

# Vaccine Controversies: the Case for Freedom and Informed Consent

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The most controversial issue that AAPS has ever been involved in is vaccine mandates. The controversy involves a stark confrontation between individual rights and public health, along with many scientific questions.

AAPS policy is based on a resolution passed by the Assembly at the 2000 annual meeting:

WHEREAS: The statement of Patients' Freedoms adopted by the Assembly at the 47th annual meeting of AAPS in 1990 provides that "Patients have the freedom...to refuse medical treatment even if it is recommended by their physician and to be informed about their medical condition, the risks and benefits of treatment, and appropriate alternatives"; and

WHEREAS: There are increasing numbers of mandatory childhood vaccines, to which children are often subjected without meaningful informed consent, including information about potential adverse side effects; and

WHEREAS: Parents who exercise their freedom to refuse one or more vaccines may be subjected to penalties ranging from deprivation of the right to enroll their child in school, to threats of removing the child from parental custody and forcible vaccination; and

WHEREAS: Safety testing of many vaccines is limited and the data are unavailable for independent scrutiny, so that mass vaccination is equivalent to human experimentation and subject to the Nuremberg Code, which requires voluntary informed consent; and

WHEREAS: The process of approving and "recommending" vaccines is tainted with conflicts of interest;

BE IT THEREFORE RESOLVED: That AAPS calls for a moratorium on vaccine mandates and for physicians to insist upon truly informed consent for the use of vaccines.

In 2007, AAPS organized a "Hands Off Our Kids" coalition to fight Executive Order RP 56 issued by Texas Gov. Rick Perry, which stated: "Rules. The Health and Human Services Executive Commissioner shall adopt rules that mandate the age appropriate vaccination of all female children for HPV [human papilloma virus] prior to admission to the sixth grade."<sup>1</sup> The order incited a firestorm of protest and came to international attention.<sup>2</sup> In May 2007, the Texas Legislature overwhelmingly passed a bill vacating the governor's executive order by a veto-proof margin.<sup>3</sup> During his presidential campaign, Perry called the mandate a "mistake."<sup>4</sup>

There is increasing pressure to add HPV vaccine to the long list of vaccines already mandated for school attendance, and to reduce exemptions for all vaccines. In California, which already eliminated all exemptions except medical ones, proposed legislation would severely constrain permitted contraindications and subject physicians who write for exemptions to intense scrutiny. AAPS has written letters to several state legislatures concerning the need for informed consent for all medical interventions, including vaccines, and a statement to congressional committees opposing federal vaccine mandates.<sup>5</sup> Other than AAPS and a new organization, Physicians for In-

formed Consent (<https://physiciansforinformedconsent.org/>), medical organizations generally do not oppose mandates.

Adult vaccines are likely to be more widely mandated soon, especially in view of outbreaks of measles, pertussis, and mumps in fully vaccinated adults, whose vaccine-induced immunity apparently waned. AAPS members regularly complain to us about influenza vaccine requirements to work in hospitals or other health facilities. One physician withdrew an application for consulting privileges because of a demand to prove immunity or recent vaccination against some 15 different diseases.

The dogma is that "vaccines are safe and effective," and it is our duty to protect the "herd," especially vulnerable, immunosuppressed children, against vaccine-preventable diseases. Raising any question about this is almost certain to trigger vitriolic accusations of being a danger to the community as an "anti-science anti-vaxxer." Nevertheless, serious questions need to be explored with an open, critical mind.

## An Internist's Perspective

As an internist, I recognize that drugs are a critical tool in the fight against disease. Still, the attitude in my residency program at Parkland Memorial Hospital was that "every drug is a new disease" and "any drug can do anything." Despite the billions of dollars that are spent to "prove" safety and effectiveness to gain approval by the Food and Drug Administration, one never, ever says, "Drugs are safe and effective." Remember the miraculous COX-2 inhibitors, among many similar examples? Being a "late adopter" or "hesitant" prescriber does not mean one is "anti-science" or "anti-drug." A drug is "safe enough." The meaning is different for treating cancer or sepsis compared with prehypertension or mild bronchitis. And "effective" means "at least as good as available alternatives" and "of some benefit to some patients." The possibility of drug-drug interactions must always be kept in mind. And if a patient experiences an adverse event after taking a drug, one does not assume that it is a coincidence, even if that reaction is not listed on the package insert.

