

Kavita Shah Arora, Jane Morris, and Allan J. Jacobs, "Refusal of Vaccination: A Test to Balance Societal and Individual Interests," *The Journal of Clinical Ethics* 29, no. 3 (Fall 2018): 206-16.

# Refusal of Vaccination: A Test to Balance Societal and Individual Interests

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## ABSTRACT

While all states in the United States require certain vaccinations for school attendance, all but three allow for religious exemptions to receiving such vaccinations, and 18 allow for exemptions on the basis of other deeply held personal beliefs. The rights of parents to raise children as they see fit may conflict with the duty of the government and society to protect the welfare of children. In the U.S., these conflicts have not been settled in a uniform and consistent manner. We apply a test that provides a concrete and formal rubric to evaluate such conflicts. For some vaccinations, based on the individual medical characteristics of the disease and the risks of being unvaccinated, the test would suggest that permitting conscientious exemptions is ethical. However, for vaccinations protecting against other diseases that are more severe or easily transmitted, the test would suggest that the federal government may ethically impose laws that deny such exemptions.

## INTRODUCTION

Parental refusal to allow vaccination of their children (henceforth abridged as "vaccine refusal")

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is a long-standing phenomenon. Among the reasons for conscientious vaccine refusal<sup>1</sup> are (1) religious objections, (2) other philosophical objections such as a desire to live a natural life,<sup>2</sup> and (3) exaggerated concerns regarding vaccine safety.<sup>3</sup> Many of the latter are based on discredited work linking vaccination with autism.<sup>4</sup> Other parents may appreciate that vaccines are quite safe, but would protect their children from the minor risks of vaccines by relying on other children's vaccination to prevent their own children from contracting the diseases in question.<sup>5</sup> The degree of vaccine refusal varies. Some parents refuse all vaccines for their children. Others are willing to permit their children to receive certain vaccinations but not others, or accept vaccines on a delayed schedule.<sup>6</sup>

In the U.S., principled objections often receive legal exemption. All but three states<sup>7</sup> allow religious exemptions to laws requiring vaccination for attending school or group childcare;<sup>8</sup> 18 of these states<sup>9</sup> also permit exemptions for personal or philosophical beliefs.<sup>10</sup> The spectrum of religious, personal, and philosophical objections covered and the rigor with which these are investigated varies.<sup>11</sup>

Public health vaccination strategy can reasonably differ by disease on the basis of disease severity and communicability. For example, 47 U.S. states mandate hepatitis B immunization for admission to school, day care, or both. In contrast, only 19 states have any requirement for hepatitis A vaccination.<sup>12</sup> Only measles-mumps-rubella and polio vaccination are required in all 50 states.<sup>13</sup> Vaccination may be recommended, compulsory, or mandatory for school attendance.<sup>14</sup> European nations rely more heavily on recommendations to obtain vaccination compliance

than do U.S. states.<sup>15</sup> Because of the recent increase in the incidence of vaccine-preventable disease, some European nations have moved toward a more prescriptive approach. France recently increased the number of required vaccinations for school attendance in its mandatory vaccination policy. Italy also recently adopted a mandatory vaccination policy, but without provision for conscientious objection such as those found in most states in the U.S.<sup>16</sup> The likelihood of school age children acquiring a disease may favor a program of mandating vaccination for school attendance. Similarly, there is less urgency to vaccinate children against a disease that generally is confined to adults.

Determining that a certain strategy is conducive to health does not necessarily imply that governmental power should enforce that strategy. Health must be balanced against other goods. For example, parents expose their children to the risks of full contact sports because they believe that these provide social and character benefits that counterbalance their health risks.<sup>17</sup> The risks of injury from football are probably greater than the risks of grave consequences from varicella, but football is often encouraged (even though safer means of exercise and competition are available), while vaccination against varicella is mandatory. Thus, both parents and state agencies such as schools and public health departments balance health benefits against other factors. Parents and agencies may disagree regarding the appropriate decision. When such disagreement occurs, the balance between parents' prerogative to raise their children according to their values and the state's obligation to protect minors must take into account factors other than health and safety.

