

**Analysis of Proposed Legislative Policy Options**

**JCHC Staff Report on  
*School Vaccinations in the Commonwealth of Virginia***

submitted by

**National Vaccine Information Center**

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## **The National Vaccine Information Center**

NVIC is a Virginia-based non-profit charitable 501c3 organization founded in 1982 to prevent vaccine injuries and deaths through public education. Headquartered in Sterling, Virginia, NVIC is the oldest and largest consumer led organization in America advocating for the institution of vaccine safety and informed consent protections in U.S. vaccine policies and laws. NVIC co-founders were responsible for securing nationwide vaccine informing, recording and reporting safety provisions in the National Childhood Vaccine Injury Act of 1986.

As an independent clearinghouse for information on vaccines and diseases, NVIC does not make vaccine use recommendations and encourages everyone to become educated about the risks and complications of diseases and vaccines and consult one or more trusted health care professionals before making a vaccine decision. NVIC is supported by more than 180,000 parents, grandparents, health care professionals and citizens living in every state, who believe that civil liberties, including the human right to informed consent to medical risk-taking, must be protected in America.

For more information, visit [NVIC.org](http://NVIC.org).

## EXECUTIVE SUMMARY

The 1905 U.S. Supreme Court affirmed in *Jacobson v. Massachusetts* that state legislatures have the constitutional authority to use police powers to mandate vaccination to control epidemics of deadly infectious diseases, such as smallpox. State legislatures also have the authority to refrain from mandating vaccines, as well as to provide flexible medical and personal belief exemptions. Over the past century, all 50 states have passed laws with flexible medical vaccine exemptions; 47 states provide religious exemptions; and 16 states provide a separate conscientious or philosophical belief exemption.

Virginia provides flexible medical and religious belief vaccine exemptions for children attending public and private schools, while maintaining traditional disease control isolation procedures to address potential outbreaks of infectious disease. The Virginia health commissioner has the authority to require unvaccinated children to stay home from school if an outbreak or potential epidemic of disease is identified in the commonwealth, even though vaccinated children also can be infected with and transmit some diseases for which vaccines are mandated.

In January 2016, a bill (HB1342) was introduced into the legislature to eliminate medical and religious belief vaccine exemptions. The bill was subsequently withdrawn by patrons and referred to the Joint Commission on Health Care (JCHC) for further study.

Under current vaccine laws, Virginia has a 0.0 per 100,000 persons reported incidence rate for diphtheria, tetanus, polio, measles and rubella; a 0.4 percent reported incidence rate for mumps; 1.1 and 1.2 for hepatitis B and HIB, respectively; 4.0 for pertussis and 7.0 for varicella zoster (chickenpox).

According to the U.S. Centers for Disease Control and Prevention (CDC), in the 2015-2016 school year, an estimated 98.3 percent of kindergarten children had received five pertussis-containing vaccines (DTaP); 95.7 percent had received two measles-mumps-rubella (MMR) shots; and 93.7 percent had gotten two varicella shots. An estimated 1.2 percent of children (about 1,155 children) in public or private kindergartens in the commonwealth had a vaccine exemption, which is lower than the national 1.9 percent median exemption rate for states.

While Virginia has maintained high vaccine coverage and low vaccine exemption and disease incidence rates, emerging new science is providing evidence for strain variation and limited durability of vaccine acquired herd immunity for some federally recommended and state mandated childhood vaccines. For example, vaccinated persons can asymptotically transmit pertussis infection to other vaccinated and unvaccinated persons, including those too young to be vaccinated and those with compromised immune systems. With an unknown number of unidentified and unreported pertussis infections occurring in

vaccinated individuals, the tracking of cases in reported outbreaks is complicated and the removal of vaccine exemptions may have no appreciable effect on the reported incidence of disease.

At the same time, there is wider acknowledgement that, like prescription drugs, vaccines are pharmaceutical products that can unpredictably cause injury and death for both healthy and susceptible individuals. Congress and the U.S. Supreme Court have declared federally licensed and recommended vaccines to be “unavoidably unsafe” and shielded drug companies and vaccine providers from vaccine injury lawsuits in civil court. Under the 1986 National Childhood Vaccine Injury Act, \$3.5 billion dollars in federal compensation has been awarded for vaccine injuries and deaths caused by federally recommended and state mandated vaccines, although two out of three plaintiffs are denied compensation and most vaccine injury awards today are for adults injured by influenza vaccine.

The Institute of Medicine has acknowledged in published medical literature review reports between 1991 and 2013 that doctors cannot accurately predict who is more susceptible to vaccine harm due to genetic, biological and environmental high risk factors. Despite vaccine science knowledge gaps, medical contraindications have been narrowed by the U.S. Centers for Disease Control (CDC) and medical trade associations so that no family medical history and almost no personal medical history or health condition qualifies for a medical vaccine exemption.

Legislators are called upon to exercise great caution when making public health laws, which place an unequal risk burden on individuals born with certain genes and biological risk factors, or making laws that discriminate against those holding religious and conscientiously held beliefs. Respect for individual human life and liberty in public health policy and lawmaking prevents discrimination against vulnerable minorities and avoids the creation of a “tyranny of the majority,” which ultimately compromises the integrity of what is being defined as the “common good.”

Freedom of religion is a civil liberty and so is the right to be educated, whether in home or in school. Freedom of religion and conscience in America means that citizens are allowed to hold personal religious beliefs that may or may not be part of an organized religion or established church without civil liberties being taken away. These fundamental civil liberties are guaranteed under the Virginia Constitution and the Act for Religious Freedom authored by Thomas Jefferson in 1786 and reaffirmed by the General Assembly in 2007. Additionally, the General Assembly affirmed in 2013 that parents have “a fundamental right to make decisions concerning the upbringing, education and care” of their minor children.

Strict enforcement of “no exemptions” vaccine laws leads to distrust of government and fear of doctors. It is wise public policy to protect an individual parent’s legal ability to exercise conscience, religious belief and informed

consent when making vaccine decisions for a minor child, as well as to protect the legal ability of individual physicians to exercise professional judgment and conscience when evaluating whether a child should receive a medical exemption to vaccination to attend school.

The proposed removal of the religious and medical vaccine exemptions that currently exist in Virginia law poses a threat to the health of individuals biologically vulnerable to harm from vaccines, will not help individuals biologically vulnerable to harm from infectious diseases, and violates civil liberties that have been protected in the commonwealth for more than 200 years. This, along with the fact that Virginia has (1) a low infectious disease incidence rate; (2) a high vaccine coverage rate and (3) a low vaccine exemption rate among school age children, makes it hard to justify costs that will be associated with eliminating vaccine exemptions when other unmet needs, including public schools and costs to treat children and adults with chronic disease and disability, are competing for funding resources in the commonwealth.

Therefore, after analyzing the effectiveness, safety, costs, ethics, legality, administrative feasibility, cultural and political acceptability of nine proposed legislative policy options in the Aug. 3, 2016 Joint Commission on Health Care staff report, the National Vaccine Information Center urges the Commission to take no action (Option #1) and preserve current medical and religious exemptions to vaccination in the commonwealth.

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## **Section 1: Introduction**

For public health policies and laws to be accepted by citizens, they must serve the needs and well being of individuals, as well as of society as a whole. As a consumer health education and informed consent advocacy organization, the National Vaccine Information Center (NVIC) <sup>1</sup> evaluates federal vaccine policy <sup>2</sup> and law <sup>3</sup> and state vaccine laws <sup>4</sup> not only from a public health perspective but also from the perspective of how the vaccine policy or law will impact the health and well being of individuals, which includes how it will affect exercise of civil liberties (human rights).<sup>5</sup>

We recognize that the individual perspective is different from the population-based one that primarily underpins public health policy and law. However, because populations are composed of individuals and the whole is only as healthy as the sum of its parts, we maintain that the health and human rights of individuals must be respected and valued appropriately in vaccine laws to prevent deterioration of the integrity of what is being defined as the “common good.” Although the 1905 U.S. Supreme Court affirmed in *Jacobson v. Massachusetts* <sup>6</sup> that state legislatures have the constitutional authority to use police powers to mandate vaccination to control epidemics of deadly infectious diseases, such as smallpox, legislatures also have the legal authority to refrain from mandating vaccines and to include exemptions in vaccine laws that protect individuals.

### **Susceptible Individuals Vulnerable to Vaccine Injury and Death**

This is especially important when evaluating vaccine policy and law. As noted by the Institute of Medicine, National Academy of Sciences, in reports published between 1991 and 2013, biodiversity and gaps in vaccine science prevent identification of susceptible individuals at greater risk for suffering vaccine harm due to genetic, biological or environmental factors that are unknown, or that doctors cannot accurately predict.<sup>7 8 9 10 11 12</sup>

Despite these significant knowledge gaps about individual high risk factors for vaccine injury and death, federal health officials and medical trade organizations have narrowed medical contraindications to vaccination so that no family medical history - and almost no personal medical history or health condition, including immunodeficiency – officially qualifies for a medical vaccine exemption.<sup>13 14</sup> At the same time, medical trade associations are lobbying for elimination of all non-medical vaccine exemptions in vaccine laws.<sup>15 16 17 18 19 20</sup>

### **Removal of Vaccine Exemptions Unlikely to Affect Herd Immunity**

Additionally, herd immunity cannot be achieved when, for example, vaccines do not contain strains that match circulating disease <sup>21</sup> or vaccine acquired immunity quickly wanes and cannot prevent vaccinated persons from asymptotically

transmitting infection to other vaccinated and unvaccinated persons,<sup>22 23 24</sup> including those too young to be vaccinated and those with compromised immune systems. Removal of vaccine exemptions will have no appreciable effect on the already low reported incidence of infectious disease when vaccinated persons with atypical or no symptoms of disease are not identified and reported.<sup>25 26</sup>

### **Flexible Vaccine Exemptions Protect Minorities and Civil Liberties**

When a pharmaceutical product like a vaccine can cause injury, death or fail to work for a vulnerable minority of individuals, public policymakers and lawmakers are called upon to exercise great caution when creating medical policies and mandates that could result in the majority placing an unequal risk burden on or discriminating against a minority. Inclusion of flexible vaccine exemptions in vaccine laws prevents an inhumane application of utilitarianism<sup>27</sup> that devalues individual human life and discriminates against those holding religious and conscientious beliefs about vaccination.

Current exemptions in Virginia vaccine laws protect not only civil liberties and a parent's legal ability to exercise freedom of conscience, religious belief and informed consent<sup>28</sup> when making vaccine decisions for a minor child, but also protects the legal ability of individual physicians to exercise professional judgment and conscience when evaluating whether a child should receive a medical exemption to vaccination based on the child's medical history and health at the time of vaccination.

### **Good Health Is Measured by An Absence of Chronic Disease, Low Maternal and Infant Mortality Rates**

Although a bill (HB1342) was introduced into the legislature in January 2016 to eliminate the medical and religious vaccine exemptions<sup>29</sup> for the apparent purpose of further reducing the already low infectious disease and low vaccine exemption rate among young school children in the commonwealth, it is important to acknowledge that the health of a nation or a state is not measured solely by the absence of infectious disease, high vaccine coverage rates and low vaccine exemption rates. For example, over the past two decades, there has been a dramatic and disproportionate increase in neurodevelopmental disabilities and mental illness in children from socially advantaged families, but the medical, social and environmental factors to explain this unexpected increase have not been identified yet by public health authorities.<sup>30</sup>

There continues to be uncertainty about all the ways that mandatory vaccination laws impact public health outcomes, including infectious disease, chronic disease and disability, and infant and maternal mortality rates. For example, the United Health Foundation uses a number of health measurements, including infant mortality rates, to annually evaluate the overall health of different states in the U.S.<sup>31</sup> Analysis of that data in Section 7 raises questions about high vaccine

coverage rates and low vaccine exemption rates relative to certain health measurements in Virginia and other states, such as infant mortality rates (IMR), as well as total health outcomes.

### **Measuring Effectiveness, Safety, Cost, Ethics, Legality, Administrative Feasibility and Cultural and Political Acceptability of Policy Options**

In light of vaccine safety knowledge gaps and emerging scientific evidence altering long held assumptions about vaccine safety and effectiveness, and in consideration of the rising costs to fund and administer mandatory vaccination programs that compete with funding resources for other unmet needs in the commonwealth, we offer this analysis of the nine proposed legislative policy options outlined in the Aug. 3, 2016 Joint Commission on Health Care (JCHC) staff report <sup>32</sup> from the perspective of effectiveness, safety, cost, ethics, legality, administrative feasibility, and cultural and political acceptability.

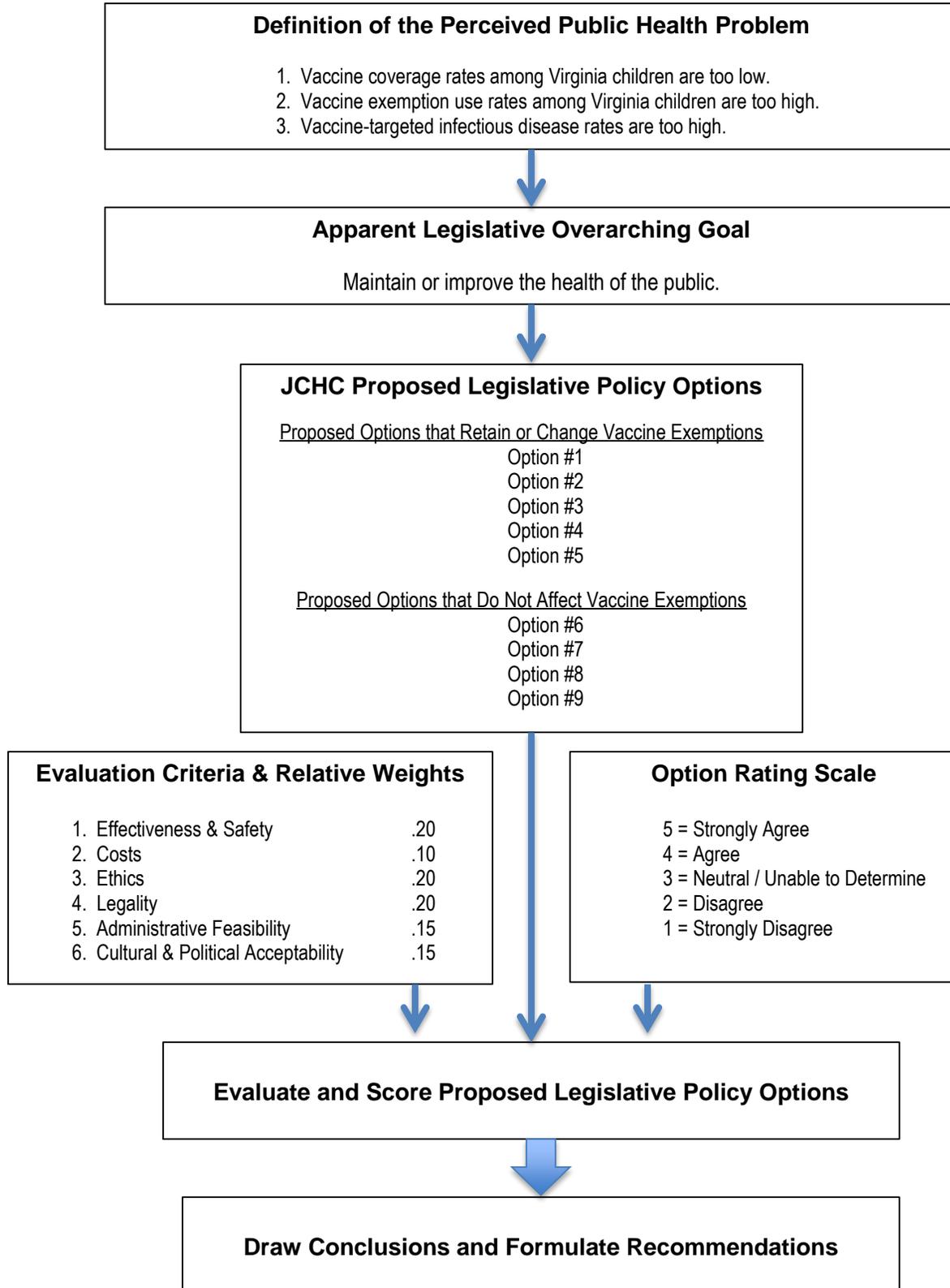
Additionally, there are numerous statements of “fact” in the JCHC staff report that either are not consistent with published peer reviewed literature in the fields of science, medicine, law and ethics or fail to acknowledge disagreement within these academic disciplines. To offer balance, we have selected a few more prominent examples to discuss in this public comment.

Our response is organized into seven sections and follows a standard legislative policy analysis format. Following this Introduction, we will discuss:

- Section 2: Definition of the perceived public health problem
- Section 3: Apparent legislative goals
- Section 4: Current law and proposed legislative options
- Section 5: Analytical methods
- Section 6: Legislative policy option assessment and scoring results
- Section 7: Discussion and conclusions

We used a standard policy analysis process <sup>33 34 35</sup> as depicted in Figure 1. This diagram shows that we began by reviewing the JCHC staff report to ascertain the perceived public health problems and legislative goal. We evaluated the proposed legislative policy options in relation to existing Virginia law. We then reviewed the current health policy analysis literature to establish our method and metrics. The methods and rationale for use of particular criteria, weights and rating scales are described in Section 5.

**Figure 1-1. NVIC Legislative Policy Analysis Process**



## Section 2: Definition of the Perceived Public Health Problem

Although a description of the perceived public health problem was not clearly articulated in the JCHC staff report, we assume from statements made in the report that the primary concerns of HB1342 patrons and JCHC staff, for which they seek legislative remedy in Options #1-9, are:

1. Current vaccine exemption laws need to be changed because the public health in the commonwealth is being compromised or will be compromised by infectious diseases, such as measles and pertussis, being transmitted by unvaccinated children and those who have not received all state mandated doses of 12 federally recommended vaccines, which include diphtheria, pertussis, tetanus, HIB (daycare), hepatitis B, HPV, measles, mumps, rubella, pneumococcal (daycare), polio and varicella zoster.<sup>36</sup>
2. Current vaccine exemption laws need to be changed because medical and religious vaccine exemption use is too high among children being educated in the commonwealth and this compromises the public health.
3. Current vaccine exemption laws need to be changed because the incidence of vaccine-targeted diseases in the commonwealth is currently too high or could become too high because too few children receive all state mandated doses of 12 federally recommended vaccines and this compromises the public health.
4. Current vaccine exemption laws need to be changed because medical and religious vaccine exemption use is too high among children being educated in the commonwealth and this compromises the public health.
5. Current vaccine exemption laws need to be changed because the incidence of vaccine-targeted diseases in the commonwealth is currently too high or could become too high because too few children receive all state mandated doses of 12 federally recommended vaccines and this compromises the public health.
6. Current vaccine exemption laws need to be changed because medical and religious vaccine exemption use is too high among children being educated in the commonwealth and this compromises the public health.

