way, banning citizens from causing indiscriminate harm to others (through disease transmission) may be justified even if the religious (or philosophical) individual sees no reason to accept it.[158]

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[155] John D. Lantos and Mary Anne Jackson, "Vaccine Mandates are Justifiable Because We are All in This Together," *The American Journal of Bioethics* 13(9) (2013): 2.
[156] Lantos and Jackson, 2.
[157] Ibid.
[158] Ibid., 18.

However, this view may still be problematic. Critics may respond by claiming that Flanigan does adequately account for the harm caused to religious and philosophical objectors by forcing them to betray their deeply held religious and philosophical beliefs. In terms of public policymaking, it may be unreasonable to discount this view. If this approach is adopted, then it is reasonable, in accordance with Kass's ethics framework for public health, that some non-medical exemptions may be permissible in order to fairly balance the overall burdens and benefits of the immunization requirement. This position more closely aligns with the thinking of many public health experts that have argued that the availability of medical and non-medical exemptions to vaccine requirements for children balances out the infringement on parental autonomy.[159, 160]

A third objection to vaccine requirements for residents of long-term care facilities questions the benefit of extending life through vaccination. Verweij has raised the point that a death from non-treatment of pneumonia or a related pneumococcal disease (assuming palliative care to ease the dying process) may entail less suffering than the overall burdens associated with a slower and lengthier death from Alzheimer's disease or another form of advanced dementia.[161]

On the whole, Verweij's objection seems to overgeneralize the instances in which a quick death is preferable. It is plausible that a death from pneumonia without antibiotics may be relatively quick and painless (given sufficient medication to overcome the severe physical pain associated with pneumonia). Still this option is likely only to be attractive if one thinks the overall burdens of continued life are substantial. Regardless, a decision of

[159] Lachmann, 300.; Salmon et al.
[160] To account for greater freedom of familial autonomy, many states have introduced religious and philosophical exemptions. Currently, 48 states have religious exemptions and 21 states have philosophical exemptions (Omer et al., 1983).
[161] Verweij, 540-1.

this magnitude would be best left up to the demented individual, if she left an advance directive, or a proxy decision-maker. More to the point, though such cases may occur, this does not preclude the possibility of an immunization requirement for long-term care facility residents. Instead, it might be reasonable to exempt individuals entering a long-term care facility with such late-stage dementia that they would be appropriate candidates for hospice care from immunization requirements. In these cases, should one of these late-stage dementia hospice patients contract a pneumococcal infection, they would be quarantined from the rest of the long-term care facility population in accordance with standard exemption procedures and, while they would not receive treatment with the intention of curing the infection, they would receive palliative care with the intention of easing the dying process.

Considering these important objections has been useful in clarifying the acceptability of exemptions to immunization requirements, but it would seem that the use of vaccine requirements for pneumococcal vaccines among residents of long-term care facilities might still be justified. If my arguments in favor of immunization requirements in long-term care facilities are accepted, it will also be important to survey foreseeable policy implications of such a proposal and address any additional issues this proposal raises now, thereby concluding with an ethical and also, hopefully, implementable policy proposal.

V. Policy Implications

Establishing an immunization requirement for long-term care facilities has several policy implications that will be addressed now in an effort to promote the swifter adoption of such a policy should the technology become available in the near future. Due

to the nature of long-term care facility populations, immunization requirements in long-term care facilities will raise questions of autonomy and informed consent that are different from those of school requirements and other public health measures that affect the general public. For example, many long-term care facility residents have underlying chronic conditions, some of which may be related to brain functioning and thus complicating a resident's ability to make rational, autonomous healthcare decisions. Special considerations must be taken to ensure these vulnerable individuals are respected and treated in accordance with the highest moral standards.

At certain stages of particular diseases, obtaining informed consent from individuals can be ethically difficult if not logistically impossible. In long-term care facilities, many patients may exist in the grey area of the ability to give valid and meaningful informed consent, particularly when these persons enter into a long-term care facility.[162] As the patient's mental ability declines, there may come a point at which the patient is no longer able to give consent, yet they will still retain the ability to have some understanding of the procedure. In situations where the patient can still understand the procedure, assent should be sought from the patient in conjunction with proxy consent.[163] However, if the patient is far from competent, then an advanced directive or proxy decision-maker should bear the sole consent-giving responsibility. [164]

In instances of medical emergency, such as an outbreak, when an advance directive or proxy decision-maker is unavailable, all effort should be made by the attending physician to thoroughly consider the patient's medical records and what is known of the patient's beliefs to make the decision that seems to best fit with what the

[162] Beauchamp and Childress, 121.
[163] Ibid., 122.
[164] Ibid.

patient would have wanted were she able to voice her own opinion. For example, if the patient has a strong history of accepting immunization and there are no medical contraindications to immunization, it might be acceptable to make the decision to immunize on the patient's behalf.[165] Nevertheless, in all other situations, every action should be pursued to obtain a proxy before a decision to immunize is made. In sum, respect for the autonomy of the individual should be maintained to the greatest extent possible given the specific circumstances.