In this article, we first will discuss the science of vaccination, then the ethical issues as elucidated by previous work. We then will propose a rubric for analyzing situations in which parents and authorities differ regarding the need for vaccination. We will explain how this rubric provides a tool to accomplish this in a way that complements or improves on previous approaches.

### **Risks and Benefits of Vaccination**

The factual bases for vaccine refusal have largely been scientifically refuted. There is no scientific support for the notion that vaccines overwhelm the infant immune system.<sup>18</sup> Most additives in vaccines are safe in the absence of anaphylaxis to a component ingredient.<sup>19</sup> No reputable study has suggested a link between autism and any vaccine.<sup>20</sup>

Severe vaccine complications are unusual, but can occur. A 1994 report from the Institute of Med-

icine's Vaccine Safety Committee acknowledged several such complications.<sup>21</sup> These included Guillain-Barré syndrome with diphtheria/tetanus (DT/Td/T)<sup>22</sup> and oral polio vaccines,<sup>23</sup> brachial neuritis with DT/Td/T,<sup>24</sup> thrombocytopenia with measles-mumps-rubella (MMR),<sup>25</sup> a risk of polio in the patient or a contact from the oral polio vaccine,<sup>26</sup> a risk of death from vaccine-strain viral measles infection, and anaphylaxis to components of almost any vaccine. An updated report in 2011<sup>27</sup> also recognized a likely relationship between disseminated infection with the live virus varicella vaccine.<sup>28</sup> Rotavirus vaccine may be associated with intussusception.<sup>29</sup> The combined diphtheria-tetanus-acellular pertussis-inactivated polio-haemophilus B (DTaP-IPV-Hib) vaccine has some association with febrile seizures.<sup>30</sup> In the rare case that a vaccine causes a serious adverse effect, U.S. patients are potentially eligible for compensation through the National Vaccine Injury Compensation Program. This program, funded by the U.S. Health Resources and Services Administration, ensures that liability concerns are separated from both the vaccine manufacturer and healthcare provider and thus removes a potential barrier to maintaining high rates of vaccination.<sup>31</sup>

However, the risks associated with *not* vaccinating far exceed those of vaccination. Unvaccinated children are more likely than their vaccinated peers to contract vaccine-preventable diseases. For example, a retrospective cohort study between the years 1985 to 1992 reported that school-aged unvaccinated children were 35 times more likely to contract measles than those who were vaccinated.<sup>32</sup> This study reported a higher relative risk among younger children, with those aged five to nine having a risk of measles 170 times that of their vaccinated classmates. The study also predicted that in communities with higher numbers of unvaccinated children, the incidence of measles will rise even in vaccinated children. In Colorado, children not vaccinated due to a personal belief exemption were 5.9 times more likely to acquire pertussis than their vaccinated peers. This relative risk increases to 10.6 if all nonvaccinators are included—not just those with a known personal belief exemption. In Michigan, geographic clusters with a high number of non-medical vaccination exemption are three times more likely to experience pertussis during an outbreak.<sup>33</sup>

The protective effects of vaccinations apply to an entire community due to herd immunity or, in the absence of this, relative herd protection.<sup>34</sup> Without herd immunity a population may harbor a pathogenic organism indefinitely; but with herd immu-

nity, an outbreak, although possible, will be self-limiting. The percentage of immunized individuals required to attain herd immunity depends on the ease with which the disease is transmitted. A highly infectious disease for which a single infected person is expected to spread the disease to 15 people requires a higher proportion of the community to be vaccinated than does a less infectious disease for which an infected person can be expected to spread the disease to only two or three people.<sup>35</sup> Measles is highly contagious, probably requiring a vaccination rate of greater than 95 percent to attain herd immunity; the corresponding rate for diphtheria is estimated to be 79 percent to 84 percent.<sup>36</sup> This is at the low end of coverage for serious communicable diseases of childhood. Herd immunity also is affected by the efficacy of the vaccine. This ranges from 99 percent seroconversion for the measles vaccination<sup>37</sup> to much lower rates for the influenza vaccine.<sup>38</sup> Absence of sufficient herd protection can produce dramatic outbreaks, like the outbreak in California of 113 cases in early 2015.<sup>39</sup> Those at risk include children too young to be vaccinated,<sup>40</sup> those who cannot be vaccinated for medical reasons,<sup>41</sup> and those who do not derive immunity from the vaccine.<sup>42</sup>

