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Restoring the Balance Between Children's Interests and Public Health: A Commonsense Agenda for Childhood Vaccines

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The burgeoning childhood vaccine schedule and rising rates of autism-spectrum disorders, autoimmune disease, and immune-related illnesses in children have created a climate of concern about routine vaccines that has led to a decline in rates of childhood vaccination and trust in public health authorities. This report summarizes the grounds for concern by examining the HepB mandated vaccine and offers a first-principles framework for understanding how the 1986 National Childhood Vaccine Injury Act drove a wedge between parents' and children's interests on the one hand and the state's interests on the other. It concludes by offering some recommendations for a commonsense policy agenda for the childhood vaccine schedule that can improve children's health and restore trust in our public health agencies.

> He claimed that if a man was called a "scientist" during his lifetime, and an "honored" one at that, it was the end of him as a doctor. The honor and glory of it all would get in the way of his treatment of his patients just as elaborate clothing hinders a man's movements.
>
> These "honored scientists" went about with a suite of followers, like some new Christ with his Apostles. They completely lost the right to make mistakes or not to know something, they lost the right to be allowed to think things over.

> The man might be self-satisfied, half-witted, behind the times, and trying to conceal the fact, and yet everyone would expect miracles from him.
>
> —Alexander Solzhenitsyn, *Cancer Ward*

Introduction: Ground Shift

It only takes one. Call it a red pill or a white pill, but hardly anything shifts the ground of trust in public health and medical science more than discovering that just one childhood vaccine has been added to the schedule without a reasonable evaluation of risks and benefits. The case of Bill Ackman, billionaire founder and CEO of Pershing Square Capital Management, illustrates the point. On June 20, 2024, Ackman posted on X about the Hepatitis B vaccine:

> When my last child was born, on the first day of her life we were told that she needed a HepB vaccine. It was not presented as a choice and I foolishly did nothing to stop the nurse. My older three daughters did not receive the vaccine at birth.
>
> Those that question the growing, now 72-shot regimen for children are considered by some to be wackos and anti-vaxxers.
>
> I think the skepticism is appropriate and prudent as we are obligated as parents to make sure that we are not causing harm to our children who are not capable of providing informed consent.[1]

Ackman continues to hammer away at the importance of skepticism in the face of apparent dereliction by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). On November 23, 2024, responding to a Bloomberg columnist who had accused him of being a "wingnut," Ackman spelled out the grounds for his position:

> If you want to begin your research on vaccines, I would start with the Hepatitis B vaccine which currently is injected in infants on the first day of their life. According to the package label for the vaccine, it was tested on 147 infants for five days before being approved by the FDA and becoming a day-one-of-life vaccine. Five days. That's despite the fact that systemic adverse reactions occurred in 10.4% or 15 of the 147 infants. Please see page four of the package insert which can be found here.[2]

> The side effects and risks are on pages five and six. They are horrifying. I would paste them here, but it would create too long a post.
>
> The vaccine was created for prostitutes, intravenous drug users, and healthcare workers. It became standard of care for infants on day one of life due to lobbying by Merck. I am told by healthcare experts that if hospitals simply tested the mothers for Hep B the injection would be entirely unnecessary.
>
> When you consider the risks versus the benefit of this vaccine for an infant that is not having unprotected sex, is not a prostitute, is not an intravenous drug user, or healthcare worker etc., who in their right mind would give this vaccine to their child on the first day of life?[3]

Ackman is not alone. Public trust in vaccines appears to be falling both in the U.S. and abroad,[4] and evidence suggests that childhood vaccination rates are edging down as well.[5] Vaccinations are widely credited with reducing disease-specific morbidity and mortality,[6] but with the ballooning of the vaccine schedule since the 1986 National Childhood Vaccine Safety Act, questions have emerged about rising rates of non-vaccine-specific illnesses in children, especially autism-spectrum disorders,[7] chronic disease, and immune-related illness and auto-immune conditions.[8] Specifically, the concern is whether vaccines may *increase* rates of unrelated illnesses while lowering morbidity and mortality for the target disease.[9]

It is high time conservatives took a commonsense look at promoting changes in the way we approach childhood vaccinations in the U.S. with the aim of improving transparency on the part of vaccine manufacturers. We must find a new balance that respects the common good while allowing parents the freedom to prioritize the health care needs of their own children.