This leads us to the question, if immunization requirements are implemented, what should be done in instances when a person refuses vaccination? It will be useful to clearly define the scope and form of immunization requirement exemptions to avoid any confusion and eliminate any ambiguities.

First and foremost, to ensure compliance with regulations and avoid concerns regarding access to vaccines, an exemption from the immunization requirement should not be easier to obtain than the vaccine itself. As discussed above, the cost of the vaccines are likely to be covered by private insurance or Medicare for most individuals. For those who do not have insurance and cannot afford the cost of the vaccine, it would be in the best interest of the state to allocate funds to cover the cost of these additional vaccines, given the vaccine's presumed cost-effectiveness over the long-term and the marginal expense incurred by the relatively few vaccines the state could anticipate covering. Long-term care facilities should also ensure that adequate numbers of vaccines and staff are on hand to meet the expected demand and to minimize any delay in the administration of vaccines that would prevent individuals from entering a long-term care facility in a timely fashion.

[165] Ibid., 190.

At the same time, efforts must be undertaken to increase the robustness of the exemption process. To do this, the immunization requirement exemption process should be standardized and the clerical requirements set at the level of the strictest childhood vaccination exemptions.[166] For example, letters simply expressing one's desire not to be vaccinated should not be considered sufficient to obtain an exemption.

Educating physicians on how to discuss long-term care facility immunization requirements with their patients will also be essential to reducing the number of people seeking exemptions. In discussing vaccine requirements with patients, administers of the vaccine in long-term care facilities should be offered special training aimed at improving their cultural sensitivity to certain groups less likely to accept immunization. For example, physicians should take extra measures to carefully explain the risks of both accepting and refusing immunization to patients with known religious objections and/or cultural apprehensions to vaccines. As patients' interests may vary from their actions based on a range of constraints on their interests, doctors may have to devote extra time to certain subsets of the general population to ensure the decision to provide consent is given with a sufficient level of comprehension.[167] Respect for autonomy does not demand that doctors ignore a patient's individual context, such as their beliefs or culture.[168] Ultimately any successful vaccination campaign will include a substantial effort to educate physicians and other healthcare professionals administering vaccines to ensure they have the ability to thoroughly and appropriately discuss the benefits and risks of vaccination of with groups of people who have a history of refusing immunization.

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[166] Salmon et al., 778.; Sara Mahmoud-Davis, "Balancing Public Health and Individual Choice: A Proposal for a Federal Emergency Vaccination Law," *Health Matrix: Journal of Law-Medicine* 20 (2010): 222.
[167] Beauchamp and Childress, 136.
[168] Ibid.

Additionally, as vaccinations are not just therapies for patients, but are also part of a larger public health program, it would be appropriate for doctors to disclose how an individual's choice to vaccinate (or not) factors into the larger public health aim in an attempt to appeal to the patient's sense of reason.[169] In other words, it would be legitimate for a provider to encourage the patient to consider how her decision not to vaccinate may affect others within a long-term care facility.[170] For example, a patient may feel pressure from her family or partner to refuse vaccination on the basis of a religious belief. However, as a result of this type of discussion with her doctor, the patient may independently recognize and place worth in the value of vaccination campaigns and decide to consent to immunization.