Vaccines seem to be immune to such considerations. And the manufacturers and physicians who administer compulsory vaccines are immune from liability.

Law professor Mary Holland writes:

...[S]tate and federal laws deprive American school children and their parents of three ordinary tort law protections: free and informed consent to an invasive medical procedure; accurate and complete information about vaccine ingredients and possible side effects; and the right to sue manufacturers and medical practitioners directly in the event of injury. The absence of these legal protections is striking compared to almost all other medical interventions. Because of the perceived overwhelming benefit from vaccines, U.S. federal and state law treat compulsory vaccination of children in a radically different way. Compulsory childhood vaccination is the most salient deviation from the ethical and professional standard of informed consent in civilian medicine.<sup>6</sup>

## The Duty to the “Herd”

The first ethical question is whether one is ever required to risk one's life or health—or the well-being of one's child—to benefit another, or even to save a life?

In the common law of torts, no one can be legally obligated to provide any level of help to another in need. “Tort law expressly indicates that an individual cannot be forced to give up a portion of his liberty to benefit another, no matter how little the cost or how great the benefit.”<sup>7</sup> One's moral obligation is, of course, a different question. And obviously, one may not deliberately harm others or neglect to take reasonable precautions.

The law imposes quarantines to prevent transmission of contagious diseases. This is imperfect protection, as asymptomatic persons may unknowingly infect others. The possibility that a single index case could unleash a deadly epidemic is the rationale for mandatory vaccination. For measles, a 95% vaccination rate is frequently asserted to be necessary for herd immunity to stop outbreaks and shield those who cannot be vaccinated. Let us not forget that vaccination is also imperfect.

The fact that one does not have the right to expose another to disease has apparently expanded to the belief that one is obligated to be maximally vaccinated—as if one could transmit a disease that one does not have. Why else would unvaccinated children be treated as lepers were once treated—excluded from school or even other public spaces? Children as well as parents may be made to feel guilty for being unvaccinated.

An Ohio teenager achieved worldwide fame for testifying before Congress about getting vaccinated against his mother's wishes. “Without vaccination, he said, even his school had come to see him as ‘a health threat.’ That pushed me further to get my vaccines despite my mother's beliefs because I saw the threat as being imposed by her.” He had posted on social media that his parents were misinformed, and “God knows how I'm still alive.”<sup>8</sup> He is the poster boy for a movement to allow minors to consent to vaccines—to protect themselves and the “most vulnerable.” State laws allowing children as young as 12 to consent to vaccines are being promoted.<sup>9</sup>

Accepting the premise that society may coerce and impose risks on some for the benefit of the herd—or allow minors to assume the risk—leads to complex, quantitative questions. Who benefits and how much? Who must suffer and how badly? How much information is needed to make consent truly informed?

## The Smallpox Story

The exalted status of vaccination and the legal precedent for mandates start with smallpox.

When I was a child, almost everyone had a scar from a smallpox vaccination. In 1980, the World Health Organization (WHO) declared that the deadly, extremely contagious disease had been eradicated, thanks to its aggressive global surveillance and vaccination campaign: a historic triumph over what some called the worst disease ever known to man. In 1979, WHO recommended that most vaccinations be stopped.

Despite the horrors of the disease, vaccination was controversial from the beginning. At a sponsored workshop at a meeting of the American Legislative Exchange Council (ALEC), we were shown an old poster warning that vaccination might turn a person into a cow. (Vaccine at the time was made from cowpox virus.) This was apparently intended to mock today's vaccine skeptics.

In the late 19th century people in Leicester, England, were so opposed to vaccination that 61 parents went to prison rather than allow their babies to be vaccinated.<sup>10</sup> Whether they believed

the threat of turning into a cow is not known, but the vaccine was called “poisonous, filthy, loathsome, damnable stuff.” It was made from pus, and tetanus may have been one of the contaminants.<sup>11</sup> People did die from the vaccine, even the modern version. It has been called “the most dangerous vaccine known to man.”<sup>12</sup>

Despite the Compulsory Vaccination Act of 1853 in England, there were outbreaks in 1854, 1855, and 1856, culminating in the Great Outbreak of 1871, with 42,000 deaths.<sup>10</sup> The town of Leicester, which developed a method of quarantine rather than vaccination, fared better than other similar towns.<sup>13</sup>

In an 1889 book, Alfred R. Wallace wrote that since vaccination was both useless and dangerous, “the enforcement of vaccination by fine and imprisonment of unwilling parents is a cruel and criminal despotism, which it behooves all true friends of humanity to denounce and oppose at every opportunity.”<sup>14</sup> Of course, today's manufacturing procedures are far more sophisticated, and vaccines are not contaminated with organisms that can cause tetanus or syphilis.