If this is a fairly accurate description of the problem perceived by bill patrons and JCHC staff, we maintain that there is lack of evidence to demonstrate there is a public health problem requiring a change in current vaccine laws.

**Virginia Vaccine Coverage Rates Are High:** In the 2015-2016 school year, the CDC reported an estimated 98.3 percent of kindergarten children had received five DTaP shots; 95.7 percent had received two MMR shots and 93.7 percent

had received two varicella zoster shots.<sup>37</sup> In addition, the CDC reported that among Virginia adolescents in middle and high school in 2015, 82.2 percent had received a pertussis booster shot (Tdap).<sup>38</sup>

**Virginia Vaccine Exemption Rates Are Low:** According to the CDC, Virginia had one of the lowest vaccine exemption rates of all states, with 1.2 percent of children entering kindergarten in the 2015-2016 school year exempted for medical or religious reasons, which was lower than the national median exemption average of 1.9 percent.<sup>39</sup> Only 254 kindergarten children attending public or private schools had medical vaccine exemptions and 901 had religious vaccine exemptions in the 2015-2016 school year, for a total of 1,155 children out of a kindergarten population in Virginia of approximately 100,000 students.

**Virginia Infectious Disease Rates Are Low:** According to the VDH, as of 2014, the most recent five-year annual incidence rate for measles was 0.0.<sup>40</sup> In 2014, two cases in individuals with up-to-date MMR vaccinations were reported. In 2015, one case in an individual with up-to-date MMR vaccinations was reported.<sup>41</sup>

Provisional data from the CDC indicated that, in 2015, the Virginia pertussis incidence was 4.0 cases per 100,000 persons (334 cases), which is lower than the national median rate of 5.7.<sup>42</sup> The incidence rate for reported cases of pertussis is low in the commonwealth, even though cases of pertussis are seriously underreported in the U.S. due to asymptomatic carriage and transmission of pertussis among vaccinated infants, children and adults.<sup>43 44</sup>

Additionally, the VDH reports that the five-year annual incidence was 0.0 for diphtheria, polio, tetanus, and rubella, was 0.4 for mumps and 7.0 for chickenpox. The rates for two additional diseases were 1.1 and 1.2 for hepatitis B and HIB, respectively, diseases that appears to mostly occur in adults. Lastly, two diseases for which vaccines are recommended – pneumococcal and human papilloma virus – are not reportable diseases in Virginia.<sup>45</sup>

**Virginia Has Traditional Disease Control Mechanisms in Place:** The Code of Virginia states, “Upon the identification of an outbreak, potential epidemic, or epidemic of a vaccine-preventable disease in a public or private school, the commissioner has the authority to require the exclusion from such school of all children who are not immunized against that disease.”<sup>46</sup> This traditional disease control mechanism has been in place in vaccine laws in Virginia and other states for decades to respond to infectious disease outbreaks or potential epidemics. However, as noted in Section 1, it is important to recognize that traditional disease control mechanisms are unable to prevent transmission when vaccinated individuals can be infected with disease and transmit without showing symptoms or only mild symptoms of infection.<sup>47 48 49 50 51</sup>

**Freedom of Conscience and Religion is Protected Under Virginia Law:** The proposed removal of the religious vaccine exemption poses a threat to fundamental civil liberties guaranteed under the Virginia Constitution,<sup>52</sup> as well as the Act for Religious Freedom authored by Thomas Jefferson in 1786<sup>53</sup> and reaffirmed by the General Assembly in 2007.<sup>54</sup> The Virginia Constitution guarantees that every citizen is “equally entitled to the free exercise of religion, according to the dictates of conscience,” and shall not be required to “support any religious worship” or undergo “any religious test whatsoever” to participate in society.

This means that in the commonwealth, citizens are allowed to follow their conscience and hold personal religious beliefs that may or may not be associated with an organized religious or state recognized church. Additionally, the General Assembly affirmed in 2013<sup>55</sup> that parents have “a fundamental right to make decisions concerning the upbringing, education and care” of their minor children.

There is no evidence of a public health emergency or compelling state interest to violate freedom of conscience and religion and discriminate against parents with religious beliefs regarding vaccination or to prohibit physicians from exercising freedom of conscience when evaluating medical vaccine exemptions to protect the health of individual children in the commonwealth.

### **Section 3. Apparent Legislative Goals**

As noted above, we assume that the primary legislative goals of HB1342 patrons and the legislative remedies embodied in Options #1-9 outlined in the staff report were proposed to maintain or improve the health of the public. Therefore, our analysis will focus on the following questions with regard to the apparent legislative overarching goal:

1. Is there good evidence for the need to raise vaccine coverage rates among school aged children, which are already at record high levels of 95 to 98 percent for measles and pertussis vaccine, for example?
2. Is there good evidence for the need to seek further reductions in the incidence of vaccine targeted diseases, which either already have no reported cases or a very low incidence, such as polio, diphtheria, tetanus, measles, mumps, rubella, HIB and hepatitis B, or are unable to be further reduced with current vaccines, such as pertussis?
3. Is there good evidence for the need to eliminate or significantly reduce the already low 1.2 percent religious and medical vaccine exemption rate for children entering kindergarten in the commonwealth, a rate that is already below the national median rate of 1.9 percent?

4. Is there good evidence that there is a public health emergency and a compelling state interest to violate fundamental civil liberties guaranteed under Virginia law for more than 200 years and discriminate against a small minority of families exercising freedom of conscience and religious beliefs regarding vaccination, or to prohibit physicians from exercising freedom of conscience when evaluating medical vaccine exemptions to protect the health of individual children?
5. Will the legislative policy Options #1-9, especially those that propose a change to current vaccine laws, have a positive or negative impact on child health and public health in the commonwealth?

## **Section 4. Current Law and Proposed Legislative Options**

This section of the paper briefly describes the current applicable laws and proposed legislative policy options identified in the JCHC Staff Report. The legislative options are divided into two groups: (1) options that either retain or propose to eliminate, restrict or redefine medical or religious vaccine exemptions and/or change the process for obtaining vaccine exemptions under current law; and (2) options that propose to address various non-exemption laws and regulations.

It should be noted that the suggested amendments in the JCHC staff report only reference some of the existing applicable VA Code and completely omit amendments that would be required to be made to the Virginia Constitution,<sup>56</sup> the Religious Freedom Restoration Act,<sup>57</sup> the Parental Rights Act<sup>58</sup> and various sections of the Virginia Administrative Code.

**Current Virginia Vaccination Laws:** Under the 2015 Code of Virginia, there are three Virginia laws that govern vaccination of children: – VA Code § 22.1-271.2,<sup>59</sup> VA Code § 22.1-271.4,<sup>60</sup> and VA Code § 32.1-46.<sup>61</sup> A brief overview of the three laws is below. Provisions that apply to the proposed legislative remedy options are provided verbatim and italicized.

**VA Code § 22.1-271.2 – “Immunization Requirements.”** This law is divided into seven sections:

- A. school admission requirements and proof of vaccination;
- B. conditional school admission;
- C. religious and medical exemptions;

“No certificate of immunization shall be required for the admission to school of any student if:

- i. the student or his parent submits an affidavit to the admitting official stating that the administration of immunizing agents conflicts with the student's religious tenets or practices; or*

ii. *the school has written certification from a licensed physician, licensed nurse practitioner, or local health department that one or more of the required immunizations may be detrimental to the student's health, indicating the specific nature and probable duration of the medical condition or circumstance that contraindicates immunization.*"

- D. school exclusion;
- E. school recordkeeping and reporting;
- F. Haemophilus Influenzae Type b exception; and
- G. Board of Health rulemaking authority.

**VA Code § 22.1-271.4 – “Health Requirements for Home-instructed, Exempted, and Excused Children.”** This law addresses (sections are not numbered):

- educational requirements for home-schooled and other particular children;
- requirement of such children to comply with the same vaccination requirements as children attending a school;
- requirement to submit, upon request, proof of vaccination to district superintendent; and
- religious and medical exemptions
  - “No proof of immunization shall be required of any child upon submission of an affidavit to the division superintendent stating that
  - (i) *the administration of immunizing agents conflicts with the parent's or guardian's religious tenets or practices or*
  - (ii) *a written certification from a licensed physician, licensed nurse practitioner, or local health department that one or more of the required immunizations may be detrimental to the child's health, indicating the specific nature of the medical condition or circumstance that contraindicates immunization.*”

**VA Code § 32.1-46 - “Immunization of Patients Against Certain Diseases.”**

The law covers the following:

- A. requirement that Virginia children are vaccinated according to the schedule published by the federal Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP) and others and, at a minimum, be vaccinated for the following diseases (and receive the following minimum number of doses):
  1. Hepatitis B (3),
  2. Diphtheria (4),
  3. Tetanus (3),
  4. Pertussis (4),
  5. Haemophilus Influenza Type B (2-3),
  6. Measles (2),
  7. Rubella (1),

8. Mumps (1),
  9. Chickenpox (1),
  10. Polio (3-4),
  11. Pneumococcal (1-4), and
  12. Human Papillomavirus (3);
- In accordance with vaccine administration and financing provisions;
- B. Health provider requirement to provide parents with certificate identifying the vaccine and doses given;
  - C. Vaccine prescription and administration standards;
  - D. The provisions of this section shall not apply if:
    1. *“the parent or guardian of the child objects thereto on the grounds that the administration of immunizing agents conflicts with his religious tenets or practices, unless an emergency or epidemic of disease has been declared by the Board”*;
    2. *“The parent or guardian presents a statement from a physician licensed to practice medicine in Virginia, a licensed nurse practitioner, or a local health department that states that the physical condition of the child is such that the administration of one or more of the required immunizing agents would be detrimental to the health of the child”*; or
    3. HPV vaccination requirement exception based on the parent or guardian’s “sole discretion”
  - E. Regulation that allows sharing, without a parent’s authorization, their child’s name, address, phone number, birth date, social security number, and vaccination records among physicians, physician assistants, nurse practitioners, licensed institutional health care providers, local and district health departments, the Virginia Immunization Information System, and the Virginia Department of Health; and
  - F. Board of Health requirement to make annual revision recommendations to the Governor, General Assembly and JCHC.

Additionally, four of the proposed legislative remedy options potentially involve changes to other Virginia laws and regulations:

- The provisions in Option #4 could affect the laws and regulations that govern nurse practitioner scope of practice, services that can be provided by local health departments, and the Virginia School Entrance Health Form;
- Options #7 and #8 could involve modification of existing continuing education laws and regulations for multiple types of providers;
- Option #8 could involve modification of existing laws and regulations that govern the Department of Health programs and appropriations;

- Option #9 also could involve modification of existing laws and regulations that govern the Department of Health and Department of Education programs and appropriations.

**Overview of Proposed Legislative Policy Options:** In the Aug. 3, 2016 JCHC staff report, nine legislative policy options were proposed to meet the legislative goals of lowering religious and medical vaccine exemption rates and reducing the actual increases or potential for increases in the incidence rates of 12 diseases targeted by vaccine mandates. On Table 4-1. *Proposed Legislative Option Core Components* some of the existing structures and processes that would be affected or need to be created are identified for each of the proposed legislative policy options.

**Table 4-1. Proposed Legislative Option Core Components**

Option Core Components	Option #1	Option #2	Option #3	Option #4	Option #5	Option #6	Option #7	Option #8	Option #9	
	<b>Vaccine Exemption Options</b>					<b>Non-Exemption Options</b>				
Religious Exemption	No change	Remove	Remove	Remove	No change	Silent	Silent	Silent	Silent	
Medical Exemption	No change	Change	Silent	Change	Silent	Silent	Silent	Silent	Silent	
Philosophical Exemption					Add					
Local Health Department Services				Change						
Nurse Practitioner Scope of Practice				Change						
School Health Entrance Form		Change		Change						
Medical Exemption Form		Change		Change	Change					
Religious Exemption Form	No change	Null	Null	Null	Change					
New Documentation Requirement		Add			Add	Add				
Alternate Vaccination Plan						Add				
Provider Continuing Education							Add	Add		
DOH Vaccine Messaging								Add		
Vaccination Reporting / Review									Add	

The proposed legislative policy options are discussed below and are divided into two groups: (1) options that either retain, restrict or change legal vaccine exemptions; and (2) options that do not affect legal vaccine exemptions.

## **Proposed Options That Retain, Restrict or Change Vaccine Exemptions**

### **Option #1. Take No Action.**

**JCHC Full Text:** *Take no action*

**Interpretation:** Option #1 would require no change to the statutory language related to religious and medical exemptions contained in VA Codes § 22.1-271.2, § 22.1-271.4 or § 32.1-46 (see above italicized text). It applies to all children educated in a public or private school or homeschool setting and does not change current vaccine laws. It would not change where a child can be vaccinated or who may provide vaccines or vaccination-related care to a child and would not require changes to the current religious or medical vaccine exemption forms.

### **Option #2. Eliminate The Religious Exemption, Restrict Medical Exemption To Contraindications**

**JCHC Full Text:** *Reintroduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, removing religious and medical exemptions and by adding an exemption for medical contraindication as the only exemption.*

**Interpretation:** Option #2 would not only require striking all the statutory language related to religious exemptions contained in VA Codes § 22.1-271.2 and § 32.1-46, it would also require striking all such language in VA Code § 22.1-271.4. This law change would apply to all children being educated in public or private schools or in a homeschool setting in the commonwealth.

Enacting Option #2 would eliminate the legal right for parents with conscientiously held religious beliefs regarding vaccination to receive a religious exemption for their children to be educated in the commonwealth. There was no explanation in HR1342 or in language describing this option in the JCHC staff report explaining what kind of legal sanctions parents, who refuse to comply with forced vaccination policies, would face for exercising freedom of conscience and religion protected by the Bill of Rights of The Virginia Constitution; the Virginia 1786 Act for Religious Freedom; the Virginia 2007 Religious Freedom Act and the Virginia 2013 Parental Rights Act.

It also would seriously affect the current medical exemption law and would require striking the language in all three of the above laws that permit licensed physicians and other authorized health care professionals administering vaccines to determine whether a child's health and medical history could make administration of one of more vaccines "detrimental to" the child's health.

It appears to deny physicians and authorized health care providers the legal right to grant a child a medical exemption if the child's past medical history or current health problems do not qualify for a "medical contraindication." However, the term "medical contraindication" was not defined in HB1342 or described in Option #2 in the JCHC staff report.

For the purpose of this analysis, we assume that the term "medical contraindication" refers to reasons to withhold or delay vaccinations recognized by the U.S. Department of Health and Human Services. Vaccination guidelines that list federally approved "vaccine contraindications" are published by the CDC's Advisory Committee on Immunization Practices (ACIP) and are routinely adopted by medical trade associations and state health departments.<sup>62</sup>

As noted in Section 1, under current restrictive federal and medical trade vaccine contraindication guidelines, 99.99 percent of children (and adults) do not qualify for an "official" medical exemption to vaccination.<sup>63</sup> Therefore, Option #2 would take away the ability of a child's own pediatrician or family doctor from providing personalized care and legally require doctors and other authorized vaccine providers administering vaccines to strictly adhere to very narrow vaccine contraindication guidelines approved by the federal government. It would remove an individual physician's legal right to exercise professional judgment and conscience when granting a child a medical vaccine exemption after evaluating the child's personal and family medical history and current state of health.

It would also require changing the medical exemption language in the Virginia School Entrance Health Form.<sup>64</sup>

An outstanding question is whether passage of a law that changes the qualifying conditions for a medical vaccine exemption would immediately nullify all of the temporary and permanent medical exemptions for children in Virginia on file in schools. Some of the vulnerable children with medical exemptions may or may not qualify for a "medical contraindication" under narrow federal vaccine contraindication guidelines. The text of HB1342 and Option #2 outlined in the JCHC staff report was silent on how this option would be implemented and which children would be affected by severely restricting the medical vaccine exemption to exclude almost all children from qualifying for it.

### **Option #3. Eliminate The Religious Exemption**

**JCHC Full Text:** *Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, eliminating the religious exemption.*

**Interpretation:** Option #3 would require striking all statutory language related to religious exemptions contained in VA Codes § 22.1-271.2, § 22.1-271.4 or § 32.1-46. This law change would apply to all children being educated in public or private schools or in a homeschool setting in the commonwealth.

As with Option #2, adoption of Option #3 would eliminate the legal right for parents exercising conscience and religious beliefs regarding vaccination to receive a religious vaccine exemption for their children to be educated in the commonwealth. There was no explanation in HR1342 or in language describing this option in the JCHC staff report explaining what kind of legal sanctions parents, who refuse to comply with forced vaccination policies, would face for exercising freedom of conscience and religion protected under Virginia law.

### **Option #4. Eliminate Religious Exemption, Modify Medical Exemption to Prohibit Nurse Practitioners and Local Health Departments from Issuing Medical Exemption Statements Potentially Clarify Documentation Requirements**

**JCHC Full Text:** *Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, eliminating the religious exemption and providing that medical exemptions can only be obtained from a licensed physician and must say what the physical condition of the child is, which vaccines are being exempted, whether the exemption is temporary or permanent and if temporary when the exemption will expire.*

**Interpretation:** Option #4 would require striking all statutory language related to religious exemptions contained in VA Codes § 22.1-271.2, § 22.1-271.4 and § 32.1-46. This law change would apply to all children being educated in public or private schools or in a homeschool setting in the commonwealth.