Off the Rails: Some Background

The National Childhood Vaccine Injury Act (NCVIA) of 1986 replaced ordinary liability for vaccine manufacturers via personal injury lawsuits with a national federal program of compensation for those found to have been injured by vaccines, determined by special masters of the U.S. Court of Federal Claims through the National Vaccine Injury Compensation Program (NVICP).[10] During the 1970s and 1980s, expensive lawsuits had rendered manufacturers increasingly skittish about producing the DTP (diphtheria, tetanus, and pertussis) vaccine,[11] one of three routinely administered vaccines.[12] Hence the 1984-style name of the 1986 act. By removing

damage liability, Congress hoped to proliferate safe vaccines, moving injury compensation to a national taxpayer-funded collective.

Unfortunately, by decoupling vaccine products from responsibility for damages, the act removed the economic motivation for manufacturers to ensure product safety. At the same time, it transferred the task of proving harm on behalf of parents from highly trained plaintiffs' lawyers with acute incentives to make the best possible case to employees of the Federal Claims court with neither the incentive nor the skill to follow best practices of evidence discovery.

Today, 84 injections from infancy to adolescence are recommended by the CDC and required in most states for entry into public schools. Many private schools and parochial school systems follow public school requirements. Five states (California, Connecticut, Maine, New York, and West Virginia) provide no exemptions except physician-certified medical exemptions.[13] Thirty states and the District of Columbia provide for religious exemptions.[14] Thirteen states provide for religious and personal exemptions.[15] Two remaining states do not specify whether non-medical exemptions should be religious or personal.[16] No states provide exemptions for parental skepticism about the safety of the vaccine schedule—although personal or religious exemptions may be used to encompass such concerns.[17] The reason states do not provide exemptions related to health and safety is that the vaccine schedule, although merely "recommended" by the CDC, functions as a medical treatment mandate as a gateway to school entry.

As a general rule, informed consent is satisfied when a patient or guardian is able to assess the benefits, risks, and alternatives to the proposed treatment before deciding whether to take it or forgo it. When mandating a treatment, the state effectively exercises informed consent *on behalf of patients*, arguably deciding that the benefits to the public outweigh individual risks. In such a situation, it might make sense for the state to allow limited exemptions for very important countervailing interests (such as religious freedom), but exceptions will not be provided for parents to second-guess the risks and benefits already determined by the state.

In principle, the state takes into account three separate targets: individual risks, individual benefits, and the public benefits that may accrue to all from reduced levels of disease burden. When it mandates a treatment, the state presumably finds that the public benefits override the incentive for the individual to seek treatment. If not, the mandate would not be needed, and the self-interest of the patient would accomplish the whole goal of the state.

The hepatitis B vaccine serves as a helpful case study. What type of potential vaccine injuries documented by the package insert[18] did Bill Ackman

call "horrifying?" To answer this question, one must distinguish between the clinical trial data (Section 6.1 of the insert) and the post-marketing experience (Section 6.2). The clinical trial data for this vaccine come from a brief period of observation after administering treatments to a small set of healthy children and adults. No medium-term or long-term observations are reported, nor are comparisons between treated subjects and control groups.

More information for patients and regulators is collected post-licensure through a process of voluntary reporting: either the Vaccine Adverse Event Reporting System (VAERS) or the Vaccine Safety Datalink (VSD). These collection systems report injuries and side effects that occur after vaccination. Because reported voluntarily, the post-licensure data do not allow researchers to determine the incidence of adverse events: The denominator is unknown. Further, the linkage between treatment and an adverse event is merely anecdotal and proximate, not causal. Thus, to the extent that clinical trial data are insufficient to draw robust safety conclusions, patients are effectively used as test subjects post-licensure, but without knowledge that they are part of the test and without hope that their own adverse experiences will be scientifically useful as they would be in the case of a controlled trial. Voluntary adverse event data are suitable for identifying safety signals, but not for drawing conclusions about real risks. In sum, the available data about risks come from the clinical trial data, which suffer from small sample sizes, a lack of control groups, and limited time horizons, and from the post-licensure data, which suffer from a lack of statistical usefulness.