In the early 1900s, Massachusetts imposed a vaccine mandate in response to a smallpox outbreak, with a fine of \$5 (about \$125 today). This was upheld by the U.S. Supreme Court in the 1905 case of *Jacobson v. Massachusetts*, the case that serves as a precedent for all vaccine mandates.<sup>15</sup>

The Court did not give states blind deference. The Court's paradigm was clear, writes Mary Holland: a mandate in “an emergency”; when there was “imminent danger”; and when an “epidemic that imperiled an entire population.” It cautioned, however, against the potential abuse of police power. Also, the Court expressly created a medical exemption from vaccination, when a person was not a fit subject for vaccination and it “would be cruel and inhuman in the last degree” to vaccinate him. Because of *Jacobson*, medical exemptions exist in all 50 states.<sup>6</sup>

Beginning in 1916, judicial interpretations of *Jacobson* started to broaden, to include the implied power to prevent epidemics, not simply to respond to existing ones. Courts have given great deference to legislatures and agencies, and potential plaintiffs opposing vaccination mandates presumably considered direct challenges futile. Instead, since the 1960s when states began to compel children to receive six or more vaccines in multiple doses, litigation has centered on exemptions. Courts have upheld extreme penalties for noncompliance, including loss of education, social isolation, parents' loss of custodial rights, child neglect sanctions against parents, and even forced vaccination.<sup>6</sup>

Compulsion has been considered proper in balancing individual rights against public health. In *Prince v. Massachusetts*, the U.S. Supreme Court highlighted “the interest of the child to be free of a preventable disease.”<sup>16</sup>

Since one dread disease had been vanquished, public health authorities set their sights on eradicating others as well, beginning with polio and measles. Diseases once considered inevitable would become preventable, they promised.

There is one problem remaining with smallpox. The virus is not actually extinct, but survives in high-security freezers at the Centers for Disease Control and Prevention (CDC) in Atlanta and in Moscow—and probably in biological weapons. A possible attack with such weapons is not a conspiracy theory; it was the scenario in the Dark Winter exercise held at Andrews Air Force Base in June 2001.<sup>17</sup> The exercise projected 3 million cases and 1 million deaths in the fourth generation of smallpox cases, 2 months after an attack. Some scientists said the Dark Winter assumptions were overly pessimistic, and others said the outcome could be worse. Thanks to our celebrated triumph over smallpox, the current population is likely as susceptible as the Native Americans, who were devastated when Europeans, who had some immunity, brought the disease to the New World.

We hope that our remaining stockpiles of vaccine will still be effective. AAPS petitioned the CDC for better preparedness, including voluntary vaccination.<sup>19</sup>

The long-term consequences of vaccination include potential recrudescence of a disease as immunity wanes, its emergence in a more virulent form, or its replacement with something worse.

### Calculating Risks and Benefits

No one claims that vaccines are 100% safe and effective. The assertion is that “the risk of the diseases in question is an order of magnitude larger than the very rare chance that a modern vaccine will cause a serious, long-term problem.”<sup>16</sup>

One may cite, for example, the CDC’s estimate of a 1 in 1,000 risk of encephalitis, a 2 in 1,000 risk of death, or a 1 in 1,700 to 1 in 3,300 risk of long-delayed subacute sclerosing panencephalitis from measles.<sup>16</sup> The glaring statistical fallacy is failure to recognize that these are *conditional* probabilities. They must be multiplied by the risk of getting measles, which is near zero in most areas of the U.S. today. On the other hand, the risk of complications of a vaccine applies to everyone who receives the vaccine.