As with Options #2 and #3, adoption of Option #4 would eliminate the legal right for parents to exercise freedom of conscience and religion and receive a religious exemption for their children to be educated in the commonwealth. There was no explanation in HR1342 or in language describing this option in the JCHC staff report explaining what kind of legal sanctions parents, who refuse to comply with forced vaccination policies, would face for exercising freedom of conscience and religion protected by Virginia law.

In addition, Option #4 restricts the legal right to grant medical vaccine exemptions to licensed physicians. Therefore, adopting this option would require striking all statutory language in VA Codes § 22.1-271.2, § 22.1-271.4 and § 32.1-46 that permit licensed nurse practitioners and authorized health care providers, who are not physicians, in local health departments to issue medical vaccine exemption statements for their patients. Adoption of Option #4 may also require modification of the laws that govern the scope of practice for a nurse practitioner. Similarly, it may require redefining the services that authorized health care providers working in local health departments may provide. It is unclear whether adoption of this legislative option would restrict the legal right to grant medical vaccine exemptions to only physicians licensed in Virginia, as is currently required by one of the three applicable vaccine laws.

Option #4 also proposes that specific language be included in medical vaccine exemption statements granted by physicians. It should be noted that all three current vaccine laws already contain very similar language that is being proposed in Option #4. Specifically,

VA Code § 22.1-271.2

*...one or more of the required immunizations may be detrimental to the student's health, indicating the specific nature and probable duration of the medical condition or circumstance that contraindicates immunization.*

VA Code § 22.1-271.4

*...one or more of the required immunizations may be detrimental to the child's health, indicating the specific nature of the medical condition or circumstance that contraindicates immunization*

VA Code § 32.1-46

*...states that the physical condition of the child is such that the administration of one or more of the required immunizing agents would be detrimental to the health of the child*

Additionally, the current School Health Entrance Form already requires that the child's health care provider render their professional opinion that administration of one or more vaccines would be detrimental to a child's health and record the reasons that the vaccine(s) are contraindicated, the specific vaccines that were not administered to the child, and whether the contraindication is permanent or temporary and, if temporary, the expiration date.

We assume that the proposed language in Option #4 related to the medical exemption was intended to modify and make it consistent in VA

Codes § 22.1-271.2, § 22.1-271.4 and § 32.1-46 and in Section II of the School Entrance Health Form.

**Option #5. Add Philosophical Exemption, Require Parent Documentation Of Vaccine-Specific Religious And Philosophical Objections**

**JCHC Full Text:** *Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, splitting the religious exemption into two parts – a religious exemption and a philosophical exemption. Both the religious and philosophical exemptions would be required to include what vaccines the person objects to based on religion or philosophical beliefs.*

**Interpretation:** Under Option #5, the statutory language related to the religious exemption contained in VA Codes § 22.1-271.2, § 22.1-271.4, and § 32.1-46, would change. This option contains a provision adding a philosophical vaccine exemption that distinguishes between a vaccine exemption based on exercise of freedom of conscience and religion and a vaccine exemption based on philosophy or philosophical beliefs, which are not defined in the JCHC staff report, but are generally defined as a particular set of ideas about knowledge, truth and the nature and meaning of life.<sup>65</sup> This law change would apply to all children being educated in public or private schools or in a homeschool setting in the commonwealth

Additionally, the current religious and medical exemption forms would need to be changed.

**Proposed Options That Do Not Affect Vaccine Exemptions**

**Option #6. Permit Physicians to File Alternative Vaccination Plans, Require Such Children to Be Fully Vaccinated by Kindergarten**

**JCHC Full Text:** *Introduce legislation to amend section 22.1-271.2 and section 32.1-46 of the Virginia Code, adding a subsection allowing physicians to file alternative vaccination plans provided that the child receives all required vaccines before kindergarten.*

**Interpretation:** Option #6 would require amending all three applicable vaccine laws - VA Codes § 22.1-271.2, § 22.1-271.4, and § 32.1-46. Exactly what would constitute an “alternative vaccination plan” or where and with whom the plan would need to be filed is not described in the JCHC staff report. How an “alternative vaccination plan” would apply to children younger than kindergarten age, who are currently subject to

vaccination laws, or who are enrolled in daycare and preschool programs is also not described.

Also unknown is if or how “alternative vaccination plans” would affect the legal right for parents to obtain religious and medical vaccine exemptions for their children to be educated in the commonwealth.

### **Option #7. Improve Physician Childhood Vaccination CME.**

**JCHC Full Text:** *Introduce legislation to amend Chapter 29 of Title 54.1 of the Virginia Code to improve the continuing medical education (CME) of physicians on childhood vaccinations.*

**Interpretation:** Although not fully described in the staff report, we assume that adoption of Option #7 would amend the provisions under VA Code § 54.1-2912.1<sup>66</sup> and perhaps in other regulations to encourage or mandate that a portion of the required continuing medical education hours for physicians can be met by taking courses on childhood vaccines. Under the current law, it appears that the Board of Medicine has the regulatory authority to ensure the professional competence of physicians as stated in VA Code § 54.1-2912.1 that the “Board shall prescribe by regulation such requirements as may be necessary to ensure continued practitioner competence which may include continuing education, testing, and/or any other requirement.”

The staff report language under Option #7 does not describe (1) the mechanism by which the Board would require or simply make available a particular childhood vaccine education course; (2) which medical specialties would be required or allowed to take the course; and (3) how many CME hours would be offered. There is no indication whether the childhood vaccine education course would be voluntary or mandatorily required for continued licensure or what the CME course content would be and who would develop and teach it, or how the program would be financed by the state.

Currently, physicians have the option of fulfilling some of their CME requirements by taking any number of readily available courses on vaccination topics online. Most of those courses do not address and/or emphasize the importance of physician compliance with legal vaccine safety informing, recording and reporting mandates under the National Childhood Vaccine Injury Act of 1986,<sup>67 68</sup> which requires physicians and all vaccine providers to (1) give vaccine benefit and risk information to parents of children *before* children are vaccinated; (2) to record serious health problems that occur after vaccination in the permanent medical record; and (3) to report serious health problems, hospitalizations, injuries and deaths that occur following vaccination to

the federal Vaccine Adverse Events Reporting System (VAERS). Because there is no penalty for non-compliance, these vaccine safety informing, reporting and recording mechanism are not being followed by the majority of U.S. physicians and other vaccine providers.<sup>69 70 71</sup>

#### **Option #8. Increase VDH Funding to Design Vaccine Education Messages for the Public and Vaccine Providers**

**JCHC Full Text:** *Introduce budget amendment (language and funding) for the Virginia Department of Health to design more effective messages concerning vaccination programs for different communities and for the continuing education of physicians and other health care providers.*

**Interpretation:** The statutes and regulations to be amended to enact this option were not identified in the JCHC staff report. Programs addressing these topics are readily available from the CDC and medical trade associations, such as the American Academy of Pediatrics (AAP).

#### **Option #9. Increase Monitoring and Reporting of Vaccine Uptake and Exemptions in Public and Private Schools and in Homeschool Settings**

**JCHC Full Text:** *Request by letter of the JCHC Chair that the Health Department and the Department of Education work with local school divisions and private schools to improve reporting by schools and home schools to make certain that schools with low vaccination rates are filing reports properly and timely and the reports are reviewed for the reasons for low vaccination rates. A report to the Commission detailing the results of the agency efforts will be provided by October 1, 2017.*

**Interpretation:** Under current VA Code the following reporting statutes apply:

VA Code § 22.1-271.2 states, in part:

E. Every school shall record each student's immunizations on the school immunization record. The school immunization record shall be a standardized form provided by the State Department of Health, which shall be a part of the mandatory permanent student record. Such record shall be open to inspection by officials of the State Department of Health and the local health departments.

Within 30 calendar days after the beginning of each school year or entrance of a student, each admitting official shall file a report with the local health department. The report shall be filed on forms

prepared by the State Department of Health and shall state the number of students admitted to school with documentary proof of immunization, the number of students who have been admitted with a medical or religious exemption and the number of students who have been conditionally admitted, including those students who are homeless children or youths as defined in subdivision A 6 of § 22.1-3.

G. The Board of Health shall promulgate rules and regulations for the implementation of this section in congruence with rules and regulations of the Board of Health promulgated under § 32.1-46 and in cooperation with the Board of Education.

VA Code § 22.1-271.4 states, in part:

Upon request by the division superintendent, the parent shall submit to such division superintendent documentary proof of immunization in compliance with § 32.1-46.

VA Code § 32.1-46:

F. The State Board of Health shall review this section annually and make recommendations for revision by September 1 to the Governor, the General Assembly, and the Joint Commission on Health Care.

Although under VA Code § 22.1-271.2, schools are required to submit annual reports for all students, they are required to do so on the state VDH data collection tool which only requires that schools with kindergarten and 6<sup>th</sup> grade students submit annual immunization data.<sup>72</sup> The VDH Annual School Self-Reports of Immunization Coverage report indicates that it only assesses compliance for schools with kindergarten and 6<sup>th</sup> grade programs.<sup>73</sup> It appears that there is no law or administrative regulation that requires the Virginia Department of Health, Department of Education or local schools to collect, report or analyze immunization data for students not enrolled in a public or private school.

Lastly, under VA Code § 32.1-46 the VDH is already required to submit an annual report to the JCHC.

## **Section 5. Analytical Methods**

This section discusses the methods used to conduct our legislative policy analysis. It identifies and describes the groups of criteria used to evaluate legislative remedy options that (1) propose to retain or eliminate, restrict or redefine medical or religious vaccine exemptions and/or change the process for obtaining vaccine exemptions under current law; and (2) propose to address

various non-exemption laws and regulations. It identifies the relative weights assigned to criteria groups and describes the rating scale we used to assess each criterion to determine how likely a particular option would meet criteria for the purpose of achieving proposed legislative remedy goals.

### **Criterion Groups and Definitions**

After reviewing current health policy literature, we identified six groups of criteria commonly used to conduct legislative policy analysis that would be applicable to this topic.<sup>74 75</sup> The criteria groups we selected with the most relevant considerations for each group are listed below.

#### **1. Effectiveness and Safety Criterion**

Will the proposed option be safe and effective in terms of reducing the use of vaccine exemptions? Will it be safe and effective in reducing the incidence of vaccine-targeted diseases? Will the option be safe and not increase risks for injury and death for certain individuals or groups of individuals? Will it improve an individual's overall long-term health? Will the option support evidence-based clinical practice guidelines that acknowledge the need for personalized health care plans and shared medical decision-making to optimize positive health outcomes for individuals?

#### **2. Costs Criterion**

Will costs to the state, parents, providers and schools be non-existent or minimal if the proposed option is adopted and enforced? Is there no or minimal risk of incurring significant costs to monitor compliance and defend legal challenges after the option is implemented? Are there funds in place to cover potential cost increases if the option is adopted?

#### **3. Ethics Criterion**

Will the proposed option respect individual autonomy and the human right to informed consent to medical risk taking and exercise of civil liberties? Will it be consistent with internationally recognized human rights? Will it recognize the precautionary principle in public policymaking to "first, do no harm?" Will the option result in preserving the value of protecting individual lives and minority subgroups of susceptible individuals at higher risk for suffering vaccine harm? Will it avoid creating inequality and disparities in health care? Will it effectively serve the "common good?"

#### **4. Legality Criterion**

Is the proposed option consistent with existing U.S. and Virginia law? Will it recognize long established civil liberties protected in U.S. and Virginia law? Will it strike an appropriate balance between individual rights, including parental rights, and public health policy goals? Will the option minimize the likelihood of legal challenges?

**5. Administrative Feasibility Criterion**

Can the proposed option be implemented with existing infrastructure and staffing resources? Will the option avoid increasing administrative burdens on parents, vaccine providers and schools? Will the option’s administrative implementation and enforcement be effective and avoid creating unintended consequences?

**6. Cultural and Political Acceptability Criterion**

Is the proposed option culturally and politically acceptable to Americans and, in particular, to citizens residing in the Commonwealth? Will adoption of the option avoid increasing fear and distrust of public health officials, medical doctors and government that could negatively impact acceptance of future public health policies? Will it decrease political unrest and avoid creating social tension?

**Criterion Group Relative Weights**

The criteria groups we evaluated are not equivalent in terms of the potential effects that adoption of different proposed legislative remedy options could have toward reducing use of vaccine exemptions and reducing the incidence of vaccine-targeted diseases. They are also not equivalent in terms of issues related to cultural values, beliefs and exercise of basic human rights protected in U.S. and Virginia law that are most important to families who will be most affected by proposed vaccine law changes. Therefore, we assigned a relative weight to each group that reflects these considerations as shown below. Because of insufficient available data on costs, we assigned that criterion the lowest weight. The sum of relative weights for the groups is 1.0.

1. Effectiveness and Safety .....	.20
2. Costs.....	.10
3. Ethics .....	.20
4. Legality.....	.20
5. Administrative Feasibility.....	.15
6. Cultural and Political Acceptability .....	.15

**Option Rating Scale**

The overall likelihood that an option would meet the considerations for a criteria group was estimated using a five-level Likert agreement rating scale. We would have preferred to also consider cost projections, QALY estimates, conditional disease forecasting model estimates and other quantified sources of information, but we were unable to find such data online and this limited our ability to weight and rate some criteria groups with precision, particularly the cost criterion, as mentioned previously.

The five-level Likert rating scale we used to estimate whether adoption of the option would meet the conditions specified within the criteria group is the following:

5. Strongly Agree
4. Agree
3. Neutral / Unable to Determine
2. Disagree
1. Strongly Agree

The results for each option were reviewed for consistency within and across all options.

### **Option Score Calculations**

The total score for an option is the sum of its rating for a criteria (1 to 5) multiplied by the relative weight for that particular criteria. For example, a rating of “4” for the effectiveness and safety criterion would be multiplied by .20, the relative weight for that criterion. Thus, the criterion score would be .80 (4 x .20). The six weighted criterion scores for each option were summed to compute the option’s overall score. The minimal score an option could receive is 1.0 and the maximum is 5.0.

## **Section 6: Legislative Policy Option Assessment and Scoring Results**

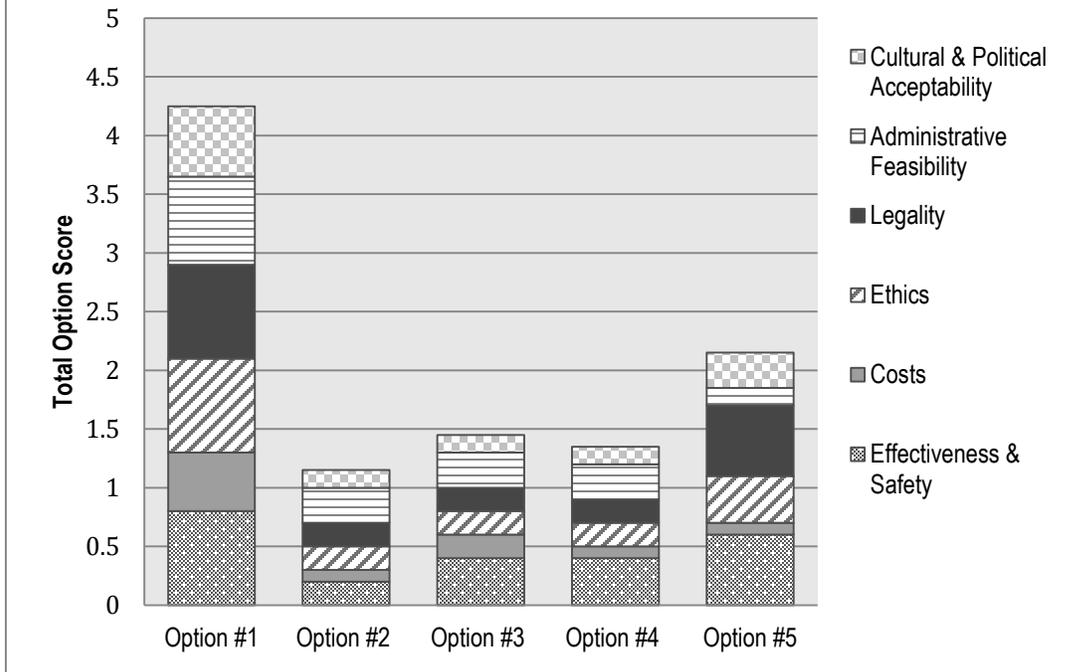
This section of the paper is divided into two parts. The first part is an overview that shows the criterion ratings and total scores for the proposed legislative policy Options #1-9 contained in the JCHC staff report. The second part discusses the criterion ratings for the highest rated option.

### **Proposed Legislative Policy Options Criterion and Total Scores**

The ratings results are shown on Table 6-1 *Proposed Legislative Option Scores*. Table 6-1 shows the raw criterion ratings and total weighted scores for each proposed legislative option.

Additionally, Figure 6-1 *Vaccine Exemption Policy Options, Total Weighted Scores* and Figure 6-2 *Non-Exemption Policy Options, Total Weighted Scores* show the total and individual weighted criterion scores for proposed vaccine exemption and non-exemption policy options. For each option, differences in the height of each colored section of the bar reflect differences in criterion-specific weighted scores. The differences in total height show differences in total scores.