For the hepatitis B vaccine, according to the FDA package insert, the clinical trial data are based on "434 doses of RECOMBIVAX HB, 5 mcg... administered to *147 healthy infants and children* (up to 10 years of age) who were *monitored for 5 days* after each dose."[19]

> Injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever (≥101°F oral equivalent), diarrhea, fatigue/weakness, diminished appetite, and rhinitis.[20]

So far, these reactions would not be counted as severe, though a sample size of 147 with no control group and no follow-up is hardly reassuring. But the insert next reports that "3258 doses of RECOMBIVAX HB, 10 mcg, were administered to *1252 healthy adults who were monitored for 5 days* after each dose."[21] These reports include all of the reactions reported in children, as

well as some more troubling reactions, including upper respiratory infection, paresthesia, insomnia, and hypotension.[22]

What would a parent like Bill Ackman be expected to conclude from reading the package insert? Would the fact that more (and more troubling) adverse reactions occurred in adults than in children yield any comfort? Not at all. First, the adult sample is *nearly nine times the size* of the child sample. Since the child sample is likely too small to make confident estimates of incidence, a parent cannot rule out that a similar set of reactions in children would have been observed in a larger sample. Second, some of the reactions reported by adults could not have been reported (or observed) in small infants since an infant cannot communicate those reactions. Since the most frequently reported systemic adverse reactions were similar in adults and children, it would be natural to suppose that the less common adverse reactions may also be similar. Unfortunately, the clinical trials were not sufficient for drawing robust conclusions. A careful parent will be expected to ask the hard questions: What do we really know here about safety?

That these things occurred in healthy children and adults over a five-day period establishes *nothing other* than proximity to vaccine administration. There is absolutely no declaration of causality here. Not even a declaration of correlation is likely warranted, since this would require a more robust sample size (more than 147 children) and a proper experimental design (randomized and controlled). It is therefore unclear what a parent or physician reading the package insert should conclude about risk.

At a minimum, a parent like Ackman would want to be assured that there is evidence that these symptoms are not caused by the treatment and not even correlated with it, but absent a randomized placebo-controlled trial of appropriate duration, such an assurance cannot be given. Skeptics of the existing vaccine schedule claim that none of the vaccines currently recommended by the CDC was licensed based on such a study.[23] If this is true, it holds because new vaccines are often compared in clinical trials to previously approved vaccines rather than to unvaccinated controls or to saline (or other immunologically inert substance) controls. There is genuine debate about the appropriate placebos for vaccine development.[24]

A parent like Ackman, however, even if satisfied that any single vaccine has been appropriately tested, might still have questions about the overall vaccine load.[25] This is a known concern related to the multiplication of pharmaceutical treatments in general, especially in the elderly.[26] There may be threshold effects (adverse events triggered by passing a certain total amount of otherwise safe treatments) or interaction effects (adverse events triggered by the interaction of separately safe treatments). The

only way to handle this ethically is to design studies to compare numbers and combinations of vaccines to no vaccines and alternate numbers and combinations. But with 84 doses on the recommended schedule, testing all of the combinations against each other and against none at all would be logistically and scientifically formidable.

Thus, the relevant agencies rely on surveillance after authorization. Such a move makes children part of an untested regimen—the vaccine schedule in total—but the lengthy package inserts do not spell out this fact. There is no assurance of safety; there is only recourse to apology (and a possible claim for damages) after the fact. For hepatitis B, the package insert states of the post-marketing experience that "additional adverse reactions have been reported with use of the marketed vaccine," and the list of events (Section 6.2) presumably motivated Ackman's label "horrifying."[27] Included are such disorders as systemic lupus erythematosus (SLE); elevation of liver enzymes; multiple sclerosis; myelitis including transverse myelitis; seizure and febrile seizure; optic neuritis; and more.[28] No attempt is made to say whether these events were reported in children or in adults.