Notably, the risks of disease complications today, for measles, rubella, and chickenpox, are much higher than in pre-vaccination days, perhaps largely because in the shift in age distribution toward infants and adults.<sup>20</sup>

Just what is the probability of a “very rare” complication? And what is meant by “serious”? Very costly regulations are passed to protect children from certain risks—such as a hypothetical but small, perhaps unmeasurable decline in IQ from lead in paint chips that they might eat. A risk as low as 1 in 10,000 or even less might be considered unacceptable to allow, much less mandate.<sup>10</sup> How much of a risk of loss of language, paralysis, unmanageable behavior problems, seizures, or autoimmune disorders can a child be mandated to take to protect the herd or hypothetical other children from the risk of a “preventable” disease in the event of an outbreak? This question must be addressed.

And what risks should physicians mention to patients? A non-zero risk of serious, long-term disability is likely to cause “vaccine hesitancy,” which WHO has named one of the top ten global public health threats in 2019.<sup>21</sup>

There are many vexing questions. What is an acceptable risk to the patient or parent? How high a risk can society require a person to take for the greater good? Can society demand that a person prove that a risk exists before exempting him from a vaccine? Or is it the responsibility of authorities to demonstrate that a risk is less than a certain threshold? What is the standard of proof? What constitutes evidence?

A series of case reports that might constitute evidence or even “proof beyond a reasonable doubt” in a legal sense, as in the famous Brides in the Bath case,<sup>22</sup> may be dismissed as “anecdotes,” labeled “misinformation,” and even suppressed if considered to cause vaccine hesitancy. Absence of evidence in the form of long-term, placebo-controlled studies of adequate power to rule out an uncommon delayed effect is treated as evidence of absence. Pertinent material, such as details of settlements in the Office of Special Masters of the U.S. Court of Federal Claims, popularly known as “vaccine court,” are sealed. So how can one really know the risks?

### An Epidemic of Doubt

According to a survey of 2,000 adults funded by the American Osteopathic Association, 45% cited at least one source that caused doubt about vaccine safety, most commonly from on-

line articles or distrust of the pharmaceutical industry. While the majority had a favorable view of vaccines (31% said “I think the benefits of vaccination outweigh the potential risks of vaccine side effects,” and 51% said “I think vaccines are safe and effective”), 9% were unsure of whether vaccines are safe and effective, 6% think the “risks of vaccine side effects outweigh the potential benefits of vaccination,” and 2% think vaccines are “unsafe and ineffective.”<sup>23</sup>

Americans are more trusting than others. In France, 33% of 1,000 respondents answered “no” to the question of whether vaccines are safe. The percentage was 24% in Russia, 22% in Switzerland, and 21% in Austria.<sup>24</sup>

This doubt is considered a public health threat, and family physician Paul Ehrmann, D.O., like many others, declines to accept new patients who refuse to vaccinate. “People know that a lot of practices won’t accept patients who don’t vaccinate, so when they find one that will, they spread the word to their community that it’s a safe place. Whether intentional or not, those doctors are often seen as endorsing anti-vaxxer beliefs,” Dr. Ehrmann said. “Policy changes are likely the most effective means to change behaviors, if not hearts and minds.”<sup>23</sup>

The source of the doubt, which is purportedly responsible for the return of measles, is said to be “America’s ailing culture.” According to commentator Peter Beinart in *The Atlantic*, people lack historical memory, are more concerned about their own child than the collective, and have diminished trust in government and medical experts.<sup>25</sup>

“Vaccines are a victim of their own success,” stated epidemiologist Saad Omer to the U.S. Senate Committee on Health Education Labor & Pensions (HELP).<sup>26</sup> Fears of a comeback of “horrible” childhood diseases, with “millions” dying—as indeed they did before better nutrition and sanitation in this country and still do in Third-World countries—are prevalent in the medical community, according to Omer. I lived through those bad old pre-vaccine days. Most children, including my sisters and me, got the childhood diseases, which were accepted as a rite of passage. Dire consequences were rare enough that we did not hear of them. What we also did not see or hear about was autism, EpiPens® in school because of life-threatening food allergies, severe asthma attacks, and high rates of learning disabilities. Whether the constantly growing number of vaccines might be related is a question many parents are raising. It is hard to argue that children are on the whole healthier than in 1950, even though they seldom get chickenpox or measles.