Vaccine refusal puts people who do not vaccinate at higher risk of complications if they contract a vaccine-preventable disease. The herd protection effect increases the expected age at which an unvaccinated person is likely to encounter an infectious agent and contract a disease. Some diseases for which vaccination is required have more severe consequences in adults. For example, in the prevaccination era, the average age of a patient with measles was just under five years old. However, a model suggests that if vaccination coverage was 20 percent below the threshold for herd immunity, the average age of a case of measles would be 19.1 years. This increases the risk of serious complications by a factor of 4.5. Severe outcomes would also be expected to increase in cases of varicella (by a factor of 2.2) and rubella (by a factor of 5.8).<sup>43</sup>

### **Inconsistency of Vaccination Regulation**

When a parent refuses to vaccinate a child, both the child (the “index child”) and the surrounding community are endangered by this decision. Because of the risks to the index child, communicability is not the exclusive determinant of vaccine policy. For instance, vaccination against tetanus, a noncommunicable infectious disease<sup>44</sup> that can be prevented by other measures following possible exposure, is mandatory for school attendance in most U.S. jurisdictions.

Beyond this, U.S. vaccination policy among the states is hard to rationalize. Maps that list requirements for different vaccines show poor overlap in vaccination requirements for different diseases, although some patterns exist. More states require vaccination for more-severe pathogens. Also, states are more likely to require vaccination against pathogens for which vaccines have long been available (for example, tetanus/diphtheria/pertussis and pneumococcus).<sup>45</sup> While individual state rules reflect local state policy processes, there is little uniformity in statutes for newer vaccines (for example, human papilloma virus and influenza), age of population required to be vaccinated (schools, day care centers, colleges, *et cetera*), breadth of exemptions permitted, or degree of scrutiny that different states apply to requests for exemptions.<sup>46</sup>

Vaccine policy in the U.S. is inconsistent with governmental approaches to other medical interventions and to nonmedical practices. Even when early intervention programs for major psychomotor problems or visual impairment are available gratis or at low cost to preschool and school age children, parents are not required to take advantage of these programs. These optional, non-invasive interventions are much more likely to benefit a child’s health than immunization against tetanus or varicella.

Social acceptability may influence the tolerance of societal harms. For example, a nine-year-old child can play full contact hockey but cannot come to school if not immunized against tetanus. Perhaps this is because religious beliefs leading to vaccination refusal are less respected by the general population than the social prestige that most in the U.S. associate with contact sports.<sup>47</sup> Clearly, governmental requirements in the U.S. that are designed to protect children’s health and safety have no consistent grounding in a balance of harm and benefit, let alone a comprehensive vision.

### **The Ethics of Vaccination Requirements**

The question, then, is whether bioethical analysis can rationalize this area of concern. In a strictly majoritarian democratic society, the discussion would end there; *vox populi vox dei*,<sup>48</sup> as it were. However, society looks to other germane ideals. These, however, may conflict with each other in their application, as well as with democratic processes. First, society, often through government, has a *prima facie* obligation to protect the vulnerable. When the state does this, it is called “police power” in U.S. law.<sup>49</sup> Second, liberal ideals demand that people be allowed to pursue their own vision and act upon their own beliefs whenever possible. A third, con-

troversial, ideal is multiculturalism. This ascribes to individuals the prerogative of associating together in communities within a sovereign state in which they can realize their values and practice their customs.<sup>50</sup> Irrespective of any of these other values, the integrity of the family and the default power of parents to make decisions has been acknowledged legally<sup>51</sup> and ethically.<sup>52</sup> This includes rearing children in accordance with group beliefs and values. These five conflicting principles—majoritarianism, protection of the vulnerable, liberalism, multiculturalism, and respect for the value of the family—have been reconciled inconsistently. As Levin and colleagues noted, a regime of inconsistency in balancing minority values against considerations related to the health and safety of children is likely to discriminate against the marginal and the unpopular.<sup>53</sup>