The insert warns that "[b]ecause these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure."[29] The language of the insert is a tacit admission that post-licensure data collection is not adequate even to collect *incidence* data. Together with the clinical trial data (Section 6.1), these merely potential effects do seem to warrant the alarm that Bill Ackman advocates. The reader of this insert, ordinarily a parent, will not be able judge the risk-benefit ratio *for the treated* child based on Sections 6.1 (clinical trial data) and 6.2 (post-marketing experience). It goes without saying that physicians are also *unable* to judge the risk-benefit ratio. Surely, regulators and the pharmaceutical manufacturers are also unable to judge the risk-benefit ratio. For these determinations, statistically useful data from beyond five days would have to be collected, including both disease prevention (benefit) compared to baseline and likelihood of adverse events based on a true denominator.

And what about the benefit? If assurance of minimal risk cannot be offered, is assurance of medical benefit offered? Here, the declarations in the package insert fail the test of common sense, although parents will not be able to observe this through the haze of fine print.[30] What a parent wants to know is whether this specific vaccine, with the aforementioned risk-profile, will spare his or her child some specific and concrete harm under ordinary assumptions about exposure to disease. What the package insert says instead is that the vaccine has been shown to produce antibodies

to hepatitis B (Sections 12.1, 14.2, and 14.3) and *appears to have protected* infants whose mothers tested positive for hepatitis B antigens—appears because instead of comparing infants who received the vaccine to infants who did not receive the vaccine, the study compared them only to historical (unvaccinated) controls. For the rest of the infants and children whose mothers did not test positive, nothing is known about the efficacy of the vaccine under ordinary circumstances, because infants and children *are not exposed to hepatitis B under ordinary circumstances*.

Therefore, we can conclude that the vaccine provides a robust antibody response to a disease to which they are not regularly exposed, and how long that antibody response lasts is unknown (Section 2.4). In other words, for children not exposed to hepatitis B, there is *no known benefit*. It is hard to imagine why anyone would sign up for an injected treatment with no known benefit. Perhaps one might appeal to remote hypotheticals: If your child becomes an IV-drug user, if your child becomes a prostitute, etc. These might persuade some parents if there were no risks at all or few, but the risks are non-zero and could be much larger—we do not know. More importantly, the regulators and state legislators do not know. And for all that, since it is unknown how long the antibody response lasts, even for the remote hypothetical cases (e.g., if your child becomes an IV-drug user), benefit cannot be established.

After reviewing such evidence as would be available to a parent, Bill Ackman's case for skepticism does not appear to be "wingnut" at all. What parent would subject a beloved child to a laundry list of *possible* adverse events on the basis of five days of evidence with no known benefit for typical circumstances? The whole case for the hepatitis B vaccine looks reckless—even a dereliction of regulatory duty—especially when we consider that the addition of the hepatitis B vaccine to the CDC list of recommended vaccines generated tremendous revenue for Merck. Who is regulating the regulators? And is the hepatitis B vaccine just one oversight in an otherwise sound regulatory apparatus, or is it business as usual because no one has been looking under the hood?

The foregoing analysis uses one particular vaccine as a case study. Details and specifics for other vaccines vary.[31] Specific numbers of days of observation range from three or four days to 30, 42, or 180. Numbers of observed children vary but are generally small in sample size. But it takes only one egregious example of abdication to provoke the type of concern indicated in Ackman's post. Article 13 of the 1949 Geneva Convention relative to the treatment of prisoners of war asserts that "no prisoner of war may be subjected to physical mutilation or to medical or scientific experiments of any

kind which are not justified by the medical, dental, or hospital treatment of the prisoner concerned, and carried out in his interest." We owe our children at least as much as we owe prisoners of war.