Government-funded studies of health outcomes in unvaccinated children versus vaccinated children have not been reported and have probably not been done. A pilot study of a convenience sample of home-schooled children showed that, based on mother’s recollection, vaccinated children were more likely to have been diagnosed with pneumonia, otitis media, or a neurodevelopment disorder.<sup>27</sup> The study is obviously limited; further investigation is needed.

A compendium of abstracts on relative risks of specific conditions in children who did or did not receive specific vaccines is available from Children’s Health Defense.<sup>28</sup>

What about a link between measles-mumps-rubella (MMR) vaccine and autism? Wakefield et al. suggested investigating the possibility in 1998, based on parental observations related to their autistic children who were suffering bowel symptoms.<sup>29</sup> This incited a storm of objections, and assertions that “overwhelming evidence,” most importantly the 2002 Danish study by Madsen et al.,<sup>30</sup> which was critiqued in this journal,<sup>31</sup> disproved such a link. Nevertheless, it was not until 2019 that a study<sup>32</sup> including an “unvaccinated” control group appeared. The control group had not yet been vaccinated *with MMR* at the time of an autism

diagnosis. Brian Hooker<sup>33</sup> pointed out a number of flaws in the study. It does not have adequate power to rule out a risk as high as 1 in 10,000.

Discerning physicians and parents are not content with generalized reminiscences or blanket statements that “vaccines do not cause autism, sudden infant death syndrome, or sterility” (claims now banned by Facebook policy<sup>34</sup>). It is impossible to prove a universal negative—and is the statement refuted by finding an example? Apparently not, because a causal relation cannot be proved. There are many stories of severely damaged children who were allegedly thriving until receiving a vaccine. Parents bring them to legislative hearings, and post stories, photographs, and videos online. Are they fake, or attempts to blame a vaccine for a pre-existing condition, or the result of some undiagnosed disease? Glib reference to “overwhelming evidence” or “decades of vaccine science” does not address the concern. Specifics are needed, and evidence that can place an upper bound on the probability that this could happen to *your* child.

### Vaccine Safety Studies and After-Market Surveillance

For any drug or vaccine, it is impossible to rule out rare but devastating complications in pre-market studies. These may occur only long after a study is complete. Post-licensure surveillance is essential.

The National Childhood Vaccine Injury Act (P.L. 99-660), passed in 1986, required the secretary of the U.S. Department of Health and Human Services to consult with the Institute of Medicine (IOM) to conduct a review of the scientific literature related to a set of serious adverse events following immunizations recommended for use in children. The vast majority of conclusions in the report state that the evidence was inadequate to accept or reject a causal relationship between the vaccine and the effect.<sup>35</sup>

The rapid safety-signal detection for rare adverse events from vaccines is the Vaccine Adverse Event Reporting System (VAERS), to which anyone can file a report at <https://vaers.hhs.gov>. It is a passive system; reporting is not required. Its limitations include reporting bias, inconsistent quality, inability to assess causation, and incomplete ascertainment.

How incomplete is it? A study was conducted by Harvard Pilgrim Health Care between June 2006 and October 2009, involving 715,000 patients. During this time, 1.4 million doses of 45 different vaccines were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6% of vaccinations) were identified. It was calculated that fewer than 1% of vaccine adverse events are reported: The CDC states that it receives only 30,000 reports per year, of which 10% to 15% are “serious”—resulting in “permanent disability, hospitalization, life-threatening illness, or death.”<sup>36</sup> Researchers stated that “there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.”<sup>37</sup>

In other words, there may be as many as 450,000 serious adverse events occurring after vaccination in the U.S. every year. While CDC asserts that these “are rarely caused by the vaccine,”<sup>36</sup> the IOM has called the evidence inadequate in most cases to rule out causality.

Ten years after the Harvard Pilgrim study, we have no better information about the completeness of reporting.

### What Is in Vaccines?

Labels on food must list ingredients, and package inserts

list ingredients in vaccines, but patients may not find them accessible. A bill proposed in the Arizona Legislature in 2019 would have required physicians, as part of informed consent, to provide the benefits and risks of each vaccine, the manufacturer’s package insert, and how to report a vaccine-adverse event.<sup>38</sup> The measure was strongly opposed by the Arizona Medical Association, which stated in an email to its members that the bill “will have the effect of scaring parents and reducing the number of vaccinations.” The “‘Big Government’ intrusion into the physician-patient relationship” was purportedly worsened by requiring information on “how to make a claim through the National Vaccination Injury Compensation Program.”<sup>39</sup>

Patients might indeed be frightened by a list of ingredients, especially as people are taught to fear minuscule amounts of “chemicals,” such as formaldehyde, which is generated naturally by human metabolism. But there are ingredients of concern.