**Figure 6-1. Vaccine Exemption Policy Options, Total Weighted Scores**

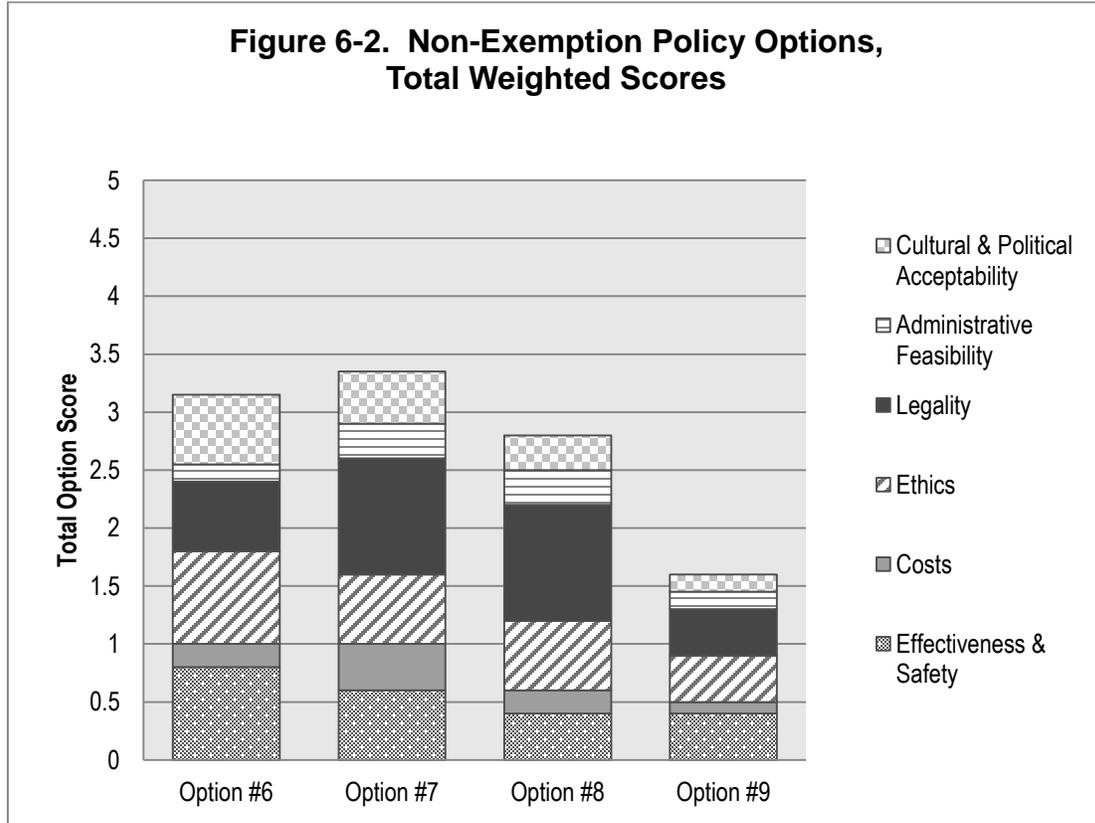


As shown in Table 6-1 and Figures 6-1 and 6-2, Option #1, which proposes to leave current vaccine laws unchanged, was scored higher than any of the other proposed vaccine exemption options which propose to eliminate, restrict or redefine medical and/or religious vaccine exemptions and/or change the process for obtaining vaccine exemptions under current law. Option #1 also scored higher than Options #6-9 that propose to address various non-exemption laws and regulations.

**Table 6-1. Proposed Legislative Option Scores**

Assessment Criteria  Rating Scale 5 = Strongly Agree 4 = Agree 3 = Neutral / Unable to Determine 2 = Somewhat Disagree 1 = Strongly Disagree	Criterion Relative Weights	Options That Retain or Change Exemptions										Options That Do Not Change Exemptions									
		Option #1 Take no action		Option #2 Eliminate religious exemption, restrict medical exemption to contraindications		Option #3 Eliminate religious exemption		Option #4 Eliminate religious exemption, prohibit nurse practitioner granting medical exemptions		Option #5 Add philosophical exemption, require documentation of nature of objection		Option #6 Permit MD alternative vaccination plans, require full vaccinated by kindergarten		Option #7 Improve physician childhood vaccination CME		Option #8 Fund VDH vaccine messaging and provider vaccination CE		Option #9 Increase monitoring and investigation of school vaccination reporting			
		R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S		
<b>Effectiveness and Safety</b> Will the proposed option be safe and effective in terms of reducing the use of vaccine exemptions? Will it be safe and effective in reducing the incidence of vaccine-targeted diseases? Will the option be safe and not increase risks for injury and death for certain individuals or groups of individuals? Will it improve an individual's overall long-term health? Will the option support evidence-based clinical practice guidelines that acknowledge the need for personalized health care plans and shared medical decision-making to optimize positive health outcomes for individuals?	.20	4	.80	1	.10	2	.40	2	.40	3	.60	4	.80	3	.60	2	.40	2	.40		
<b>Costs</b> Will costs to the state, parents, providers and schools be non-existent or minimal if the option is adopted and enforced? Is there no or minimal risk of incurring significant costs to monitor compliance and defend legal challenges after the option is implemented? Are there funds in place to cover potential cost increases if the option is adopted?	.10	5	.50	1	.20	2	.20	1	.10	1	.10	2	.20	4	.40	2	.20	1	.10		
<b>Ethics</b> Will the option respect individual autonomy and the human right to informed consent to medical risk taking and exercise of civil liberties? Will it be consistent with internationally recognized human rights? Will it recognize the precautionary principle in public policymaking to "first, do no harm?" Will the option result in preserving the value of protecting individual lives and minority subgroups of susceptible individuals at higher risk for suffering vaccine harm? Will it avoid creating inequality and disparities in health care? Will it effectively serve the "common good?"	.20	4	.80	1	.20	1	.20	1	.20	2	.40	4	.80	3	.60	3	.60	2	.40		
<b>Legality</b> Is the proposed option consistent with existing U.S. and Virginia law? Will it recognize long established civil liberties protected in U.S. and Virginia law? Will it strike an appropriate balance between individual rights, including parental rights, and public health policy goals? Will the option minimize the likelihood of legal challenges?	.20	4	.80	1	.20	1	.20	1	.20	3	.60	3	.60	5	1.00	5	1.00	2	.40		
<b>Administrative Feasibility</b> Can the proposed option be implemented with existing infrastructure and staffing resources? Will the option avoid increasing administrative burdens on parents, vaccine providers and schools? Will the option's administrative implementation and enforcement be effective and avoid creating unintended consequences?	.15	5	.75	2	.30	2	.30	2	.30	1	.15	1	.15	2	.30	2	.30	1	.15		
<b>Cultural and Political Acceptability</b> Is the proposed option culturally and politically acceptable to Americans and, in particular, to citizens residing in the Commonwealth? Will adoption of the option avoid increasing fear and distrust of public health officials, medical doctors and government that could negatively impact acceptance of future public health policies? Will it decrease political unrest and avoid creating social tension?	.15	4	.80	1	.15	1	.15	1	.15	2	.30	4	.60	3	.45	2	.30	1	.15		
<b>Totals</b>	1.0		<b>4.25</b>		<b>1.15</b>		<b>1.45</b>		<b>1.35</b>		<b>2.15</b>		<b>3.15</b>		<b>3.35</b>		<b>2.80</b>		<b>1.60</b>		

**Figure 6-2. Non-Exemption Policy Options, Total Weighted Scores**



As stated in previous sections of this analysis, we evaluated and assessed the nine proposed legislative remedy options with a focus on how current vaccine laws or changes to laws will affect the health and well being of individuals, which includes the impact on exercise of civil liberties (human rights). We generally focused on the potential of a particular option to positively or negatively affect the health and well being of Virginia parents and their children, including children at high risk for suffering vaccine reactions, and how a particular option could positively or negatively affect relationships with pediatricians, primary care doctors, other health care providers and state government officials (public health, school, social service, law enforcement), as well as result in no change or increases/ decreases in costs associated with implementation of the option.

## Proposed Policy Option #1 – Discussion of Individual Criterion Scores

Below, we describe why particular ratings were assigned to Option #1 as it relates to the six criterion groups: effectiveness & safety, cost, ethics, legality, administrative feasibility, and cultural and political acceptability. Additionally, in particular instances, we contrast option #1 criterion ratings to those of other proposed options to illustrate the rationale for assigning particular criterion ratings.

We note, however, an important caveat. The merits of the proposed non-exemption policy options (Options #6, #7, #8 and #9) cannot be accurately evaluated “in a vacuum” when the status of vaccine exemptions is unknown. Thus, we had to make an assumption about what type of vaccine laws would be in effect in terms of provided vaccine exemptions. For the purpose of assessing the merits of the proposed non-exemption options as it relates to the six criteria groups – we assumed that the current medical and religious exemptions, essentially, Option #1 (Take No Action), would be in effect. If this assumption is incorrect, then the criterion ratings for all non-exemption options would need to be re-evaluated and revised.

As described above in Section 4, recommending Option #1 involves no change to current vaccine laws, which currently provide for religious and medical vaccine exemptions. The total score for Option #1 is 4.25 out of a possible score of 5.0. The overall score of 4.25 is the sum of the following six weighted criterion scores discussed below.

Under Option #1 that preserves the current law governing vaccine religious and medical vaccine exemptions, the commonwealth has high vaccine coverage rates among kindergarten children, low disease incidence rates and low vaccine exemption rates among children. This option will not incur additional costs and no additional administrative burdens will be placed on state employees. Additionally, Option #1 continues to offer moderate protection of the health of vaccine susceptible children through the retention of a flexible medical exemption and preservation of the religious belief exemption.

### **Effectiveness & Safety Criterion.**

This criterion was rated as a “4” – we agree. Recommending Option #1 moderately meets the safety and effectiveness conditions as defined for this criterion.

**Safety:** The reason we did not rate this criterion a “5” – strongly agree – is because the state’s vaccine law requires parents to give their healthy children vaccines that carry an unpredictable risk of injury, death or failure, which can be greater for susceptible individuals with genetic and biological high risk factors that science has not defined, and doctors cannot accurately predict.<sup>76 77 78 79</sup> Additionally, due to very narrow one-size-fits-

all federal vaccine recommendations that provide almost no medical contraindications, many parents whose children have already suffered severe vaccine reactions or permanent vaccine injury are unable to find a doctor to provide a medical vaccine exemption, which places their children in danger of being harmed further.<sup>80</sup>

We also note that Option #1 will preserve intact a child's access to current health care providers and protect the legal right of pediatricians, primary care physicians and other vaccine providers to personalize care for children being educated in the commonwealth. In contrast, for example, adoption of Option #4 specifically will restrict access to current health care providers and Option #2 places personalized health care in jeopardy for children being educated in the commonwealth.

Since the definition of medical exemption in Option #2 all but eliminates the medical exemption, it is of critical importance to note that Option #1 respects and acknowledges biodiversity. It will *not* increase the risk of inflexible and inappropriate implementation of vaccine mandates, which inherently jeopardizes the health of individually susceptible children with genetic and other biological risk factors that make them more vulnerable to vaccine reactions, injury and death.

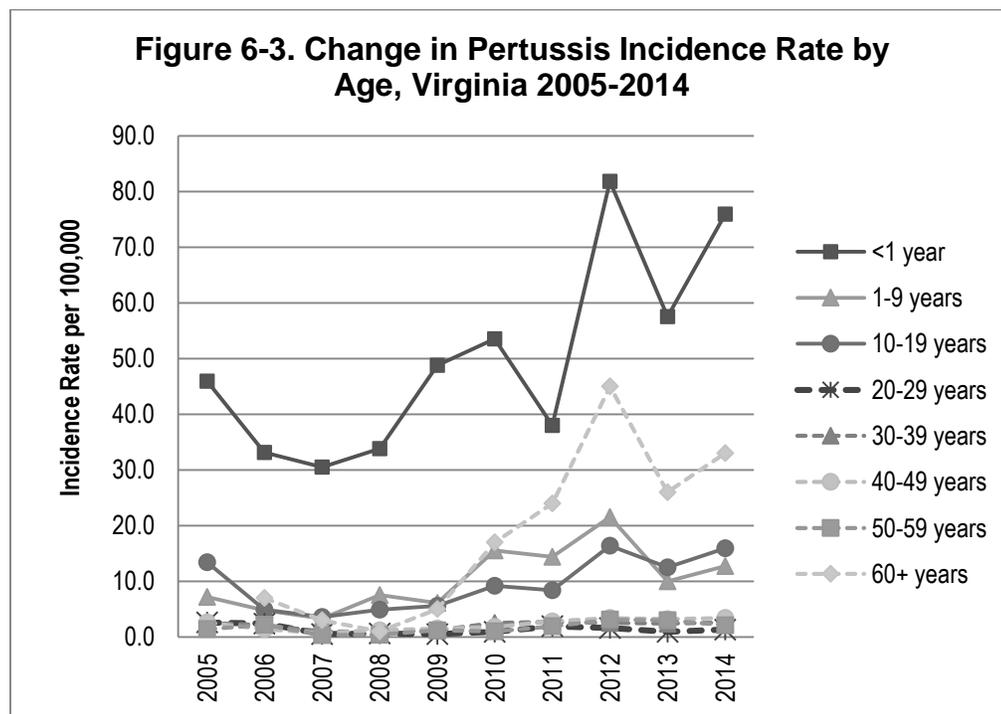
Option #1 also respects and acknowledges the importance of protecting the legal right for parents to exercise freedom of thought, conscience and religious belief regarding vaccination. It also protects the legal right for doctors to exercise professional judgment and conscience when evaluating whether or not a child qualifies for a medical vaccine exemption.

**Effectiveness:** Although Option #1 minimally meets the effectiveness criterion, it is more effective than Options #2-5, which will not only make vaccine laws in Virginia less safe but will not be effective in further decreasing the incidence of a number of the vaccine targeted infectious diseases. Vaccines provide at best only temporary immunity and some vaccines, like pertussis, cannot prevent asymptomatic infection and transmission by vaccinated persons. We note a substantial amount of peer reviewed medical literature spanning many decades clearly showing that disease incidence cannot be lowered by simply increasing uptake of available vaccines.

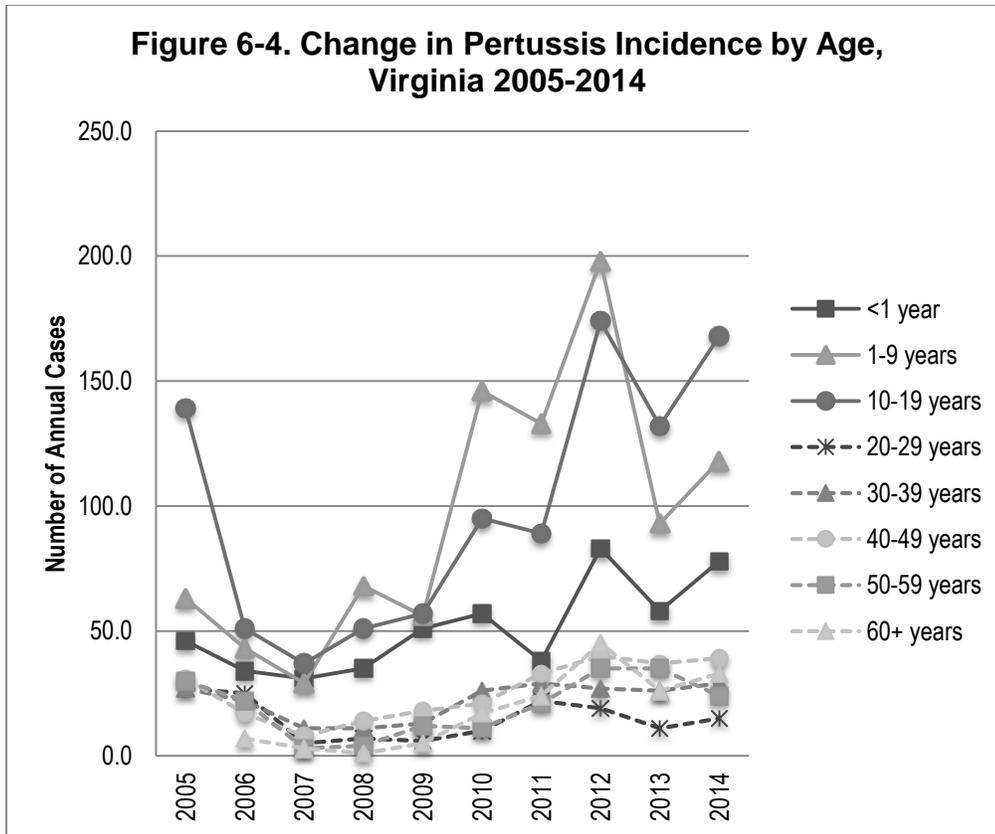
In particular, outbreaks of measles, mumps and, especially, pertussis, cannot be blamed on the less than 1.7 percent of unvaccinated or partially vaccinated school children in the U.S. but are primarily associated with three types of vaccine failures: (1) artificial vaccine acquired immunity wanes, sometimes lasting only a few years after vaccination;<sup>81 82</sup> (2) evolution of strains of viruses or bacteria that do not match currently circulating strains causing infection and illness;<sup>83 84 85 86</sup> and (3) the

vaccine may prevent severe disease but does not prevent infection<sup>87 88</sup> and transmission, including atypical symptoms or asymptomatic transmission among vaccinated persons.<sup>89 90</sup>

For example, Figure 6-3 *Change in Pertussis Incidence Rate by Age, Virginia 2005-2014* shows the annual incidence rates reported to the Virginia Department of Health between 2005 and 2014.<sup>91</sup> Note the steady increase in incidence rates among infants less than one year of age. By one year of age, the vast majority of these infants will have had 3 doses of DTaP vaccine administered at two, four and six months of age and, since 2011, many of their mothers will have received Tdap vaccine during pregnancy.



Additionally, Figure 6-4 *Change in Pertussis Incidence by Age, Virginia 2005-2014* shows the increase in number of cases by age reported to the VDH. Note the steady increase in number of reported cases in children less than one, between one and nine and 10 and 19 years of age. These are highly vaccinated children most of whom will have received five pertussis-containing vaccines by early adolescence. These data demonstrate how use of ineffective pertussis vaccines does not reduce pertussis infection and transmission among highly vaccinated children and therefore, fails to convey vaccine acquired “herd” or “community” immunity.



In the California outbreak of measles outbreak in 2015, 30 percent of the reported measles cases with vaccine records had received one or two MMR shots.<sup>92 93</sup> When a child or adult has received two doses of measles containing vaccine (MMR) and three to six doses of pertussis containing vaccine (DPT/DTaP/Tdap) and still can be infected while showing atypical or no symptoms or transmit the infection to other vaccinated people, it is impossible to accurately identify all cases of the disease and report it,<sup>94 95</sup> which prevents health officials from accurately measuring disease incidence or accurately measuring the impact of vaccine mandates and exemptions on disease incidence.

**Costs Criterion.**

This criterion was rated as “5” – we strongly agree. Recommending Option #1 well meets the cost conditions as defined for this criterion.