Risks to the child cannot be justified on the basis of some external goal, however worthy it may be. The risk-benefit ratio must be justifiable *for the child*, not merely for some third party or some aggregate third party. Any departure from this standard treats the child as a means to an end. The FDA, the CDC, and the Department of Health and Human Services owe Bill Ackman and all parents an accounting of their determinations of the common good that supposedly justify mandated administration of the hepatitis B vaccination to children. The case does not have to persuade everyone, but it ought to seem fair to an impartial observer—one with no financial stake in the decision.

Lost Balance: A First Principles Assessment of How We Got Here

Informed consent to a treatment or intervention can be given only if the person giving consent is competent to act, receives thorough disclosure, acts voluntarily, and consents to the intervention. Thus, a patient must be able to assess the benefits of, risks of, and alternatives to the proposed treatment before deciding whether to take it or forgo it. For children, the basic principle of informed consent is substitution of judgment. A parent or legal guardian consenting for a child must act with the aforementioned conditions and in the interests of the child. Further, as a fiduciary, the parent or legal guardian can consent to a treatment only if he or she would consent to it himself or herself under similar circumstances. Consenting for oneself may include due consideration of long-term and comprehensive benefits and risks to self and a reasonable willingness to play the role of a good citizen and adopt some kind of burden for the sake of the common good.

When parents decide on behalf of their children, any risk to the child is a double risk to the parent. First, the risk of injury to the child is a risk to the parent of failing in a parent's duty to protect; second, the risk of injury to the child is also a risk of the pain the parent will suffer when the child suffers. These acute risks arise from the very nature of the parent-child relationship and compel parents, in acting to protect their children, to take *greater care* for those children than they do for themselves. That good parents routinely take greater care for their children than for themselves is a fact requiring little proof. Returning to the categories of informed consent, I consider each in turn: assessment of risks, time horizon, and common good.

Assessment of Risks. As in all other product markets, parents require assistance to comprehend the risks correctly. In ordinary markets, reputation and price signals convey tremendous amounts of information about quality and user experience that would not otherwise be available to the consumer. An example of this is Uber ratings: Riding with an unknown driver carries some risk; the combined (verified) ratings of thousands of other riders help a prospective rider to assess the risk appropriately.

In the absence of reputation and price signals, as in the case of medical treatments, parents are best served when they have expert agents who are informed and have resources to ensure that the risks of treatments are reasonable. Plaintiffs' lawyers and courts of law serve this function reasonably well and help to represent parents who require assistance in proving harm (for example, medical malpractice). Products or treatments that lead to high damages are exactly the ones to which a prudent parent would not consent on behalf of a child. Thus, damages post-hoc can provide a roughly equivalent path to product safety in the absence of ex-ante market signals provided that high standards of liability are in practice.

Time Horizon. People are disposed to weigh a present risk as more than a distant risk and a present benefit as more than a distant benefit. Parents will weigh a near or present risk of injury or death as far more devastating than the prevention of something remote and uncertain. Parents (and anyone acting on their behalf) will have to overcome a strong present-time bias to meet the test of prudence. Risks will have to be very small today in comparison with anticipated future benefits.

Common Good. The common good may surely—and ethically—factor into a personal decision to accept a risky treatment as in, for instance, the case of the novel COVID-19 vaccinations. Parents, however, are in a special position: They naturally and justly accept much lower risks for their children in exchange for a general, diffuse benefit. Nature endows parents with an innate preference for their own children. "Aristotle notes that the reason for affection of the sort parents feel for children has to do with the unique (*idion*) and possessive relationship they have with them (Pol. II.1.1262b23)."[32] The state takes this role from parents only reluctantly in cases of extreme abuse or neglect, because it is not easy to find substitute caregivers with so strong an affection for the child. That affection provides innate rewards for the tremendous gifts of time and sacrifice that parents make for their offspring.