### Approaches Based on Medical Ethics

Proposed bases for resolution of conflicts over healthcare decisions regarding individual children fall into several categories. These include child autonomy, best interests, the harm principle, family-oriented views, and micro-economic analysis.<sup>54</sup> The best interests standard has been applied to childhood vaccination by Chervenak<sup>55</sup> and by Dawson.<sup>56</sup> Both authors prefer persuasion, but are willing to invoke governmental power to compel vaccination for serious illnesses. But the best interest standard tends to focus primarily on physical or health-related interests, and does not generally account for the psychological, familial, religious, or cultural interests of a child that may play a part in vaccine refusal.<sup>57</sup> Furthermore, issues of probability, proximity, and severity are difficultly to reconcile. That is, it is not immediately clear whether it is in the best interest of a child to undergo the risk of one painful injection and a potentially mild injection-site reaction, versus the small probability of contracting hepatitis A. Thus, under the best interest standard, a surrogate decision maker must determine the highest net benefit among the available options, assigning different weights to interests the patient has in each option and discounting or subtracting inherent risks or costs.<sup>58</sup>

Douglas Diekema prefers to use an approach based on John Stuart Mill's harm standard as the touchstone for intervention in the case of vaccination, as Diekema argues it is more reasonable and more precise than the best interests standard.<sup>59</sup> He further qualifies the nature of the harm that he would accept as a trigger for U.S. states to override parents, restricting it, for example, to situations in which the threat of harm is serious and urgent, rather than

public health considerations more broadly. Applying this standard to vaccinations, Diekema finds state intervention warranted only in unusual circumstances. Others, such as Jessica Flanigan<sup>60</sup> and Roland Pierrek,<sup>61</sup> have used the harm principle to justify a more vigorous approach to required vaccinations. However, the harm standard can be indeterminate in practice; Giles Birchley documented that two judges in the same jurisdiction used the harm principle in virtually identical child custody cases to reach opposite conclusion.<sup>62</sup> Lainie Friedman Ross's restrained parental autonomy standard has the advantage of including all familial interests in the calculus, but does not solve the problems of weighing probability, proximity, and severity consistently and uniformly. Indeed, it is impossible to eliminate these problems as long as different decision makers with different values are adjudicating these conflicts.

### Approaches Based on Public Health Ethics

Widespread compliance with vaccination mandates is required to prevent communicable diseases that give risk to outbreaks and epidemics. Therefore, the ethical analysis of this phenomenon also belongs to public health ethics with its communitarian focus, rather than solely to traditional medical ethics with its focus on the individual.

It is hardly questioned that governments may act to "protect the lives, health . . . comfort and general welfare of the people," termed "police power" in U.S. law.<sup>63</sup> Governments have asserted this power for at least 4,500 years.<sup>64</sup> The United Kingdom's Nuffield Council on Bioethics outlines an "intervention ladder" to rank the different ways that governments can impact individuals' choice.<sup>65</sup> Although the Nuffield Council outlines eight specific options, the ladder "rungs" can largely be collapsed into four areas—education, organization, incentivization, and compulsion. A state that wanted to increase childhood rates of vaccination could mount public service campaigns (education). It could operate a medical care system that ensured that children were seen by a physician regularly (organization). It could pay parents to vaccinate their children or direct physicians to vaccinate all children unless a parent raised specific objections (incentivization). Or, it could require that children receive the vaccination as a condition for school attendance (compulsion). Public health ethics asks when governmental intervention is appropriate to effect policies that are themselves, other things being equal, desirable.