### Human Fetal DNA

The human diploid cell lines (e.g. WI-38<sup>40</sup> and MRC-5) used to produce many common vaccines have their origin in induced abortions. These vaccines include rubella, measles, mumps, rabies, polio, smallpox, hepatitis A, chickenpox, and herpes zoster. Many others are in the pipeline.<sup>41</sup>

Some may try to base a request for a religious exemption on grounds analogous to the “fruit of the poisoned tree” legal doctrine, or to scruples about using the findings of Nazi medical research. Established religious authorities, however, including the Roman Catholic Church, say it is morally acceptable to use products derived from remote abortions for a serious reason such as protecting life and health.<sup>42</sup> Some jurisdictions in the U.S. fail to recognize the primacy of the individual conscience, a belief firmly held by our Founders, many of whom were religious dissenters and came to the New World seeking freedom to practice their faith.

There might be health as well as moral considerations. Vaccines contain fragments of human fetal DNA, which some suggest may become incorporated into host DNA. They also contain fragments of human endogenous retrovirus K (HERV-K).<sup>43</sup> A suggested mechanism whereby this might be harmful is disputed.<sup>44</sup> Statistical analysis of change points in the rising incidence of autism reportedly correspond to the replacement of vaccines cultured in animal cells with those cultured in human cell lines, but not to changes in diagnostic criteria.<sup>43,45,46</sup>

### Viruses

Live virus vaccines contain “attenuated” viruses that have been passed through cell cultures to obtain a virus that maintains immunogenicity for the wild virus while mutating into a less virulent form. (Of course, there is also the possibility that mutation could make an innocuous virus more virulent.)

“From early- to mid-twentieth century, directing the evolution of the world’s most dangerous viruses through various animal species and gentling them as a rancher would a wild horse, was the holy grail of medicine,” write Kent Heckenlively, J.D., and Judy Mikovits, Ph.D. “The question that would haunt researchers...was whether in the attempt to conquer one disease a researcher might inadvertently create another.”<sup>47</sup>

Animal cells in cell cultures used to make vaccines contain many viruses, most of which are apparently harmless, at least in that species. Vaccines have been found to be contaminated with many viruses or viral DNA, such as the SV-40 virus in early polio vaccines.<sup>48</sup> In 2011, molecular biologist Judy Mikovits announced a discovery that at least 30% of our vaccines are contaminated with gammaretroviruses, and that these viruses are linked to autism, myalgic encephalomyelitis/chronic fatigue syndrome,

and other neurologic diseases. Her career, unlike that of other early investigators of the human immunodeficiency virus (HIV), was destroyed.<sup>47</sup>

Might an internist be tempted to think: “Every virus is a new disease,” or “any virus can do anything”? This would be an overstatement, but consider how the generally innocuous Zika virus is identified as the cause of microcephaly, and HIV, which virologist Peter Duesberg has called a “harmless passenger virus,” as responsible for the AIDS epidemic. Parenthetically, note that the presence of antibodies to HIV is used to diagnose the condition, but antibodies are not protective, as it is the lack of T-cell immunity that allows the characteristic opportunistic infections. The presence of antibodies is used as evidence for vaccine-induced immunity, as one cannot ethically expose test subjects to the disease. How reliable is this evidence?

### **Aluminum**

Most vaccines today contain aluminum adjuvants. This is generally accepted to be safe, because of the very small quantity, although aluminum is a known neurotoxin. The important amount, however, is not just the amount administered, but the amount that gets concentrated in the brain or other tissue, and the immune reactions that small quantities may trigger.