Recommending Option #1 does not require passing new legislation to develop and implement new programs requiring increased staffing or additional administrative burdens. Therefore, costs are contained.

In comparison, to varying degrees, all of remaining proposed legislative options (Options #2-9) involve new or modified laws and regulations, which will increase costs to state agencies, schools and to parents, health

care providers and insurers. At a minimum, new costs to state agencies and schools will be incurred to promulgate, issue, implement, monitor and track compliance with new regulations and procedures. There will be new costs associated with changing school entrance health forms, changing exemption forms, developing new continuing education content, and developing vaccine messaging programs.

Option #4 will increase costs because it will restrict access to basic health care in lower cost medical settings, such as public health clinics, and to health care provided by lower cost non-physician providers, such as nurse practitioners.

In contrast to Option #1, adoption of Options #2, #3 and #4 will incur other costs that parents, insurers and the state will have to cover when vaccine injuries suffered by susceptible children, who are forced to comply with inflexible vaccine mandates, occur. These costs include both (1) short and long-term medical and rehabilitative care that will be paid by parents, health care providers, medical insurance programs including Medicaid and private programs, and state-funded social services programs. The costs to health care providers include providing treatment and, as required under federal law, reporting vaccine reactions to the federal Vaccine Adverse Reporting System.

In addition, children who suffer vaccine injuries are often permanently disabled and have learning disabilities and other types of chronic brain and immune system dysfunction that require public schools to cover the costs of developing and providing individualized special education programs. Although the federal Vaccine Injury Compensation Program (VICP) is supposed to cover the lifetime costs of raising and educating a vaccine injured child and, to date, the program has paid out over \$3.5 billion in awards, two out of three vaccine injury claims are denied and the majority of awards today are for adults injured by influenza vaccine.<sup>96 97</sup> When a vaccine injured children is denied federal compensation, this shifts all costs for short and long-term care and special education to parents and to the state, including state public schools.

Most importantly, the state would be subject to covering unbudgeted and potentially significant legal and court costs associated with challenges that arise in opposition to any new law that eliminates or restricts citizen access to basic human rights and civil liberties.

#### **Ethics Criterion.**

This criterion was rated as “4” – we agree. Recommending Option #1 moderately meets the ethical standards defined for this criterion.

It was not rated “5” because, for some parents of vaccine injured children or children at high risk for vaccine injury, the current one-size-fits-all federal vaccine policies and vaccine mandates create inequalities and disparities in health care for their children. Additionally, it is a violation of human rights to deny these parents the ability to follow their conscience and religious beliefs protected in Virginia laws, or to exercise, on behalf of their minor children, the human right to informed consent to medical risk taking.<sup>98</sup>

The current mandatory vaccination program, when rigidly enforced by physicians and public health officials, downplays the need to individualize care for vulnerable subgroups of children by ignoring the precautionary principle<sup>99</sup> to “first do no harm.” When children are treated as if they are all the same genetically and biologically when, in fact, they are *not* the same, the overall “common good” is compromised because the health of a population is the sum of the health of all individuals within that population. When vulnerable at-risk individuals are denied personal medical care and cannot access needed medical vaccine exemptions, which is occurring in Virginia today, or their parents are unable to exercise an exemption for conscientiously held religious beliefs, and those children are injured or die as a result, then the health and well being of the entire population suffers.

Ethically, Option #1 will continue to protect the health of vaccine susceptible children while also protecting civil liberties codified in Virginia laws, including freedom of religion. All of the proposed options that include elimination of the religious exemption, namely Options #2, #3 and #4, completely fail to satisfactorily meet the conditions necessary for a public health policy or law to be ethical.

### **Legality Criterion.**

This criterion was rated as “4” – we agree. Recommending Option #1 moderately meets the legality conditions as defined for this criterion.

It was not rated “5” because, although we agree that Option #1 is mostly consistent with existing Virginia law, as previously described, it still denies some basic human rights and civil liberties because the state is mandating use of a pharmaceutical product that carries an unpredictable risk of injury or death that can be greater for some individuals. In contrast, the remaining proposed policy and legislative remedy options that would completely eliminate the religious vaccine exemption – Options #2, #3 and #4 - would clearly not be consistent with existing Virginia law and were rated as “1” – we strongly disagree that the proposed options are consistent with Virginia law.

There are specific legal concerns that are raised by adoption of Option #2 because it could invalidate permanent medical exemptions already filed

with the schools when the contraindicating health condition of the child stated by the physician on the medical exemption form does not qualify under federal vaccine contraindication definitions. The creation of a state “medical contraindication test” based on federal government vaccine use guidelines would intrude into the nature and scope of physician and licensed nurse practitioner judgment and practice.

The legality of the proposed exemption option that adds a philosophical exemption (Option #5) was rated as “3” – neutral / unable to determine – because it also involves the existing religious exemption statute and could not be evaluated given the limited information provided in the JCHC report. However, it is important to note that the definition of philosophy or philosophical beliefs is generally accepted as a particular set of ideas about knowledge, truth and the nature and meaning of life. Legally, exercise of freedom of philosophy is qualitatively different from exercise of conscience and religious belief, which are defined as human rights and protected in Virginia law.

By proposing the creation of two exemptions in Option #5, one that allows exercise of freedom of conscience and religion, and one that allows exercise of philosophical beliefs, the law is changed to require that parents explain in detail to state officials the reasons for taking either of those exemptions in order to obtain them. This violates the Virginia Act for Religious Freedom that prohibits a “religious test” or inquiry by the state about a citizen’s religious beliefs as a pre-requisite for exercising civil liberties and rights.

Similarly, due to lack of information, we were also unable to assess the legality of Option #6, which creates a new vaccine law involving creation of alternative vaccination plans by physicians. It would require all children using an “alternative” vaccination schedule, which was presumably different from the federally recommended child vaccination schedule, to comply with vaccine mandates by kindergarten age. Therefore, it could not be evaluated and was also rated as “3” – neutral /unable to determine.

The remainder of non-exemption policy options were rated as “5” – we agree that they are consistent with existing law – because they appear to only involve administrative actions that do not require creation of new laws.

**Administrative Feasibility Criterion.**

This criterion was rated as “5” – we strongly agree. Recommending Option #1 well meets the conditions of administrative feasibility as defined for this criterion.

Recommending Option #1 does not require passing new legislation and, subsequently, it does not require state agencies to issue new regulations or develop and implement any new programs.

In contrast, all of the other proposed policy options involve considerable modification to existing administrative systems and some will require creation of entirely new programs and infrastructure. In particular, implementing Options #2, #3, #4, #5 and #6 will involve amending the Virginia Administrative Code, requiring multiple state agencies to issue new regulations and directives, updating school health entrance forms, changing or creating new exemption forms, modifying computerized tracking and monitoring systems, as well as issuing guidance notices and working with parents, health care providers and school personnel.

Additionally, some of the proposed options will be rejected by an unknown number of parents and health care providers and a process for handling and adjudicating disagreements by the state will need to be developed and staffed. In the event that disputes cannot be handled in a way that results in a mutually acceptable outcome, are there administrative systems and state financial resources available to force parents to comply?

If the efforts to force parents to violate their conscience and religious beliefs regarding vaccination do not succeed, are state agencies, attorneys and the courts prepared to publicly identify and impose legal sanctions including fines and jail sentences on parents and place children in the custody of the state?<sup>100 101 102</sup>

Is the state prepared to expel children from all public and private schools when they do not have every dose of every state mandated vaccine and deny them a public education if their parents refuse to violate their conscience and religious beliefs regarding vaccination<sup>103</sup> or if they have a health history or condition that does not strictly qualify as a “medical contraindication” under federal definitions?

Is the state prepared to file truancy charges against children and their parents?

Is the state prepared to refer non-compliant parents to Child Protective Services alleging criminal parental or medical abuse and neglect for failure to obey “no exceptions” compulsory vaccine mandates?<sup>104</sup>

For all these reasons, we argue that adopting proposed legislative policy Options #2-#6 will not meet the administrative feasibility criterion.

### **Cultural & Political Acceptability Criterion.**

This criterion was rated “4” – we agree. Recommending Option #1 moderately meets the cultural and political acceptability conditions as defined for this criterion.

Although Option #1 is preferred by most parents, it was rated as a “4” because it isn’t acceptable for all parents, especially those whose children are already vaccine injured or at high risk for vaccine reactions but who have been denied a medical exemption by doctors rigidly adhering to narrow federal vaccine contraindications.

Parents in Virginia and other states are being pressured by pediatricians and other vaccine providers to strictly comply with federal child vaccination guidelines and schedules. When they do not comply, their children are being denied medical care.<sup>105</sup> This inflexible implementation of federal government vaccine policy has created fear and distrust of doctors and public health officials.<sup>106</sup>

Additionally, doctors in Virginia and in all states are under considerable pressure from federal health officials, HMOs and those advocating for implementation of “no exceptions” vaccination policies to ignore the precautionary principle and deny medical vaccine exemptions to children for whom the risks of vaccination could be higher than for other children.<sup>107</sup> Many doctors fear being harassed by public health officials or their peers for giving medical vaccine exemptions.<sup>108</sup> In addition, they are at risk for economic sanctions by HMO employers pressuring them to achieve a 100 percent vaccination rate with all federally recommended vaccines among their patients.<sup>109</sup>

Despite these concerns, for the following reasons, Option #1 is the highest rated as it relates to cultural and political acceptability. Key stakeholder groups, especially parents who have significant concerns about the health of their children, will view the proposed vaccine exemption policy options that require complete elimination of the religious exemption – in particular, Option #2, Option #3 and Option #4 – as completely unacceptable. They will also reject near elimination of the medical exemption as proposed under Option #2.

As noted under the Administrative Feasibility criterion, efforts by the state to force parents to comply with inflexible laws they disagree with and have good reason to conclude will harm their children, will result in considerable discontent and discord that will be made known to the public. Most certainly, eliminating the religious belief exemption and severely restricting the medical vaccine exemption will create social tension and increase fear and distrust of physicians and public health and school officials, as is occurring in California, where legislators narrowly passed a bill (SB277) that repealed the personal belief vaccine exemption despite large public

protests last year.<sup>110 111 112</sup> After the Governor signed the bill into law in June 2015, citizen lawsuits were filed, which are costing the state unbudgeted and unpredictable legal and staff costs.<sup>113</sup> If there are lessons to be learned from California, it is that arbitrary restriction and elimination of vaccine exemptions increases social tensions and leads to public protests and lawsuits.

In summary, proposed Legislative Option #1 – TAKE NO ACTION – will meet the legislative goals identified in Section 3 because they are already being met under current vaccine laws with regard to low incidence of vaccine-targeted diseases, such as pertussis and measles; high levels of vaccine uptake; and a very low vaccine exemption rate of one percent for children attending public or private schools in the Commonwealth.

Importantly, recommending Option #1 protects freedom of conscience and religion that has been guaranteed in the Commonwealth to citizens for more than 200 years.

## **Section 7. Discussion and Conclusion**

It is critical for legislators to support public health policies and enact laws that protect the health and well being of the community, while equally ensuring that individuals and vulnerable minorities within the community are not harmed. Nowhere is this more important than creating vaccine law, because vaccines are pharmaceutical products given to healthy people and vaccines carry an often unpredictable risk of injury, death and failure, which can be greater for some individuals. That fact was affirmed by the U.S. Congress when it enacted the National Childhood Vaccine Injury Act in 1986 and created an administrative federal vaccine injury compensation program (VICP) alternative to a vaccine injury lawsuit in civil court, a program that has paid more than \$3.5 billion to children and adults who have died or been injured by federally licensed, recommended and mandated vaccines.

There is a special duty for legislators to proceed with caution when proposing laws that require “no exemptions” use of vaccines that can injure and kill healthy children and pose a greater risk for those more susceptible to serious complications from vaccination. Applying crippling societal sanctions, such as denial of education to a child, whose parents are exercising freedom of conscience and religious belief regarding vaccination, requires the state to demonstrate there is an urgent and compelling state interest to override civil liberties and place vulnerable individuals and minorities in harm’s way.

There has been widespread misunderstanding about the reasons for why growing numbers of parents and concerned health care professionals in the U.S. and around the world are questioning the safety and effectiveness of narrow

vaccine policies and restrictive vaccine laws. These issues are germane to the proposed legislative policy options that were proposed in the JCHC staff report, a report which made a number of statements about vaccine science, policy, law and ethics that provided limited evidence, references and perspective. Following is a further discussion of issues related to information presented in the staff report and the legislative policy option criteria impacting safety and effectiveness, costs, legality, ethics, administrative feasibility and cultural and political acceptability of those options.

## **Human Health and Biodiversity**

Although vaccination is widely described as the most important discovery and effective public health program in the history of medicine,<sup>114</sup> in the 21<sup>st</sup> century it is becoming clear that public health is about more than increasing the numbers of vaccinations given during childhood and enacting laws compelling all infants and children to use them. As scientists explore the impact on human health of epigenetics<sup>115 116</sup> and the microbiome,<sup>117</sup> which are unique to each individual, new information is emerging about the role that infectious microorganisms play in maintaining good health.<sup>118 119</sup> This cutting edge science, which acknowledges the importance of biodiversity, is raising new questions about the prevailing view taken since the 19<sup>th</sup> century that viruses and bacteria are the “enemy” and must be suppressed or “eradicated” with the mandated use of an increasing number of drugs and vaccines.

## **Vaccine Laws Controversial Throughout History**

The history of medicine is full of disagreements among physicians and patients about the safety and effectiveness of medical interventions that pose individual risks for those being asked to take the risk. Most medical interventions are prescribed by physicians for sick people to make them well. A healthy individual who is not sick weighs the benefits and risks of using a pharmaceutical product to maintain health much differently than sick individuals weigh the benefits and risks of taking a pharmaceutical product to return to good health.

Vaccines are pharmaceutical products prescribed by physicians for healthy people, especially children. In the U.S. use of vaccines is also mandated by federal government health officials with the approval of state legislatures. As documented in this analysis, vaccines can cause reactions, injury and death - or fail to work - for both healthy children and those who are genetically and biologically more susceptible to suffering adverse responses to vaccination.<sup>120</sup> Therefore, parents are understandably concerned about both protecting their children from suffering harm from infectious diseases, as well as preventing harm from use of pharmaceutical products like vaccines.

Strict enforcement of laws requiring people, especially healthy children, to be vaccinated have been controversial since smallpox vaccine laws were enacted in the 19<sup>th</sup> century.<sup>121</sup> In Victorian England, protests against compulsory smallpox

vaccination laws that included stiff fines and imprisonment for people refusing to comply were often led by parents, notably mothers, who watched their healthy infants become covered in smallpox-like lesions, suffer irreversible brain damage or die after doctors vaccinated them.<sup>122</sup> In response, England added a conscientious belief exemption to vaccination.<sup>123</sup> Today, Canada and most European countries strongly recommend, but do not legally require children to receive the large numbers of vaccinations required in the U.S. as a condition of being able to attend school.<sup>124 125</sup>

### **Child Vaccinations Triple, Chronic Disease Epidemic Grows**

In the late 20<sup>th</sup> and early 21<sup>st</sup> centuries, when U.S. health officials tripled the numbers of vaccinations recommended for children – from 23 doses of seven vaccines to 69 doses of 16 vaccines -<sup>126 127</sup> and states increased the numbers of vaccinations required for children to attend school, parents began to more closely examine vaccine science, policy and law as vaccine benefit and risk information became more accessible to the public. Questions were raised about why new vaccines, such as hepatitis B and chickenpox, were being required for school attendance when they did not fit the smallpox model of being highly contagious, able to be easily transmitted in a public setting, and causing a high rate of permanent injury and death among children.

Many of the questions parents have about the safety and effectiveness of vaccine policies and laws have coincided with the escalating numbers of federally recommended vaccines for children over the past three decades as more young children born healthy develop chronic brain and immune system dysfunction during childhood. The new and unprecedented child chronic disease and disability epidemic in America is having a devastating effect on families and our nation. Today, 1 child in 6 in the U.S. is learning disabled;<sup>128</sup> 1 in 9 has asthma;<sup>129 130</sup> 1 in 10 has ADHD;<sup>131</sup> 1 in 50 develops autism;<sup>132</sup> and 1 in 400 has diabetes.<sup>133</sup> Millions more are suffering with severe allergies<sup>134 135</sup> epilepsy,<sup>136</sup><sup>137</sup> anxiety and depression,<sup>138 139 140</sup> and other kinds of brain and immune disorders marked by chronic inflammation in the body.<sup>141 142 143 144 145</sup>

### **Maternal and Infant Mortality Rates High**

The U.S. has maintained one of the highest child vaccination rates and lowest infectious disease rates,<sup>146</sup> even as public health officials have been unable to explain why so many of today's highly vaccinated children are so sick and disabled. Also unexplained, is why America has the worst infant mortality rate of all developed nations, with 6 out of 1,000 babies dying before their first birthday.<sup>147 148 149</sup>

In addition, maternal mortality in the U.S. has also become one of the worst of all industrialized nations, with between 12 and 28 women in 100,000 dying within one year of giving birth, a maternal mortality rate that more than doubled between 1990 and 2013. According to the World Health Organization (WHO),

annually an estimated 1,200 women in America suffer fatal complications during pregnancy and childbirth and another 60,000 suffer near-fatal complications.<sup>150</sup>

Women having babies in the U.S. today, who represent the most vaccinated generations in our nation's history, are now also being given influenza, diphtheria, pertussis and tetanus vaccines during pregnancy, a federal maternal vaccination policy that was launched in 1997 with administration of influenza vaccine during any trimester<sup>151</sup> and was widened in 2011 with the addition of a pertussis containing Tdap shot after 20 weeks gestation.<sup>152</sup> As of 2015, about half of the nation's pregnant women or nearly 2 million women,<sup>153</sup> were either vaccinated with Tdap vaccine during pregnancy (42 percent)<sup>154 155</sup> or influenza vaccine before or during pregnancy (50 percent)<sup>156</sup> or received both vaccines.