Marcel Verweij has stated that the two most plausible "ethical allies" of public health are "the harm

principle and the consequentialist perspective.”<sup>66</sup> Jessica Flanigan relies on the harm principle to assert that policies requiring vaccination are appropriate provided that (1) the illness is contagious, (2) those who are exposed to the risks of transmission are not liable, (3) vaccination is necessary and effective at limiting contagious transmission, and (4) vaccination does not violate rights of self-defense (that is, that recipients do not have medical conditions that make vaccination dangerous to them).<sup>67</sup>

Flanigan relies on an analogy between refusing vaccination and the celebratory firing of a gun into the air, seeing both actions as subjecting unknown individuals to the risk of harm. But one is an act of commission and the other an act of omission, and it is unclear ethically whether these ought to be regarded as equivalent.<sup>68</sup> Furthermore, this analogy does not address the likelihood of the harm. An analogy to a legal act that causes trivial but finite harm, such as driving with small amounts of blood alcohol, would also be apt, but would point to the opposite conclusion.

We now turn to Verweij’s second “ally,” consequentialism. This perspective is applied in a way that conceives of benefits to a community or a society as a whole as being greater than the sum of individual benefits.<sup>69</sup> Public health ethicists tend to emphasize the collective rather than the individual. Reducing a health risk is characterized as a *public good*, which Richard Arneson defines as follows: “[A] good is public according to the degree to which it exhibits three features: (1) a unit of the good consumed by one person leaves none the less available for others (jointness), (2) if anyone is consuming the good it is unfeasible to prevent anybody else from consuming the good (nonexcludability), and (3) all members of the group must consume the same quantity of it.”<sup>70</sup>

Angus Dawson adds an additional element to the definition, that the public good “cannot be created by any individual alone: it takes collective efforts.”<sup>71</sup> He also omits the third of Arneson’s requirements. This is appropriate, at least in a public health context, because exposure to disease will vary from person to person. Thus, for example, a program to test lead levels in children will benefit those exposed to lead-based paint from old houses more than other children who live in new housing with lead-free paint. The children more likely to be exposed would “consume” more health improvement than those less likely to be exposed.

Since herd immunity confers protection from communicable diseases on immunized and unimmunized people alike, it is said to be a public good,

as well as a private good for the vaccinated individuals.<sup>72</sup> However, categorizing herd immunity as a public good does not demonstrate either that individuals are obliged to take the steps necessary to achieve it or that the government should pursue that good. An even stronger argument is that the existence of a public good does not *per se* justify the state’s use of any of the four tools at its disposal to bring that good about. At least eight hurdles remain before the state may use a given measure to try to procure the good.

First, the putative public good may not be, in fact, a good. This hurdle is easily cleared by vaccination programs. A second possible problem is that the good may not be important enough—absolutely or relatively—to warrant state action. Governments have finite resources. A program to landscape municipal thoroughfares would constitute a public good, but might best be shelved due to competition for resources by more urgent needs. A third and related hurdle is that a program may be sufficiently controversial that disruption caused by the program exceeds its value. In the case of vaccination, the disease in question must have sufficiently grave consequences to merit that vaccination be required.<sup>73</sup>

Fourth, no good is exclusively a public good, as governmental programs create direct private goods for those who create and sustain them. This can lead to influence by such individuals to maintain or expand their programs even when the value of these programs diminishes. Fifth, the creation of a public good may cause so much harm to a minority that it seems grossly unfair to institute the program. A fictional example found in two widely read U.S. works is a lottery to kill a few people for the entertainment of a large population, which is presumed to be a public good.<sup>74</sup> Sixth, even if a measure is generally acceptable in theory, the burden of a government campaign that is strict enough to bring about the public good in question can cause unreasonable harm.<sup>75</sup> This is not the same as the previous hurdle; here it is enforcement, rather than the measure itself, that creates the harm. In New York City, fines are unable to control extensive, traffic-clogging double parking. The city tolerates this practice rather than escalating to towing, license suspension, or imprisonment, all of which would be considered disproportionate to the offense. Seventh, a measure that is good in isolation may not be as good when many similar measures are aggregated. Childhood immunization recommendations in various European nations include vaccines against 17 diseases.<sup>76</sup> Other diseases such as typhoid and yellow fever can be prevented using vaccines, but these are not given in

nations that have temperate climates and good sanitation. Further progress may yield vaccines against other flavivirus diseases such as dengue and Zika, human immunodeficiency virus, malaria, and other epidemic diseases. It may be tempting, especially in tropical nations in which many of these diseases are epidemic, to add some of these to childhood immunization protocols. It may also be possible to prepare vaccines against a wide variety of mild respiratory pathogens. The proliferation of vaccines may result in pressure to give small children many injections at great cost and considerable discomfort. Thus, a public good that is *prima facie* desirable may pose a problem in a broader context.