An “emerging” inflammatory myopathy called macrophagic myofasciitis (MMF) was described in 1998.<sup>49</sup> In addition to the chronic fatigue and myalgias, up to 20% of patients develop a concurrent condition believed to be of autoimmune etiology, such as Hashimoto thyroiditis, dermatomyositis, rheumatoid arthritis, Sjögren syndrome, or a demyelinating condition.<sup>50</sup> Cognitive complaints occur in 20% to 68%, and cognitive dysfunction can be severe.<sup>51</sup> MMF may be part of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) proposed in 2011.<sup>52</sup>

Aluminum adjuvants were discovered empirically in 1926, but much is unknown about their mechanism of action.<sup>53</sup> There is increasing concern that the same components of the neuroimmune axis that play key roles in brain development and immune function are heavily targeted by aluminum adjuvants, possibly leading to permanent detrimental alterations of the brain and immune function.<sup>54</sup>

Shaw and Tomljenovic report that a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of autism spectrum disorders. The correlation was the strongest at 3–4 months of age, a period of rapid growth of the child’s central nervous system, including the regions of the brain responsible for short-term memory, social interactions, and sleep regulation, functions that are impaired in autism.<sup>55</sup>

In addition to their own adverse effects, aluminum and thimerosal may have synergistic toxicity.<sup>56</sup>

### **Other Adjuvants**

Modern vaccines that use pure recombinant or synthetic antigens are less immunogenic than the older live or killed whole-cell vaccines. Thus, an adjuvant, an agent to stimulate the immune system, is needed. Since the stimulus is nonspecific, undesirable autoimmunity can also be provoked. Giving multiple injections at one time means multiplying the dose of the adjuvants, possibly accounting for the higher incidence of adverse reactions noted by Neil Z. Miller.<sup>57</sup>

With few exceptions, alum is the only adjuvant approved for use in human vaccines. Safer, nontoxic adjuvants are needed, as well as compounds that stimulate cellular as well as antibody responses.<sup>58</sup>

### **An Epidemic of Distrust**

Vaccine hesitancy is a manifestation of growing public

distrust of public health authorities and organized medicine. The controversy over the HPV vaccine may bring this to a head. Despite intense promotion by manufacturers, vaccine uptake is less than desired. Reports of devastating disability or death in healthy, active children and teenagers following this vaccine will not go away.

The CDC declares HPV vaccines to be “very safe” and effective in preventing HPV-related cancer. The Vaccine Safety Datalink (VSD) conducted a study of 13 deaths occurring within 30 days following Gardasil® identified by participating health plans. Researchers concluded that the risk of death was not increased during the 30 days following vaccination and that no deaths were to be causally associated with vaccination after clinical review.<sup>59</sup>

However, controversy over this vaccine has caused an upheaval at the Cochrane Collaboration, noted as a beacon for objective, transparent, evidence-based science, which expelled Peter Gøtzsche, who was co-founder and director of the Nordic Cochrane Centre. Gøtzsche and two coauthors had published a scathing attack on a Cochrane review about the efficacy of HPV vaccines, saying it “was incomplete and ignored important evidence of bias.”<sup>60</sup> The board stated that Gøtzsche had a “consistent pattern of disruptive and inappropriate behaviours.” Four board members resigned in protest of the expulsion.<sup>61</sup>

Despite the triumphal narrative about the “anti-cancer vaccine,” FDA and WHO have received more than 100,000 reports of adverse events, including death, from around the world. Families who report them are labeled “antivaccine” and “antiscience” by media and government agencies. “This marginalization and bullying destroys civil public discourse and discourages scientific inquiry, when we urgently need both,” writes Mary Holland, J.D., and coauthors.<sup>62</sup>

Distrust is highly prevalent in the Third World: “The global initiative to eradicate polio is badly stuck.” In Pakistan, opposition to the vaccine campaign has gone underground since the government started to jail noncompliant parents several years ago, with parents hiding their children or using fake finger markings to pretend they have been vaccinated. Deadly attacks on vaccinators and their police escorts are on the rise. It is acknowledged that oral polio vaccine-derived virus paralyzed 105 children worldwide in 2018; the wild virus, only 33. WHO intends to stop the use of the oral polio vaccine once the wild virus is gone, but the killed virus vaccine is said not to be powerful enough to quash an outbreak. Meanwhile, with oral vaccine strain mOPV2 in Africa, virologist Mark Pallansch of CDC said, “We have now created more new emergences of the virus than we have stopped.” But Michel Zaffran of WHO, who heads the global initiative, stated, “We have to live with the risk until we have a technical solution.”<sup>63</sup> African parents may have a different perspective.