### **Vaccine Exemption Rates and State Health Rankings**

It is understandable why educated populations in a developed country like the U.S. are raising legitimate questions about enforcement of mandatory vaccination laws, which have achieved higher child and maternal vaccination coverage rates using an increasing number of vaccines but which have been accompanied by an, as yet, unexplained rise in the numbers of poor health outcomes for infants, children and mothers. A national health data resource is the United Health Foundation, which annually rates the overall health of different states using multiple health measurement outcomes, including infant mortality rates (IMR).<sup>157</sup>

IMRs are generally accepted as an indicator of the general health of a population. According to the United Health Foundation, with a 6.3 IMR in 2014-2015, Virginia ranked 28th for IMR among all states, and had an overall health ranking of 21.<sup>158</sup>

According to the narrative forwarded by those supporting few or no vaccine exemptions in vaccine laws, it would be expected that states with high vaccine exemptions rates would have high infant mortality rates and low overall health rankings. However, as shown in Table 7-1, in 2014-2015, 11 out of 16 states with the *highest* vaccine exemption rates<sup>159</sup> had infant mortality rates (IMR) *below* the national average. One of these states, Hawaii, was ranked by UHF as the highest ranking state in America.

**Table 7-1. U.S. States with Highest Vaccine Exemption Rates  
2014-2015 School Year**

States	Exemption Type <sup>1</sup>	Vaccine Exemption Rate, 2014 (CDC)	Infant Mortality Rate, 2015 (UHF)	UHF Health Rank, 2015
National Rates		1.7	6.0	
Idaho	M, R, C	6.5	5.5	17
Vermont	M, R, C	6.2	4.3	2
Oregon	M, R, C	6.0	5.1	20
Alaska	M, R	5.8	5.8	27
Colorado	M, R, C	5.4	5.4	8
Michigan	M, R, C	5.3	7.0	35
Wisconsin	M, R, C	5.3	6.0	24
Arizona	M, R	4.8	5.5	30
Washington	M, R, C	4.6	4.9	9
Maine	M, R, C	4.4	7.0	15
Utah	M, R, C	4.3	5.0	7
Montana	M, R	3.9	5.8	23
Hawaii	M, R	3.3	5.6	1
New Hampshire	M, R	2.9	7.0	5
North Dakota	M, R, C	2.7	6.2	12
California	M, R, C	2.7	4.6	16

<sup>1</sup> Exemption Type: M (Medical), R (Religious), and C (Conscience)

Conversely, as shown in Table 7-2, 15 out of 17 states with the *lowest* vaccine exemption rates, including Virginia, had infant mortality rates (IMR) *above* the national average and five of these states had the *worst* IMR and *worst* overall health rankings of states in America.

**Table 7-2. U.S. States with Lowest Vaccine Exemption Rates**

States	Exemption Type <sup>1</sup>	Vaccine Exemption Rate, 2014 (CDC)	Infant Mortality Rate, 2015 (UHF)	UHF Health Rank, 2015
National Rates		1.7	6.0	
Mississippi	M	0.1	9.3	49
West Virginia	M	0.2	7.4	47
Louisiana	M, R, C	0.6	8.4	50
Alabama	M, R	0.8	8.7	46
New York	M, R	0.8	5.0	13
Kentucky	M, R	0.9	6.8	44
North Carolina	M, R	1.0	7.2	31
Virginia	M, R	1.1	6.3	21
Indiana	M, R	1.1	7.0	41
Tennessee	M, R	1.1	7.0	43
Rhode Island	M, R	1.1	6.5	14
South Carolina	M, R	1.2	7.2	42
Maryland	M, R	1.2	6.5	18
New Mexico	M, R	1.2	6.1	37
Arkansas	M, R	1.3	7.5	48
Delaware	M, R	1.3	7.0	32
Nevada	M, R	1.3	5.1	38

<sup>1</sup> Exemption Type: M (Medical), R (Religious), and C (Conscience)

There are many factors that contribute to high infant mortality rates, including poverty, substandard nutrition and medical care, birth defects, pre-term birth, and maternal complications of pregnancy.<sup>160</sup> That said, there is pressing need for a rigorous scientific investigation into the potential significance of these data, especially in light of the assumption that restrictive vaccine laws achieving low vaccine exemption rates will, in turn, always yield better public health outcomes, including lowering infant mortality rates.

### **Virginia's Health Care and Vaccine Program Costs Escalate**

The new chronic disease and disability epidemic is manifested by escalating national health care costs.<sup>161 162</sup> The states are bearing a large portion of the costs associated with the unprecedented numbers of children and young adults requiring long term care and special education services in public school systems,<sup>163 164</sup> including in Virginia.<sup>165</sup>

In 2015, about five million citizens in Virginia had one chronic disease and two million had two or more chronic diseases. The total cost to treat chronic disease in the Commonwealth between 2016 and 2030 is projected to be \$1.1 trillion dollars, including \$51.3 billion for medical costs and \$21.3 billion annually in lost employee productivity.<sup>166</sup>

**20 Percent Special Ed Student Cost Rise in One Year.** In 2014, nearly five percent of Virginia's school children were categorized as requiring special education services and, of those, 39 percent were categorized as learning disabled. The special education category includes learning disabilities, autism, speech and language impairments, intellectual impairments, emotional disturbances and other health and learning impairments.<sup>167</sup> The average annual cost of educating a special education student in Virginia in 2014 was \$40,152 but in 2015, it was \$48,320,<sup>168</sup> a one-year 20 percent increase.

The cost to educate special education students has rapidly increased, in part, because the numbers of children with autism has rapidly increased.<sup>169</sup> After children with autism become young adults, there are few support services to assist families left to care for them.<sup>170</sup>

Funding to cover the costs of educating special education students comes from numerous sources including federal, state and local governments. Although the federal government was supposed to cover 40 percent of the cost to educate a student under the Individuals with Disabilities Education Act, they cover less than half that amount.<sup>171</sup> In 2013, the Virginia Department of Education reported that direct aid state funding for just one category of special education increased by over \$4.5 million from \$362,234,349 in 2013 to \$366,787,264 in 2014.<sup>172</sup> Despite these increases, the Commonwealth Institute found that since the 2008 recession, Virginia schools have experienced an \$800 million a year shortfall in funding.<sup>173</sup>

***Per Child Vaccine Costs Skyrocket Since 1986.*** As Virginia faces large budget deficits and seeks to cover a long list of state-provided programs and services for citizens,<sup>174</sup> the costs of financing vaccine programs have escalated dramatically since 1986. This includes the state purchase of vaccines provided in state public health clinics through the federal Vaccines for Children (VFC) program.

In the early 1980s when pharmaceutical companies were pressing Congress to provide them with a liability shield from vaccine injury lawsuits, the companies told Congress that if product liability litigation costs were reduced, childhood vaccine prices also would be reduced and contained. Congress gave vaccine manufacturers a civil liability shield in 1986 by creating the federal vaccine injury compensation program (VICP) but the pharmaceutical industry did not lower vaccine prices. In fact, just the opposite has happened since the VICP was created under the 1986 Childhood Vaccine Injury Act.

In 1986, it cost \$80 for a child to receive all federally recommended childhood vaccines in a private pediatrician's office.<sup>175</sup> According to the CDC, the cost to vaccinate one child with every recommended vaccine at federal contract prices rose over 2,300 percent between 1990 and 2012 - from \$70 to \$1,700 per child.<sup>176</sup> By October 2016, the per-child vaccination cost at federal contract prices was \$2,130, and for a child to get every dose of every federally recommended vaccine in a private pediatrician's office, it cost \$3,035.<sup>177</sup> This means that in the past 30 years, depending upon the payer, there has been a staggering 2900 to 3700 percent increase in the cost to purchase all the federally recommended vaccines for a child in America and administrative costs have to be added on top of that. These are costs borne by parents, federal taxpayers and the states.

Since the National Childhood Vaccine Injury Act became law 30 years ago, much of the per-child vaccination cost increase reflects the addition of many new vaccines to the child vaccine schedule that require multiple doses. However, even the per dose costs for purchase of the seven vaccines (DPT, MMR, polio) originally covered by the VICP in the 1986 law have continued to rise.

DHHS congressional budget requests for CDC childhood immunization expenditures increased from \$1 billion in 1997<sup>178</sup> to \$4.8 billion in 2014.<sup>179</sup> Since 1993, congressional appropriations for the VFC program created under the Childhood Immunization Act of 1993 have been earmarked for CDC to purchase vaccines from drug companies for administration to Medicaid-eligible and uninsured or underinsured children. Today the VFC program constitutes nearly half of the CDC's \$11 billion dollar annual budget.<sup>180</sup>

The federal government has become the single biggest purchaser of vaccines from drug companies. A number of state governments have also become direct purchasers of vaccines for both adults and children from drug companies at federal contract prices for all vaccines administered in the state.<sup>181</sup> This has the effect of securing advance market commitments for vaccine manufacturers, while

significantly cutting their direct marketing costs to doctors, pharmacies, insurers and other providers and distributors of vaccines states. Under the Affordable Health Care Act (ACA) insurance companies are required to provide federally recommended vaccines to children and adults without deductibles or co-pays.<sup>182</sup>

The creation of the federal VICP, along with the liability shield given to the pharmaceutical industry by Congress in 1986 and by the U.S. Supreme Court in 2011, has ensured that vaccine manufacturing and marketing in the U.S. is profitable for drug companies,<sup>183 184 185 186</sup> but has not led to a reduction or containment of health care costs for vaccine purchase.<sup>187</sup>

With the tripling of the numbers of federally recommended vaccinations since 1986, there have been concomitant increases in congressionally funded 317 “bonus award” grants given to states with high vaccine coverage rates.<sup>188 189</sup> These bonus grants awarded by the Centers for Disease Control financially incentivize states to attain high coverage rates with all federally recommended vaccines. According to a 2000 Institute of Medicine report, some state health officials have indicated they are being “punished” financially when their vaccine coverage rates are lower than those of other states.<sup>190</sup>

These federally initiated financial incentives, rewards and sanctions have encouraged state health officials to add new federally recommended vaccines to state mandates. Vaccine mandates for children have more than doubled in most states since 1986.<sup>191</sup>

***Legislative Options #2-9 Will Increase Costs.*** In light of the fact that the costs of financing vaccine programs in the states are rising and states are facing budget deficits, the additional costs of implementing “no exceptions” vaccine laws must be evaluated and weighed against competing public health program budget priorities. At a minimum and to varying degrees, adopting legislative policy Options #2-9 would incur new costs to state agencies and schools to promulgate, issue, implement, monitor and track compliance with new regulations and procedures. There will be new costs associated with changing school entrance health forms, changing exemption forms, developing new continuing education content, and developing vaccine messaging programs.

Adoption of Options #2-4 will incur other costs that will be borne by parents, insurers and the state when susceptible children forced to comply with inflexible “no exemptions” vaccine mandates suffer vaccine injuries and debilitating chronic health problems. These additional costs will include short and long-term medical and rehabilitative care that will be paid by parents, health care providers, medical insurance programs, Medicaid and private and state-funded social services programs.

In addition, public day care centers and schools will have to pay for developing and providing individualized special education programs to permanently disabled vaccine injured children. As mentioned in Section 6, although the federal VICP is

supposed to cover the lifetime costs of raising and educating a vaccine injured child and the program has paid out over \$3.5 billion in awards, two out of three vaccine injury claims are denied.<sup>192</sup> When a vaccine-injured child is denied federal compensation, all costs for short and long-term care and special education is shifted to the states and parents.

Restricting exemptions in vaccine laws also subjects states to covering unbudgeted and potentially significant legal and court costs associated with legal challenges that arise when basic human rights and civil liberties are eliminated. Therefore, when considering legislative policy Options #2-9, the question is: will changing vaccine laws to make them more restrictive reduce or increase costs and, if additional costs are incurred, can they be justified when there are other unmet public health needs requiring allocation of resources in the commonwealth?

In 2015, the United Health Foundation (UHF) rated Virginia in the top half (# 21) among states for overall health, including #16 for percentage of children aged 19 to 35 months immunized, even as there were a number of health measurement outcomes that could benefit from additional allocation of funding resources in the Commonwealth, including reducing disparities in health status according to education level (#33); reducing smoking rates (#31) and increasing physical activity among adults (#30); reducing the 6.1 infant mortality rate (#28), and reducing the occupational fatality (#27) and cardiovascular death (#25) rates.<sup>193</sup>

As law professors and bioethicists stated in 2005 when addressing the costs of using the heavy handed ruling of *Jacobson v Massachusetts* to make heavy handed public health law in the 21<sup>st</sup> century:

*“In an era of increasingly limited state funds, there is a danger that legislatures will turn to laws that restrict personal liberty as a substitute for providing the resources necessary for positive public health programs that actually prevent disease and improve health. Such symbolic “grandstanding” may be especially tempting for representatives whose reelection depends more on those who finance their campaigns than on the voters. But it shifts responsibility for protecting the public health from the government to individuals and punishes those who are least able to protect themselves. The Bill of Rights was designed to protect individuals against abuses by the state, even when the abuses have the support of the majority. This is why constitutional protection of liberty remains so important.”*<sup>194</sup>

### **Vaccine Exemptions Are Targeted and Unequal Risk Burdens Increase**

As discussed and cited throughout this legislative policy analysis, elimination of vaccine exemptions in one-size-fits-all state vaccine laws place an unequal risk burden on those susceptible to vaccine harm when genetic variation and

individual susceptibility is dismissed as unimportant and new science<sup>195</sup> challenging old assumptions about vaccine safety and effectiveness is ignored.

Public health officials, medical trade associations and media articles are citing infants too young to be vaccinated and individuals on chemotherapy or those with rare severe immunodeficiency disorders as a reason to eliminate exemptions from vaccine laws.<sup>196 197</sup> However, vaccinated children and adults do not protect these vulnerable minorities from infectious diseases when vaccines cannot prevent subclinical infection and transmission among the vaccinated.<sup>198</sup>

Even though there is evidence that the restrictiveness of non-medical vaccine exemptions in states does not significantly, if at all, lower infectious disease rates in states,<sup>199</sup> in the past five years, public health and medical trade associations<sup>200</sup> have joined with pharmaceutical industry lobbyists<sup>201</sup> to intensify their efforts to persuade state legislatures to restrict or eliminate vaccine exemptions that violate the human right to freedom of thought, conscience, religion and informed consent.

### **Bills Eliminating Vaccine Exemptions Promote Social Unrest**

It is against this backdrop that conflicting opinions about the safety and effectiveness of federal vaccine policies and state vaccine mandates for children has reached a boiling point in the U.S. Last year, Sacramento experienced the largest public protests since the Viet Nam War as many thousands of California parents and health care professionals came to Sacramento with their children and grandchildren multiple times to oppose the passage of a bill (SB277) sponsored by a pediatrician to eliminate the personal belief vaccine exemption.<sup>202 203 204 205 206</sup> Even though that California bill was enacted, it's now the subject of lawsuits filed against the state<sup>207 208</sup> and causing continuing public controversy and social unrest.<sup>209 210 211</sup>

It is important to recognize, however, that in 2015 and 2016, legislatures in multiple states rejected industry and medical trade lobbying efforts to remove vaccine exemptions after public protests. State legislators voted to preserve medical and non-medical vaccine exemptions in Washington, Colorado, Texas, Hawaii, Oregon, Oklahoma, Maine, North Carolina, Maryland, Pennsylvania and Rhode Island.<sup>212 213</sup>

The unanswered questions and growing concern that parents continue to have about one-size-fits-all vaccine policies is reflected in public surveys. In 2006 and again in 2013, the American Academy of Pediatrics (AAP) surveyed about 600 pediatricians in each of those years and the results were published in May 2014.<sup>214</sup> The 2014 poll results were publicized in an Aug. 29, 2016 article in *MedPage Today* with the headline "Is Anti-Vax Movement Growing? Pediatricians Say More Parents Are Refusing to Immunize Kids,"<sup>215</sup> which coincided with the AAP's Aug. 29, 2016 press release calling for an end to non-medical vaccine exemptions. The 2006 and 2013 poll results published in 2014

revealed that 87 percent of the pediatricians surveyed in 2013 reported experiencing a vaccination refusal from parents— up from about 75 percent in 2006.

A 2015 Gallup poll highlighted on page 9 of the JCHC staff report indicated that 84 percent of Americans surveyed believe that it is “extremely or very important” for parents to get their children vaccinated.<sup>216</sup> However, as highlighted on page 8 of the staff report, a 2014 survey conducted by the American Association for the Advancement of Science (AAAS) revealed that 30 percent of U.S. adults say that parents should be able to decline vaccinations for their children, a position also held by 13 percent of working Ph.D. and active research scientists.<sup>217</sup> This means that, although the majority of Americans believe vaccinations are important for children, one-third – representing tens of millions of Americans - support vaccine laws that allow flexible exemptions, which is the position of NVIC.

An online poll taken in January 2016 by WAVY-TV in Virginia Beach asked, “Do you think exemptions should be removed for school immunizations?” An overwhelming 84 percent of 3,055 respondents voted NO.<sup>218</sup>

### **The Safety and Effectiveness of Vaccine Policies and Laws**

When government officials fail to publish and rely upon sound science to anchor vaccine policy, while underestimating the reactivity and minimizing the significance of serious vaccine reactions suffered by individuals in order to defend inflexible vaccine laws, there is an erosion of trust in public health policy and law. When government enlists doctors to implement one-size-fits all vaccine policies that parents have concluded are not safe or effective for their children, it causes fear and distrust of doctors as well. The hallmark of good public health policy is honesty, transparency and dedication to ensuring safety and effectiveness for all people.

***Smallpox Vaccine Reactivity.*** The JCHC staff report contained information about smallpox vaccine presented from a narrow perspective and did not acknowledge the reactivity of the first vaccine to be used on a widespread basis until 1979, when the WHO declared that smallpox was eradicated. It is useful to briefly review the safety of smallpox vaccine because it was the first one to be mandated for children attending school in the U.S.