Finally, the good may simply be inconsistent with the values of society. Consider a hypothetical nation in which 80 percent of the inhabitants adhere to Christian Science beliefs and do not believe in vaccination. The government is likely to refuse to require vaccination, and may not even subsidize vaccination for those who want it for their child.

In summary, many vaccines are sufficiently effective to largely immunize individuals and to achieve herd immunity in comprehensively immunized populations. It is generally accepted that sovereign states have the power to restrict the freedom of their citizens to improve their health and safety, but that this power is not absolute. Most agree that parents are presumed to have at least default authority to make decisions on behalf of their child. We must balance the children's interest in health against their social, relational, and religious interests when deciding whether to override parental refusal of vaccination. Yet, there is no consistent approach to weighing this balance. At the same time, herd protection is a public interest, often expressed using the concept of public good. Here, too, the magnitude of the public good must be balanced against the considerations of individuals and families, as well as against competing public goods.

### **A Test to Provide a Template for Analyzing Vaccination Policy**

In this section we will apply to vaccination policy a test for adjudicating among parental interests (including their religious and cultural beliefs and practices), child welfare, and societal needs. This test, which has been proposed before in a slightly different form,<sup>77</sup> balances individual liberty and respect for cultural difference against the protection of vulnerable children. In the context of U.S. constitutional law, it balances the right to free exercise of religion against the requirement that government not unduly favor religion. This test supplies a

balanced and transparent approach that respects all parties. We will not address the important question of whether religious views are privileged over other conscientious beliefs. The interested parties here include children whose parents refuse vaccination, children whose parents approve of vaccination but who are unable to benefit from it, society as a whole (which is interested in both freedom and in public safety), the parents themselves, and possible minority groups to which the parents belong.

A detailed justification and theoretical basis for this test has been presented elsewhere.<sup>78</sup> This test is presented in table 1.

The test balances societal values and imperatives against minority values and interests. While not explicit, the need to balance risks and benefits is implicit in all elements of the test. On the other hand, it is not simply a comparison of risks and benefits. First, it is explicit about which harms to children constitute unreasonable burdens, while burdens that society should be expected to tolerate are more open-ended. Second, the test's "comparability of effect" constraint uses society's overall risk tolerance as one benchmark for assessing risk to a particular child. Third, the "benefit/harm" constraint considers not only direct harms from an undesirable practice, but also possible harms from enforcement programs.

The test has similarities to Diekema's harm principle analysis, but there are differences as well.<sup>79</sup> Unlike Diekema's test, which was written as an ethical response to individual conflicts, this test was conceived to provide legal and ethical responses to public health questions confronting policy makers. There may be situations in which Diekema might allow exemptions but where this test's consideration of public health considerations, as reified in the "indirect effects" basis, would require vaccination. Furthermore, unlike Diekema, this test does not require imminent harm to overturn a parental decision. This test, then, is complementary to Diekema's approach. The test is pragmatic, with utilitarian elements. It contrasts with deontic approaches such as the best interests approach, as this test also allows consideration of the needs of other members of the family in determining whether state interference is warranted.<sup>80</sup> While transparent and balanced, the test is not absolutely determinative. Different societies have different views as to what is an unreasonable burden upon itself or its members, and what constitutes a substantial burden on a child. However, the "comparability of effect" prong prevents society from using public health measures as an excuse to disadvantage minorities.

While others have suggested that different diseases should be treated differently with respect to compulsory vaccination,<sup>81</sup> we believe that this test provides a template that can be used to analyze which vaccinations should be required.