Furthermore, Beauchamp and Childress claim that refusing treatment or therapy based on misinformation or false belief is not considered an informed refusal and as such physicians or other providers might be obligated to challenge a patient's decision in an effort to enhance their autonomous choices.[171] With immunization requirements, physicians are right to press their patients on their decision to refuse vaccination if the physician reasonably suspects that the decision to forgo vaccination has been made on the premise of a false belief. In these situations, it might also be necessary for the physician to bring others into the conversation in an attempt to correct the patient's misconceptions.[172] However, when efforts to dissuade a patient from his false belief do not result in a change in his decision, the false belief should likely be tolerated, assuming

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[169] Ibid., 139.
[170] Natalie Stoljar, "Informed Consent and Relational Conceptions of Autonomy," *Journal of Medicine and Philosophy* 36 (2011): 383.; Leslie P. Francis, Margaret P. Battin, Jay A. Jacobson, Charles B. Smith, and Jeffrey Botkin, "How Infectious Diseases Got Left Out – And What This Omission Might Have Meant for Bioethics," *Bioethics* 19 (2005): 321.
[171] Beauchamp and Childress, 137.
[172] Beauchamp and Childress, 136.

the patient retains full autonomy. Still, in future encounters, the doctor would be justified in continuing to discuss vaccination with the patient and encouraging him to reconsider his position given the evidence the doctor has presented. If the patient is able to reasonably understand the procedure but does not retain full autonomy and dissents on the basis of a false belief, the proxy decision-maker may be justified in overriding the patient's dissent. In these contexts, it is imperative that the false belief not be misunderstood to mean divergent religious or philosophical views, but only factually incorrect beliefs founded in misinformation.

There are some further concerns these policy considerations raise that are worth addressing. One concern is that greater restrictions on obtaining non-medical exemptions could in practice place more burdens on families or individuals without actually reducing the number of non-medical exemptions. By requiring more extensive administrative work to obtain an exemption, families will plausibly be further burdened; however, it is unlikely that these additional burdens would not reduce the number of non-medical exemptions. Currently, the states with the most comprehensive non-medical exemption processes for childhood immunization requirements have the lowest levels of non-medical exemptions.[173] Convincing evidence that this trend would not translate into long-term care facility populations would need to be provided before we could presume that a stricter non-medical exemption processes would be ineffective.

A second concern is that a lengthier informed consent process may further burden already disadvantaged families. Therefore, safeguards would have to be considered to prevent any changes to non-medical exemption laws from unfairly affecting those least

[173] Salmon et al., 436.

able to object to the requirement.[174] It would not be unreasonable to enact policies in long-term care facilities that would require care providers to discuss exemptions thoroughly with their patients. Since many nursing homes already have enacted standing orders, it is unlikely that formalizing these recommendations would critically burden long-term care facility employees.

The goal of immunization is to reduce morbidity and mortality associated with a disease for the entire populace.[175] Given the nature of long-term care facilities, the possible harms from pneumococcal disease are dramatically greater within these communities as compared to the harms the disease causes the general population. Once the next generation vaccine is available, Kass's ethics framework for public health, appeal to the harm principle, and a consequentialist analysis suggest that implementing policies for formal immunization requirements in long-term care facilities could be an ethically justifiable option and may likely be a successful way of reducing morbidity and mortality associated with pneumococcal disease in the United States.

VI. Conclusion

As the United States' population ages, the number of people living in long-term care facilities is likely to increase. Long-term care facilities, similar to schools, are ideal environments for the rapid transmission of infectious diseases. Therefore, with a rapidly aging population as well as an increasing presence of drug-resistant and multi-drug resistant bacteria, infectious diseases that cause disproportionately high rates of morbidity and mortality among long-term care facility populations are becoming a critical public

[174] Matthew K. Wynia, "Mandating Vaccination: What Counts as a "Mandate" in Public Health and When Should They Be Used?," *The American Journal of Bioethics* 7(12) (2007): 2-6.
[175] Kass, 1778.

health threat.[176] Fortunately, many of these threatening infectious diseases can be or soon will be preventable through the use of vaccines.

Pneumococcal disease is a prime example of such an infectious disease. While successful in reducing invasive pneumococcal disease, the current pneumococcal vaccines have not demonstrated significant efficacy in reducing more common pneumococcal infections, such as non-bacteremic pneumococcal pneumonia. However, next generation vaccines can be expected in the near future. Designed to be age-appropriate, we can fairly assume that the new pneumococcal vaccines will better protect long-term care facility populations against pneumococcal pneumonia and other pneumococcal infections responsible for high morbidity and mortality in these groups.

In the past, immunization campaigns have been targeted almost exclusively at children. Yet, as the nature of the vaccine landscape changes, policies surrounding these new vaccines must also evolve to adapt to the advancing technology. Thus, implementing a pneumococcal immunization requirement in long-term care facilities should be seriously considered as an ethically sound and reasonably implementable policy proposal.

[176] Chen et al., 351.

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