Opinions about the safety of smallpox vaccination have been divided since 1796 when British medical doctor Edward Jenner scratched pus from a cowpox lesion onto the arm of a young boy, trying to prevent the dreaded smallpox (variola virus) infection that was the leading cause of death in children at that time. Jenner’s method of trying to prevent smallpox was considered safer than variolation, which involved scratching pus from a smallpox scab onto the arm of another person. However, variolation (also referred to as inoculation) was notorious for *spreading* smallpox rather than preventing it and the medical practice unpredictably brain damaged and killed healthy children, too.<sup>219</sup>

Without systematic testing for safety or effectiveness before it was adopted as a routine medical practice, Jenner's experiment created a new live hybrid virus called vaccinia (the words vaccinia and vaccine come from the Latin word for cow – "vacca").<sup>220</sup> Some researchers have recently questioned whether cowpox is misnamed because the virus also infects rodents and cats, while others suggest vaccinia virus is more related to horsepox than cowpox.<sup>221</sup> In addition, companies making smallpox vaccine in the late 19th century created vaccinia virus by using the skin of calves (and occasionally donkeys and rabbits) for production in an attempt to limit contamination of smallpox vaccine with viruses and bacteria that infect humans like syphilis, measles, varicella, staphylococci, and streptococci.<sup>222</sup>

Vaccinia virus was the first manmade live vaccine virus that doctors gave to humans in an effort to prevent injury and death from an infectious disease. But there were deadly side effects from smallpox vaccine, such as brain inflammation. People at greatest risk for harm were those getting the vaccine for the first time and those with a history of certain health conditions, such as a weakened immune system. After primary smallpox vaccination, vaccinia virus is shed for two to three weeks and can be transmitted to others through body secretions and, especially, through skin contact with the open vaccinia virus lesions at the site of the vaccination.<sup>223</sup>

In addition to progressive vaccinia and postvaccinial encephalitis (brain inflammation), one of the most feared complications of vaccinia virus transmission and infection is eczema vaccinatum (EV) that can cause permanent scarring similar to smallpox and end in death, especially for infants and young children.<sup>224</sup> A history of eczema or atopic dermatitis; immunodeficiency; pregnancy; infants younger than 12 months and a history of heart disease are a few of the risk factors which make some people more susceptible to suffering complications of smallpox vaccination.

A 1970 analysis of 68 deaths from smallpox vaccination in the U.S. between 1959 and 1968 found that "19 were associated with vaccinia necrosum, 36 were caused by postvaccinial encephalitis, 12 by eczema vaccinatum and 1 by Stevens-Johnson syndrome. Of the 68 who died, 24 were infants... all of the deaths from eczema vaccinatum were in children who were not vaccinated themselves but acquired vaccinia from a sibling, playmate or parent."<sup>225</sup>

In stark contrast to the information on page 29 of the JCHC staff report, which alleges that the odds of experiencing a "grave" vaccine reaction is "1 in 1 million," according to the CDC, 1 in 100 people getting smallpox vaccine for the first time experienced serious vaccine reactions; about 1 in 19,000 to 71,000 had life threatening reactions, such as encephalitis, eczema vaccinatum and progressive vaccinia; and 1 to 2 in 1 million vaccinated people died from smallpox vaccine complications.<sup>226</sup>

A more recently used vaccine, the pertussis containing DPT vaccine was licensed in 1948 and routinely given to U.S. infants and children until it was replaced in the 1990s by one with reduced toxicity, DTaP vaccine. DPT had the following serious reaction profile in previously healthy children: 1 in 1,750 DPT shots was followed by a convulsion or collapse shock (hypotonic/hyporesponsive episode);<sup>227</sup> 1 in 110,000 DPT shots was followed by brain inflammation (acute encephalopathy); and 1 in 310,000 DPT shots involved permanent brain damage.<sup>228 229</sup>

***Vaccine Policy Harms the Most Vulnerable.*** As first mentioned in Section 1, physician committees at the Institute of Medicine, National Academy of Sciences, exhaustively reviewed the medical literature between 1991 and 2013 and repeatedly stated in published reports that there continue to be significant gaps in vaccine safety science.<sup>230</sup> These knowledge gaps include the inability of doctors to accurately identify and screen individuals more susceptible to being harmed by vaccines for biological reasons. In 2012, an IOM committee concluded there were fewer than 40 published studies that addressed the safety of the current CDC recommended childhood vaccine schedule of 49 doses of 14 vaccines administered between day of birth and age six.<sup>231</sup>

However, the fact that doctors cannot predict who will be harmed by government recommended and state mandated vaccines has not been clearly communicated by public health officials or medical trade organizations to state legislators, who are being lobbied to remove vaccine exemptions and sanction parents declining one or more government recommended vaccines for their children. The response by many leaders in the medical community to questions being raised by parents and health care professionals about the safety of requiring children to receive three times as many vaccinations as were required before 1986, has been to marginalize and sanction those who are asking questions.<sup>232</sup> In the past five years, pediatricians administering vaccines have become more hostile toward parents asking questions about vaccination, and are refusing to provide medical care to children whose parents do not agree to give them every dose of every vaccine on the federal vaccine schedule - no questions asked and no exceptions.<sup>233</sup>

At the same time, the CDC and medical trade groups have significantly narrowed medical contraindications to vaccination so that, today, very few health conditions qualify as a reason for doctors to defer or withhold vaccines, even for the immunocompromised.<sup>234</sup> While doctors are being told to give fewer medical vaccine exemptions to children,<sup>235</sup> parents are reporting that pediatricians are threatening them if they refuse to allow vaccinations to be given to an acutely ill child or to children who have regressed into chronic poor health after previous vaccine reactions.<sup>236</sup>

***No Liability for Vaccine Industry.*** In the 1980s, when parents publicly asked questions about the safety of vaccines the response from vaccine manufacturers and medical trade organizations, such as the American Academy

of Pediatrics, was to lobby Congress to remove legal accountability and financial liability for vaccine safety in civil courts. In 1986, Congress granted vaccine manufacturers a partial liability shield under the 1986 National Childhood Vaccine Injury Act, a liability shield that also extended to pediatricians and other vaccine providers.<sup>237</sup>

An administrative alternative to a lawsuit in civil court, the federal Vaccine Injury Compensation Program (VICP), was created under the 1986 law.<sup>238</sup> Today, the VICP is no longer an *alternative* to a civil vaccine injury lawsuit like it was when Congress passed the law in 1986.<sup>239</sup> In 2011 in *Breusewitz v Wyeth*, the U.S. Supreme Court declared federally licensed vaccines to be “unavoidably unsafe” and effectively made the VICP the *exclusive legal remedy* for all Americans experiencing life-altering or fatal injuries from use of any vaccine that is federally licensed and recommended for children.<sup>240</sup>

This blanket product liability protection now extends to vaccine manufacturers even when plaintiffs have evidence that a federally recommended and state mandated vaccine is defective in design and the company could have made the vaccine less harmful.<sup>241</sup> In an insightful dissenting opinion, Justice Sonia Sotomayor was joined by Justice Ruth Bader Ginsburg in accurately describing and interpreting the legislative history of the 1986 National Childhood Vaccine Injury Act.

In the *Bruesewitz v. Wyeth* dissenting opinion conclusion, Justice Sotomayor warned: <sup>242</sup>

*“The majority’s decision leaves a regulatory vacuum in which no one – neither the FDA nor any other federal agency, nor state and federal juries – ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been released and marketed to the public. Manufacturers, given the lack of robust competition in the vaccine market, will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins. Nothing in the text, structure or legislative history remotely suggests that Congress intended that result.”*

Currently, all that is required for a pharmaceutical corporation to get a liability shield for a newly licensed vaccine is for the CDC to add the vaccine to the growing list of federally recommended vaccines for children, which, in most cases, are now also recommended for adults. As a result, almost every pharmaceutical corporation marketing government licensed, recommended and mandated vaccines in the U.S. today is shielded from product liability and accountability in the civil justice system. Many of the currently recommended and mandated vaccines, such as varicella zoster (chickenpox), rotavirus (infant diarrhea) and hepatitis A (diarrhea related to poor sanitation) rarely cause injury

or death in the U.S. and other diseases, such as hepatitis B and HPV (human papillomavirus), cannot easily be transmitted in public.

Although the VCIP created under the 1986 law has awarded more than \$3.5 billion to children and adults injured by federally recommended and state mandated vaccines, two out of three claimants with vaccine-related injuries are turned away with no financial assistance.<sup>243</sup> Without access to the tort system to hold vaccine manufacturers accountable for product safety, there is little incentive for federal agencies, including the Department of Health and Human Services (DHHS) and the Department of Justice (DOJ), to acknowledge risks of federally licensed and state mandated vaccines. No liability and accountability for vaccine manufacturers, providers and policymakers also gives little incentive for DHHS and DOJ to support the awarding of federal compensation to the casualties of federal one-size-fits-all vaccine policies and state vaccine mandates.

***Vaccine Safety Provisions in 1986 Law Ignored.*** The co-founders of NVIC were responsible for securing historic vaccine safety provisions in the National Childhood Vaccine Injury Act of 1986, including the legal duty for pediatricians and other vaccine providers to: (1) give parents written vaccine benefit and risk information before children are vaccinated; (2) enter into a child's permanent medical record a description of serious health problems that occur after vaccination; and (3) file a report with the federal Vaccine Adverse Events Reporting System (VAERS) when a child suffers a serious health problem, hospitalization, injury or death following receipt of a federally recommended vaccine.

However, Congress did not include legal penalties when pediatricians and other vaccine providers fail to comply with the federal law. Today, many parents do not receive written vaccine benefit and risk information before their children are vaccinated. In fact, as mentioned previously, many pediatricians are declining to provide medical care to children, whose parents do not agree to give their children every dose of every federally recommended according to the federal child vaccination schedule.

In addition, most doctors do not report serious vaccine-related adverse events to VAERS. It is estimated that only between one and 10 percent of all serious vaccine adverse events are ever reported to VAERS.<sup>244</sup> About 550,000 vaccine adverse events have been reported to VAERS since 1990, which averages to about 22,000 reports per year.<sup>245</sup> However, if only between one and 10 percent of vaccine reactions are ever reported by physicians and other vaccine providers, this means that there may have been between 5.5 and 55 million vaccine adverse events that have occurred in the U.S. since 1990, averaging between about 550,000 and 5 million occurring annually, most of which are never reported to VAERS.

It is well known that not every serious health problem that occurs following vaccination is causally related to a recently administered vaccine. However,

because of serious underreporting of vaccine adverse events, it is not known how many individuals are suffering brain and immune dysfunction or have died after federally licensed and state mandated vaccines are administered to millions of children and adults in the U.S. every year.

Importantly, VAERS was designed to be a “sentinel” warning system to assist in the post marketing surveillance of newly licensed vaccines.<sup>246</sup> Widespread underreporting of adverse events following vaccination by pediatricians and other vaccine providers prevents federal health officials from accurately monitoring the reactivity of new vaccines after they are licensed and used by millions of Americans in real-world clinical settings. It is vital that VAERS be able to conduct post-marketing surveillance because the size of pre-licensure clinical trials are small and study populations do not reflect the genetic, biological and environmental diversity of the whole population,<sup>247</sup> especially the child populations receiving the greatest number of government recommended and mandated vaccines.

***Conflicts of Interest Exist in Vaccine System.*** Although the JCHC staff report left the impression that there is absolutely no question about the integrity of the federal vaccine research, regulation and policymaking systems, there has been considerable public debate about that assumption.<sup>248</sup> As NVIC pointed out in 2011,<sup>249</sup> there are inherent conflicts of interest when congressionally funded federal health agencies responsible for vaccine safety oversight are simultaneously charged with the responsibility for: (1) conducting scientific research into the development of new vaccines; (2) creating and implementing legally binding vaccine licensing and testing regulations for pharmaceutical companies producing and marketing vaccines; (3) making national recommendations for vaccine administration and use; (4) promoting universal and mandatory use of government recommended vaccines (5) and serving as the legal respondent in plaintiff’s petitions for federal vaccine injury compensation.<sup>250</sup>

Conflict of interest issues continue to be raised about the validity of federal retrospective case controlled vaccine safety studies that cannot be reproduced by independent researchers because the studies are designed and conducted by government employees using closed large linked medical records databases.<sup>251</sup> There has been public criticism by consumer watchdog groups about the fact that Congress is permitting drug companies to pay the FDA to fast track drugs and vaccines to market, which allows them to avoid adhering to stricter licensing standards for proof of safety and effectiveness prior to licensure.<sup>252 253</sup>

For example, clinical trials that fast tracked the HPV vaccine, Gardasil, to licensure in 2006, used a bioactive placebo (aluminum containing) rather than a true, non-reactive placebo. The vaccine was only tested in 1,122 girls before being federally recommended for all 11-12 year old girls (and now, boys) and eventually mandated for sixth grade in Virginia.<sup>254 255</sup>

Also, in the past and more recently, industry and government whistleblowers have come forward reporting that critical vaccine safety and effectiveness information has been withheld from the public by federal agencies.<sup>256 257</sup> The safety of federally licensed vaccines has been the subject of a series of congressional hearings spanning three decades.<sup>258 259 260 261 262 263</sup>

In 2001, Congress directed NIH and other federal agencies to develop a formal public-private business relationship with the pharmaceutical industry, including sharing new vaccine patent profits while federal vaccine licensing standards have been and are continuing to be compromised.<sup>264</sup> The lobbying in state legislatures by special interest groups funded by industry and government to pressure state legislators to eliminate vaccine exemptions has raised legitimate questions about whether strict enforcement of “no exceptions” vaccine laws is about protecting the public health or about protecting the financial interests of corporations and institutions.

***Vaccine Mandates Can’t Prevent Disease If Vaccines Fail.*** The rationale for state vaccine laws that require all children to get multiple doses of vaccines to attend school is that children will become immune to contracting certain infectious diseases and create “herd immunity.” Also referred to as “community immunity.” The idea is that a majority of vaccinated children will prevent children too young to be vaccinated and individuals undergoing chemotherapy, organ transplants or those with rare serious immune disorders from getting sick.<sup>265</sup>

However, as stated previously, artificial, vaccine acquired immunity may not provide full immunity that blocks symptomatic or asymptomatic infection and transmission, or may only provide temporary immunity that quickly wears off.<sup>266</sup> Additionally, some organisms, like B. pertussis, have evolved to evade pressure from widespread vaccine use since the 1940’s and new pertussis strains are not covered in DTaP and Tdap vaccines mandated for children today.<sup>267</sup>

When vaccinated children and adults can have subclinical infections and silently transmit to other vaccinated and unvaccinated persons, it is impossible to know who is a carrier and who is not. Diagnosed and reported cases of pertussis are only a small portion of the actual cases of pertussis occurring in Virginia and other states every year. Outbreaks of whooping cough cannot be blamed on children attending school with vaccine exemptions when the vaccinated are transmitting infections without being diagnosed or reported. Therefore, eliminating the use of vaccine exemptions will not yield a true reduction of the incidence of pertussis.

***Pertussis Increases in Virginia and Nationally.*** For example, as shown on Figures 6-3 and 6-4, the incidence of pertussis in infants and very young children in Virginia has significantly increased. This vulnerable population, which is at greatest risk for dying from pertussis, is currently experiencing a disproportionate incidence of disease.

In 2014, CDC reported that nationally the incidence of pertussis was a surprising 169.0 cases per 100,000 infants under six months old.<sup>268</sup> A high incidence of pertussis was also reported in children over one year old and teenagers, ages groups that have a high rate of DTaP/Tdap vaccination. In the 2014 pertussis epidemic in California, the majority of the cases were in infants and children and only 10 percent had never received pertussis vaccine.<sup>269</sup> So, a high incidence of pertussis in infants and children under age one is occurring even though the vast majority are being given three pertussis containing shots in the first year of life, at two, four and six months of age.

Additionally, more pregnant women are being Tdap shots during every pregnancy. CDC surveys show that 42 percent of women, who delivered a live baby in 2015, had received a pertussis containing Tdap shot during pregnancy, while only 18 percent of mothers had never gotten a Tdap shot.<sup>270</sup> Additionally, many adults who come in contact with pregnant women or young infants are being given a booster Tdap shot.

One reason why pertussis is increasing among children under one has been discovered recently. Researchers report that compared to babies born to unvaccinated mothers, babies born to mothers who have been given a Tdap shot during pregnancy do not mount the same kind of protective antibody response when they get DTaP shots in the first year of life or when they get a booster dose at 15-18 months.<sup>271</sup>

In Virginia, forcing an additional 1,200 school aged children with vaccine exemptions to get vaccinated by removing current religious and medical exemptions will not “move the needle” toward zero cases of infectious disease when vaccinated children and adults can be infected with and transmit diseases for which they were vaccinated.

***Disease Outbreaks Among Vaccinated Children.*** In addition to pertussis vaccine failures, there have been reports of mumps outbreaks in children and college students who have received two or more MMR shots.<sup>272 273</sup><sup>274</sup> In the 2015 California measles outbreak associated with Disneyland, 30 percent of reported measles cases with vaccine records had received one, two or three MMR shots. Over half of the reported measles cases in California were in adults and only 18 percent were in school children.<sup>275</sup>

The California measles outbreak consisted of 125 reported cases,<sup>276</sup> out of a total 189 measles cases reported nationally in 2015.<sup>277</sup> The measles outbreak ended with the use of traditional disease control measures by public health officials before California legislators repealed the personal belief vaccine exemption on file for 2.5 percent of school children that year.<sup>278</sup>

## The Legality and Ethics of Vaccine Policies and Laws

At the turn of the 20<sup>th</sup> century, eight U.S. Supreme Court Justices affirmed the legal authority of states to pass smallpox vaccination laws in *Jacobson v Massachusetts* (1905).<sup>279</sup> The JCHC staff report briefly mentioned this Supreme Court decision but a fuller explanation gives perspective to the implementation of state vaccine laws in the 21<sup>st</sup> century.

In 1904, a Lutheran minister, Swedish immigrant Henning Jacobson, objected to a Cambridge, Massachusetts Board of Health law requiring all adults over age 21, who had not gotten a smallpox vaccination since 1897, to get revaccinated or pay a \$5 dollar fine. Pastor Jacobson and his son had suffered severe reactions to previous smallpox vaccinations. Jacobson argued that genetic predisposition placed him at high risk for dying or being injured if he was forced to get revaccinated, that it would be an assault on his person and violate his 14<sup>th</sup> Amendment right to liberty and equal protection under the law.