### Application of the Test to Various Vaccinations

We first discuss the test with regards to vaccination in general and then as applied to vaccinations for several specific diseases. As noted above, there are various preventive options such as testing of sight, hearing, and cognitive function that enhance children's health and that are even less invasive than vaccination, but that are not required. Society is willing to grant exemptions for the harms and costs created by refusal of early intervention, which seems directly analogous to childhood vaccination. Therefore, a vaccination refusal that subjects children to the same or lower benefit/harm ratio as the risks of declining sensory testing or early cognitive intervention should be tolerated. This constraint is found in Prong 1, Basis 2, "Direct effects," of this test, that relies on Prong 2, Constraint 2, "Comparability of effect" and Prong 2, Constraint 3, "Benefit/harm" of this test. Although universal immunization against any communicable disease provides a public good, vaccination is offensive to many parents, for a majority of reasons. The common good is incorporated in Prong 1, Basis 1, "Indirect effects," of this test. The term reifies the benefits of universal immunization and the harms, or lack of benefits, of failure to immunize. The term provides a contrast to Prong

1, Basis 2, "Direct effects," which describes private goods or harms.

Refusal of early cognitive intervention produces not only costs to the child and family, but costs to society. These consist of diversion of resources to manage the disability. Therefore, Prong 2, Constraint 2, "Comparability of effect," as applied to both Prong 1, Basis 1, "Indirect effects," as well as Prong 1, Basis 2, "Direct effects," seems to mandate that what we tolerate for early cognitive intervention refusal (for example), we should tolerate for vaccination refusal. This could apply in one of two ways, either to justify both compulsory early cognitive intervention and vaccination mandates, or to require legal exemptions from both. Thus, at this point in the analysis, either or both should be required, but not one of these without the other.

However, there is another factor to consider. Vaccination, but not early cognitive intervention, prevents transmission of communicable disease. For this reason, Prong 2, Constraint 2, "Comparability of effect" does not rescue parent refusal of vaccination. Achieving herd protection is a major reason, under Prong 1, Basis 1, "Indirect effects" to require vaccination. Nothing comparable applies to early cognitive intervention, refusal of which does not make other children ill.

However, tetanus immunization is required in U.S. states, even though tetanus is not communicable. Its effect on infected children is devastating. It causes much prolonged suffering and frequent death. But it is rare in developed nations, with an

**TABLE 1.** A test for adjudicating among parental interests, child welfare, and societal needs

Limitation of parental power. A state may limit a decision or practice involving a child's health if any of the following two bases exist, but only if none of the constraints in the second prong apply:

Prong 1. Bases for limiting parental practices. Limitation is warranted if the decision or practice has sufficiently adverse effect outside the family or minority group such that it creates unreasonable burdens for either of the following two bases:

Basis 1. Indirect effects: Society as a whole, or members of society outside the family or minority group.

Basis 2. Direct effects: Children belonging to the family or minority group, by:

- a. Creating a substantial chance of death or of major disruption of a physiological function, or
- b. Creating other objectively severe harmful effects, such as malnutrition or major psychological morbidity.

Prong 2. Constraints on government action. Notwithstanding the bases in the first prong, a state should restrict parental action only if none of the following constraints apply:

Constraint 1. Likelihood of effect. The harm underlying the restriction must be:

- a. Actual, rather than hypothetical, and
- b. Likely, rather than unlikely or rare.

Constraint 2. Comparability of effect: The harm underlying the restriction must be of a magnitude greater than harms typically tolerated for mainstream practices comparable in both impact and type of practice.

Constraint 3. Benefit/harm: Benefits of the restriction to all parties concerned should foreseeably exceed overall harms.

incidence under one per one million.<sup>82</sup> Tetanus is rare even in unvaccinated children.<sup>83</sup> The rarity of the disease invokes Prong 2, Constraint 1, “Likelihood of effect,” while the overall low burden on society does not preclude exemptions based on Prong 1, Basis 1, “Indirect effects.” Thus, conscientious exemptions for tetanus vaccination are reasonable. In practice, however, the tetanus vaccine is combined with those for diphtheria and pertussis. These two communicable diseases are serious and are common in unvaccinated populations, so they should require vaccination without nonmedical exemption. So for practical purposes, the issue is moot.