### **The Consequences for Freedom and Human Rights**

Many religious prohibitions, such as Jewish and Muslim dietary laws, are based on keeping the body free of unclean substances. Surely this would apply with even greater force to materials that are injected. If these may be overridden for hypothetical public health concerns, especially one so small as the risk of measles in the U.S. in 2019, one may ask where could one draw a line? The same question applies to overriding one’s right to liberty to act or refrain from acting without a specific religious rationale.

New York’s “bold experiment” in punitive measures for nonvaccinators may have gone too far, too fast for public acceptance. “For competent adults, forcible vaccination should represent an unconstitutional intrusion on liberty,” writes Julie

Cantor, M.D., J.D., of UCLA School of Law. “State-sanctioned forced vaccination of adults seems extreme—evocative of a police state and a sharp departure from the principle that the government may not invade our bodies to benefit others.” She writes, however, that the situation for children may be different. “Some scholars argue that vaccination may be a human right.” There are, however, pragmatic concerns: people might avoid medical care, and authoritarian actions might galvanize opposition. Incremental measures, such as lowering the age of consent, eliminating nonmedical exemptions, and developing oversight mechanisms for medical exemptions, are suggested.<sup>64</sup>

Saad Omer, director of the Yale Institute for Public Health, and coauthors caution in *Nature* that “governments that are considering compulsory immunizations must avoid stoking anti-vaccine sentiment.” There’s also a “social equity” concern that penalties not disproportionately affect disadvantaged groups. These penalties may be very severe; in Australia, family assistance payments amounting to \$18,200 per year may be withdrawn for refusal to vaccinate. Compensation should be given in the “exceedingly rare instances” in which required vaccines can cause harm.<sup>65</sup>

Cautionary articles such as these admit not the slightest doubt about whether mandated vaccines are in the best interest of patients, with rare, officially defined exceptions. Omer et al. discuss the optimal penalties to achieve the highest level of vaccine coverage. As long as coercive measures do not involve brute force, the patient has presumably consented. For children, force involving child protective services might sometimes be acceptable, these articles suggest.

Unanimity of respectable medical opinion is also assumed—and may be enforced. As Scottish general practitioner Malcolm Kendrick, best known for skepticism on statin drugs, writes: “I have to say that I thought long and hard about blogging on vaccination. It is the most brutal area for discussion that I have ever seen, and a reputation shredder.” Although he fears that his blog could instantly be taken down, he continues: “As we move towards a world where it seems that all Governments around the world are going to pass laws mandating vaccination for everyone, and people are fined, or lose their jobs, for speaking out, or refusing to be vaccinated, then I feel that some attempt to discuss the area is essential.”<sup>66</sup>

Kendricks continued: “Others have gone much further than me, others have been braver. But there should be nothing ‘brave’ about asking legitimate scientific questions. As Richard Feynman said, ‘I would rather have questions that can’t be answered than answers that can’t be questioned.’”<sup>66</sup>

Once government mandates that some human beings must be sacrificed, that informed consent can be overridden, and that physicians must not speak out, where can the line against tyranny be drawn?

### Why This Doctor Asked Questions

It is certainly easiest and safest to rely on established authorities, especially in complex areas where one has no primary expertise and limited experience. The first question I asked about vaccines was: Why are newborns given hepatitis B vaccine when their mother is not infected? Next: Why is this practice continued when some babies scream for days or even die afterward without another explanation? And then, after no answers were forthcoming but doctors were being ruined for reporting potential side effects: Why is one not allowed to ask such questions?

In 1999, AAPS reprinted a 1960 article explaining a private doctor’s view on mass immunization during the polio epidemic.<sup>67</sup>

Although the questions are complex, the physician is still the one who must advise each individual patient, according to the best of his ability and judgment. No one is in a better position: not California Sen. Richard Pan, M.D., wishing to greatly limit medical exemptions; not New York City Mayor Bill DeBlasio, imposing his will on Orthodox Jewish communities in New York, or the New York State legislators imposing their views on all with religious objections to vaccines; not federal advisory committees or bureaucrats or local public health authorities; not even the CDC.

There are many unknowns, and no certainties. But the physician must strive to do no harm, not even in the guise of serving the collective good.

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