***Jacobson v. Massachusetts Affirms Infallibility of Doctors.*** In the lower state court, Jacobson tried to present evidence that smallpox vaccine ingredients were toxic and often caused injury and even death and that medical doctors were both fallible and unable to predict who would be harmed. But the state court dismissed his concerns as unfounded and sided with medical doctors, who insisted that smallpox vaccine was safe and that doctors could, indeed, predict who is and is not a fit subject for vaccination.

Jacobson refused to pay the \$5 dollar fine and appealed his case to the U.S. Supreme Court. In a split decision with one dissenting vote, the majority of U.S. Supreme Court justices, including Oliver Wendell Holmes, issued a ruling in *Jacobson v. Massachusetts* that would affirm the legal right for U.S. state legislatures to elect to enact compulsory vaccination laws and exercise police power that restrict or eliminate individual liberty during epidemics to control transmission of smallpox.

The turn-of-the 20<sup>th</sup> century Supreme Court endorsed the view by the lower state court that smallpox vaccine was very safe and doctors knew how to screen out individuals more susceptible to vaccine reactions that could end in injury or death. Affirming physician infallibility, the Supreme Court stated, “The matured opinions of medical men everywhere, and the experience of mankind, as all must know, negative the suggestion that it is not possible in any case to determine whether vaccination is safe.”

***Compulsory Vaccination Compared to Military Draft.*** The Court majority opinion stated that in order to “secure the general comfort, health and prosperity of the state,” citizens did not have the absolute right under the U.S. Constitution to be free at all times because there are “manifold restraints to which every person is necessarily subjected for the common good.” They compared compulsory smallpox vaccination of adults with the military draft in times of war,

arguing that a citizen “may be compelled, by force if need be, against his will and without regard to his personal wishes or his pecuniary interests, or even his religious or political convictions, to take his place in the ranks of the army of his country and risk the chance of being shot down in its defense.”

**Vaccine Law Can Be Based on “Common Belief,” Not Fact.** However, clearly disturbed by Jacobson’s contention that his life was on the line, not once but repeatedly, the justices returned to the knotty problem of individual risk only to ridicule Jacobson and point out that his uneducated opinion was no match for the “common knowledge” expert opinion of medical doctors and public health officials. The U.S. Supreme Court ruling went so far as to say that - even if Jacobson could prove the medical experts were wrong about the safety of smallpox vaccination - states still have the constitutional power to enact laws based on majority opinion and “common belief” and not on truth or proven facts:

*“A common belief, like common knowledge, does not require evidence to establish its existence, but may be acted upon without proof by the legislature and the courts. The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases. In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action, for what the people believe is for the common welfare must be accepted as tending to promote the common welfare, whether it does in fact or not.”*

They said that if individuals were able to claim exemptions from smallpox vaccination because they thought they had good reason to believe they may be harmed, it would mean that,

*“Compulsory vaccination could not, in any conceivable case, be legally enforced in a community, even at the command of the legislature, however widespread the epidemic of smallpox; and however deep and universal was the belief of the community and its medical advisors that a system of general vaccination was vital to the safety of all.”*

**Vaccine Law Should Not Lead to Injustice.** But, at the very end, the justices momentarily entertained the possibility that medical doctors are not infallible and Jacobson might actually die if he was revaccinated, so they warned Massachusetts and other states that their ruling should not be misinterpreted to mean that vaccination should be forced on a person whose health condition would make vaccination “cruel and inhuman to the last degree.”

*“All laws, this court has said, should receive sensible construction. General terms should be so limited in their application as to not lead to*

*injustice, oppression or absurd consequence. It will always, therefore be presumed, that the legislature intended exceptions to its language which would avoid results of this character. The reason of the law in such cases should prevail over its letter.”*

***The Utilitarian Legacy of Jacobson v. Massachusetts.*** The U.S. Supreme Court ruling in *Jacobson v. Massachusetts* at the turn of the 20<sup>th</sup> century codified into U.S. law the use of utilitarianism as a tool for public health lawmaking. The philosophy of utilitarianism, which has its roots in hedonism, is a consequentialist theory of morality that was developed by several 18<sup>th</sup> and 19<sup>th</sup> century British philosophers as a guide to creating legislation that is based on a mathematical equation: the greatest happiness for the greatest number of people.<sup>280 281</sup>

“The greatest happiness for the greatest number of people”<sup>282</sup> was not, however, the guiding principle that served as a foundation for the Virginia Constitution or the Virginia Act for Religious Freedom, which protects the exercise of freedom of thought, conscience and religion for citizens living in the Commonwealth. Utilitarianism was not the principle that guided those who wrote the U.S. Constitution, including the Bill of Rights, which guarantees Americans freedom of speech, religion, assembly and other cherished civil liberties.

***Jacobson v. Massachusetts Used for Eugenics in Virginia*** The morally bankrupt core of using utilitarianism as a guide to public health law making was revealed in 1927, when Chief Supreme Court Justice Oliver Wendell Holmes wrote a majority opinion employing the utilitarian rationale articulated in *Jacobson v Massachusetts* to endorse the practice of eugenics in Virginia and other states. It was in Virginia that medical doctors and state officials incorrectly judged Carrie Buck, a poor 17-year old unmarried mother, to be morally unfit and mentally retarded - in effect, genetically defective - just like they incorrectly judged her daughter and mother to be genetically defective.<sup>283</sup>

In *Buck v Bell* (1927), Holmes and his fellow Supreme Court justices gave the green light to the state of Virginia to involuntarily sterilize Carrie Buck.<sup>284</sup> Using the “common good” utilitarian rationale articulated in *Jacobson v Massachusetts*, Holmes coldly declared, “*It is better for the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough!”*

***The Ends Do Not Justify the Means.*** In this merciless 1927 Supreme Court decision, just as in the 1905 *Jacobson v. Massachusetts* decision, moral principles grounded in respect for individual human life and civil liberties were stripped from U.S. law. The rationale was that if the philosophy of utilitarianism could be used to ensure the common good and protect society from infectious disease through compulsory vaccination laws, then society could also ensure the

common good with forced sterilization laws that immunize society against becoming infected with bad genes.

The morally flawed utilitarian Supreme Court ruling in *Jacobson v. Massachusetts* paved the way for the morally flawed utilitarian ruling in *Buck v. Bell*. The premise that the ends justifies the means and that the right to life, liberty and happiness of a minority of individuals can be sacrificed in the name of the “common good,” permitted U.S. public health officials and doctors to discriminate against a minority of citizens who were chronically ill and physically or mentally handicapped. It created a perfect climate for what became a tyranny of the majority.<sup>285</sup>

By 1932, mandatory sterilization laws were passed in 29 states and more than 60,000 Americans were involuntarily sterilized before the medical practice was ended by most, but not all, states in the late 1940s.<sup>286</sup>

***Informed Consent Is a Human Right.*** Utilitarianism was discredited as a pseudo-ethic at The Doctor’s Trial at Nuremberg after World War II, which gave birth to the informed consent principle articulated in the historic Nuremberg Code in 1947.<sup>287 288</sup> The next year, the Universal Declaration of Human Rights affirmed fundamental civil liberties that include the right to autonomy and freedom of thought, conscience and religious belief.<sup>289</sup> Ever since, informed consent to medical risk taking has been the central ethical principle guiding the ethical practice of modern medicine.

Utilitarianism when applied to “no exemptions” vaccine laws means that the state is not only condoning, but is enforcing, the sacrifice of an unknown number of citizens, specifically children, who were born with certain genes and have certain biological susceptibilities, in the name of the “common good.” We argue that public health laws that do that are not moral and should not be legal in the United States of America and, additionally, it is a violation of basic human rights to force parents and physicians to participate in that kind of callous disregard for individual human life.

In 2005, professors of law and bioethics at Boston University published a legal analysis of the applicability of the *Jacobson v Massachusetts* ruling to 21<sup>st</sup> century public health law.<sup>290</sup> The authors pointed out in the *American Journal of Public Health* that, “*Jacobson* was decided in 1905, when infectious diseases were the leading cause of death,” and when “Few weapons existed to combat epidemics. There was no Food and Drug Administration (FDA), no regulation of research, and no doctrine of informed consent.” They said, “Preserving the public’s health in the 21st century requires preserving respect for personal liberty,” and added, “Public health programs that are based on force are a relic of the 19th century; 21st-century public health depends on good science, good communication, and trust in public health officials to tell the truth.”

***Liability Shield and No Exemptions Threatens Liberty.*** After the U.S. Supreme Court declared vaccines to be “unavoidably unsafe” in 2011 and

absolved the pharmaceutical industry from all civil liability for injuries and deaths caused by federally recommended vaccines,<sup>291</sup> there has been no legal accountability for any corporation that develops, distributes and sells FDA licensed vaccines that cause harm. There is also no legal accountability for those who license, recommend, promote, administer or mandate vaccines, which creates a moral imperative for legislators to protect flexible exemptions in vaccine laws to ensure that parents of minor children can exercise of freedom of thought, conscience and religious belief when making decisions about vaccination for their children.

It is interesting to note that, while medical trade associations representing vaccine providers, such as the American Medical Association (AMA),<sup>292</sup> are calling on state legislators to take away freedom of conscience and religion from parents of minor children by stripping religious and conscientious belief exemptions from vaccine laws, they continue to support the exercise of civil liberties for physician members to take vaccine exemptions themselves for religious and philosophical beliefs.

In 2016, the AMA Code of Ethics states, *“In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe and effective vaccine, physicians should (a) accept immunization absent a recognized medical, religious, or philosophic reason to not be immunized.”*<sup>293</sup>

The American Nurses Association (ANA) also supports the availability of religious vaccine exemptions for their members. In a 2015 policy statement, ANA stated that *“ANA supports exemptions from immunization only for the following reasons: (1) medical contraindications and (2) religious beliefs,”* adding that *“employers should ensure that reasonable accommodations are made in all such circumstances.”*<sup>294</sup>

While it is entirely appropriate for medical trade associations and unions representing America’s health care providers to support the human right to exercise freedom of thought, conscience, religion and informed consent for their members, they should likewise support the exercise of those same human rights by patients.

***Virginia Is Home of the First Freedom.*** Virginia is the hallowed ground where the first freedom, freedom of religion - which includes freedom of thought and conscience - was first defined as a natural right and codified into American law. Virginia is the place where George Mason wrote the [Virginia Declaration of Rights](#) (1776) and Thomas Jefferson wrote the Virginia [Act for Religious Freedom](#) (1786) and where, over the years, the General Assembly has enacted the strongest religious freedom and [parental rights](#) legislation (2013) in the country.

[The First Amendment](#) of the U.S. Constitution approved by Congress in 1789 says, “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances.” That First Amendment was based on the Virginia Bill of Rights adopted by the Virginia General Assembly long before Congress approved the U.S. Constitution Bill of Rights.

[Section 16](#) of the Virginia Constitution states that:

1. “All men are equally entitled to the free exercise of religion, according to the dictates of conscience;” and
2. “No man shall be compelled to frequent or support any religious worship, place, or ministry whatsoever;” and
3. “The General Assembly shall not prescribe any religious test whatever” on citizens.

It is a violation of the Virginia Constitution to eliminate the legal right to exercise religious beliefs according to the dictates of conscience, or to force citizens to belong to an organized religion or a particular church in order to exercise conscience and religious beliefs.

The Virginia Assembly adopted Virginia’s Act for Religious Freedom in 1786, three years *before* the Bill of Rights in the U.S. Constitution was approved. This historic Act is very clear about what religious freedom means, stating in the first sentence that, “Almighty God hath created the mind free.” The Act goes on to say that, “All attempts to influence it by temporal punishments, or burdens, or by civil incapacitations... are a departure from the plan of the Holy Author of our religion...”

The Act accurately points out that legislators and rulers are “fallible,” that they do not have the right to assume “dominion over the faith of others, setting up their own opinions and modes of thinking as the only true and infallible, and as such endeavoring to impose them on others....” Even more strongly, the Act states that, “our civil rights have no dependence on our religious opinions any more than our opinions in physics or geometry.”

Finally, in a ringing defense for freedom of thought and religious liberty, the Virginia Religious Freedom Act declares without qualification that, “No man shall be compelled to frequent or support any religious worship, place or ministry whatsoever, nor shall be enforced, restrained, molested or burdened in his body or goods, nor shall otherwise suffer on account of his religious opinions or belief; but that all men shall be free to profess, and by argument to maintain, their opinions in matters of religion, and that the same shall in no wise diminish, enlarge or affect their civil capacities.....We are free to declare, and do declare, that the rights hereby asserted are of the natural rights of mankind, and that if

any act shall be hereafter passed to repeal the present, or to narrow its operation, such act will be an infringement of natural right.”

In 2007, the [Virginia Assembly reaffirmed](#) the Religious Freedom Act of 1786 with a caveat and that is, “No government entity shall substantially burden a person’s free exercise of religion... unless it demonstrates that application of the burden to the person is (1) essential to further a compelling governmental interest and (2) the least restrictive means of furthering that compelling governmental interest.” This caveat sets an appropriately high bar for substantially restricting a person’s free exercise of religious belief.

Current vaccine laws in the commonwealth that provide for flexible medical and religious exemptions do not constitute a threat to the public health in the commonwealth. There is no public health emergency that requires government to violate civil liberties, specifically freedom of religion and the right to be educated.

***The Political Costs of Taking Away Vaccine Exemptions.*** As outlined in Section 6, there are considerable administrative costs associated with restricting or eliminating flexible vaccine exemptions in a move toward “no exceptions” vaccine laws for school children, but there are political costs of doing so, as well. With the exception of Option #1, many of the legislative policy options will require creation of entirely new programs and infrastructure and changes to the Virginia Administrative Code that involve multiple state agencies issuing new regulations and directives; changing school health entrance and vaccine exemption forms, modifying computerized tracking and monitoring systems, as well as increasing staffing to counsel parents, health care providers and school personnel.

However, as the state of California is learning, when exemptions allowing exercise of conscience and religious beliefs are removed from vaccine laws, it causes confusion and disruption in schools and requires extra staffing to create a process for handling and adjudicating disputes.<sup>295 296 297 298 299</sup> If legislative policy options are adopted that eliminate vaccine exemptions and parents refuse to violate their conscience and religious beliefs, is Virginia prepared to expel children from all public and private schools when they do not have every dose of every state mandated vaccine? Is the state prepared to deny children a public or private school education if they have a health history or condition that does not strictly qualify as a “medical contraindication” under federal health agency definitions?

Will the agencies, attorneys and courts in the commonwealth impose legal sanctions, including fines and jail sentences on parents exercising conscience and religious beliefs, whose children become truant when they are excluded from school, and place those children in the custody of the state?

Will Virginia refer non-compliant parents to Child Protective Services alleging criminal parental or medical abuse and neglect for failure to obey “no

exemptions” compulsory vaccine mandates that block their children from being educated?

Inflexible implementation of federal government vaccine policy creates fear and distrust of public health officials and physicians. Physicians should be encouraged to respect the precautionary principle, not ignore it and deny medical vaccine exemptions to children for whom the risks of vaccination could be higher than for other children when safety cannot be guaranteed. Physicians exercising professional judgment and conscience when granting a child a medical vaccine exemption in order to prevent vaccine injury should be thanked, not harassed or sanctioned by public health officials or their peers for giving a susceptible child a medical vaccine exemption.

Eliminating the religious belief exemption and severely restricting the medical vaccine exemption will create social tension<sup>300</sup> and widespread publicity online and in state media as public opposition expands. It will increase fear and distrust of the public health and school officials, pediatricians and other vaccine providers, especially among citizens forced to violate their conscience and religious beliefs when making decisions that affect the health of their children.

As the professors of law and bioethics from Boston University stated so well a decade ago, *“One practical reason for protecting constitutional rights is that it encourages social solidarity. People are more likely to trust officials who protect their personal liberty. Without trust, public officials will not be able to persuade the public to take even the most reasonable precautions during an emergency, which will make a bad situation even worse. The public will support reasonable public health interventions if they trust public health officials to make sensible recommendations that are based on science and where the public is treated as part of the solution instead of the problem.”*<sup>301</sup>

**No Compelling State Interest.** Currently 47 states have a vaccine exemption for religious beliefs; 16 states additionally have exemptions for conscientious, philosophical or personal beliefs; and all 50 states have medical exemptions with no state restricting the granting of medical exemptions by licensed physicians. Vaccine laws in Virginia provide for flexible medical and religious vaccine exemptions and the commonwealth has one of the lowest vaccine exemption rates of all states (about 1 percent) for children entering kindergarten and there is a high 95 to 98 percent coverage with core vaccines for measles and pertussis among kindergarten children. In 2014, the Commonwealth had a five-year annual incidence rate for measles of 0.0 per 100,000 persons and, in 2015, it had a pertussis incidence rate of 4.0 per 100,000 persons (334 cases), which is lower than the median state rate of 5.7 percent.

The medical and religious exemptions in Virginia do not constitute a threat to the public health. There is no public health emergency that requires government to violate civil liberties, specifically freedom of thought, religion, conscience and the right to be educated.

Thus, we argue that there is no compelling state interest for the commonwealth to make vaccine laws more oppressive and deny or substantially burden a citizen's free exercise of religion or conscience by removing the religious vaccine exemption, and no compelling state interest to remove the legal right of physicians to exercise professional judgment and conscience when granting a child a medical vaccine exemption.

### **Conclusion**

A system that will not bend will break. Removing vaccine exemptions from public health laws and strictly implementing one-size-fits-all vaccine mandates that fail to respect biodiversity and civil liberties will not solve the larger problems with vaccine science and policy that industry, government and physicians promoting increased vaccine use have not acknowledged or effectively addressed.

What is at stake in the 21<sup>st</sup> century is public trust in physicians, public health officials, elected legislators and government itself. The answer is not to force vaccination in America but, instead, to restore public faith in the integrity of the vaccine system by creating vaccine laws that reflect American cultural values, including exercise of freedom of thought, conscience and religious belief. The Joint Commission on Health Care and the Virginia legislature should do that by taking no action (Option #1) and protecting flexible medical and religious exemptions in current vaccine laws.

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