While a coryza vaccine does not currently exist, coryza is, in important respects, the opposite of tetanus. It is a highly communicable infection transmitted by aerosol. It will readily spread in crowded environments like schools. The effect on those who have coryza is a few days of discomfort and possibly absence from school or work.<sup>84</sup> Coryza transmission among children is likely, so that coryza (unlike tetanus) passes Prong 2, Constraint 1, “Likelihood of effect.” However, increasing the chances of one’s child catching cold does not subject the child to unreasonable risk under Prong 1, Basis 2, “Direct effects,” nor is coryza so serious, so that (if a vaccine were available) the cost to society of sporadic outbreaks would not be substantial enough to justify denying religious exemptions under Prong 1, Basis 1, “Indirect effects.” As with tetanus, but for a different reason, parents should not be compelled to vaccinate their children against coryza, if a vaccine were to become available.

Polio occupies a third category. It carries a high mortality, and has a high rate of serious, permanent neuromuscular complications, both immediate and delayed. It is readily communicable in children.<sup>85</sup> Factors that might lead to outbreaks, such as vaccination refusal, affect society and its members under Prong 1, Basis 1, “Indirect effects.” Children who would otherwise benefit from vaccination may get polio because some are too young to be vaccinated, some cannot be vaccinated for medical reasons, and some fail to acquire immunity through vaccination. Even religious communities are not totally insular, so children in relatively closed communities (such as private Christian Science schools) may infect children outside the community. Thus, vaccination refusal creates an unreasonable risk to children outside that community. So, both Prong 1, Basis 2, “Direct effects,” and Prong 1, Basis 1, “Indirect effects,” allow categorical vaccination requirements. Certainly, the disease is real and is not rare, absent vaccination, so Prong 2, Constraint 1, “Likelihood

of effect,” does not vitiate government action. The magnitude of the harm caused by failure to vaccinate is greater than the magnitude of the harm caused by any permissible practice in society, so Prong 2, Constraint 2, “Comparability of effect,” does not apply. The external costs incurred in enforcing compliance (education, punishment, *et cetera*) are unlikely to be worse than the effects of foregoing herd protection. Governments may, therefore, ethically require vaccination for polio over all nonmedical objections.

Similar analysis, which we will not conduct, is applicable to other vaccinations for childhood illnesses. It is important to note that the terms “rare” and “substantial” used in the test are purposely left as subjective and without absolute numerical qualifiers. In a democratic, liberal society as the U.S., society (through elected representatives and the judiciary) can and should set the threshold values for such determinations.

## CONCLUSION

In our liberal society, the rights of parents to raise children as they see fit (often according to religious or deeply held personal beliefs) may conflict with the duty of the government and society to protect the welfare of children. In the U.S., these conflicts have not been settled in a manner that is uniform, logical, nor consistent. The proposed test, as discussed above, offers a concrete and formal manner to evaluate such conflicts. It does not force a government or society to intervene—only states when it *may* do so or when it *may not*. Thus, for some vaccinations, based on the individual medical characteristics of the disease and the risks of being unvaccinated, the test would suggest that religious and conscientious exemptions are ethical. However, for vaccinations protecting against other diseases that are more severe or easily transmitted, the test would suggest that the government may impose such laws that prevent such conscientious objection. As medical data accumulates surrounding the relative benefits and risks of both vaccination and nonvaccination for given diseases, the discussion and application of the test may change. Currently, the test would suggest that for many infectious diseases, state laws that ban nonmedical exemptions are ethical and liberally permissible.

## FUNDING

The first author is funded by the Clinical and Translational Science Collaborative of Cleveland, KL2TR000440 from the national Center for Advancing Translational Sci-

ences (NCATS) component of the National Institutes of Health and NIH Roadmap for Medical Research. The article is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

#### NOTES

1. We use the term “vaccine refusal” to include complete refusal as well as refusal of certain vaccines, or non-compliance with recommended vaccine schedules.

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