Every child must have a caregiver with an own-child bias for him or her because children are weak, vulnerable, easily abused, and unable to speak for themselves. By nature (supported by experience), biological or

adoptive parents are *least likely* to use the child for personal gain (sexual abuse, profit, or neglect).[33] A parent is also least likely to use the child for the public interest or, for that matter, *any* interest other than the child's. These considerations help to explain why the general willingness of adults to give their consent for the novel Covid-19 vaccinations did not extend to their children. Uptake of the COVID-19 vaccine for children was low.[34] Whereas most adults were willing to subject themselves to unknown risks for the sake of the common good (77 percent as of August 2022), the bar was apparently higher for their children (only 30 percent as of the same month).[35]

State officials, the CDC, the FDA, and other regulators do not and cannot act *in loco parentis* unless they can effectively raise the bar. Since the state cannot do so while simultaneously representing the common good, the state assumes a true and real conflict of interest when it presumes to act on the part of parents, as in the case of mandating risky treatments. This conflict of interest has not been properly acknowledged in the public health policy of the United States.

This essay cannot deal with the entire scope of ethical concerns related to vaccine mandates. Its purpose is to elucidate more clearly how the NCVIA drove a wedge between children's interests and state interests, privileging the state above children's health. Any legislative act, such as vaccine mandates, that removes parental fiduciary judgment from treatment decisions for children necessarily has to replace the significant interest of parents in protecting the good of their children with an equal and opposite significant interest in the safety of treatments.

Before the NCVIA of 1986, product liability served this function, but the act essentially stripped away any agent with an equal and opposite interest in the safety of the child. A natural balance was disturbed. Before vaccine mandates, parents would have exercised skepticism ex ante (before treatment); after mandates, plaintiffs' lawyers would have proved blame ex post (after treatment), providing incentives to vaccine manufacturers to meet the same safety standards that would have obtained before mandates. The goal of a commonsense reform agenda for vaccine policy is to restore the natural balance lost by enactment of the 1986 NCVIA.

Recommendations for Reform

The following recommendations can guide a conservative, commonsense approach to reforming the childhood vaccine protocols and regulatory environment.

- Return to holding vaccine manufacturers potentially liable for damage and death by repealing the 1986 act.

- Require appropriate safety testing rubrics for vaccines: randomized controlled trials, double-blind, long-term. The standards applied to vaccines for children should be the same as the standards applied by the FDA to any other drug approval.

    1. Immediately remove any vaccines that fall short of safety testing from lists recommended by the CDC and required for entry into public schools.

    2. Give any vaccines that fall short of safety testing an "experimental" label together with a revised informed consent package to make the risks clear.

    3. Restore informed consent for vaccines. This means ensuring that there is full and clear disclosure of risks—including that risks are unknown if safety testing has not been completed—and full and clear disclosure of known benefits.

- Subject the entire vaccine schedule to prudent review. This can be done through (1) studies designed to compare alternative schedules of vaccines by creating variation in regimen at the state or county level (cluster randomized controlled trials);[36] (2) studies that use available data to compare outcomes for vaccinated and unvaccinated children in appropriate medical data sets.[37]

- Do not give vaccines in bundles. Bundling vaccines forces parents to accept all or none.

- Remove regulatory barriers to the development of digital platforms to collect user experiences for short-term side effects in the post-licensure phases. Private companies should be able to solicit and collect these data, connecting individual patients to specific vaccine types and batches. Regulators exist in part to review safety data where it has been difficult for markets to "price in" the experience of users. Although drugs and vaccines are not like ordinary consumer goods, there is no reason why user experience data cannot be generated swiftly and made available to the public.

- Assess the impact of statutes that allow minors to consent to medical treatments including vaccines, in some cases without parental knowledge. The Public Readiness and Emergency Preparedness (PREP) Act, for example, enables the Secretary of Health and Human Services to immunize drug manufacturers from harms caused by their products under certain circumstances, specifically superseding parental rights.[38]

- Evaluate the status of financial incentives for physicians to vaccinate high percentages of their patient populations (usually created by insurers), creating a conflict of interest. Physicians should be compensated for the health of the child, not for the quantity of treatments and interventions.[39]

- Consider prudent ways to reduce the practice of dismissing families from medical care for vaccine refusal without violating the legitimate freedom of physicians. Fourteen percent of physicians report "often or always" dismissing families for vaccine refusal; the percentage among pediatricians is higher at 21 percent.[40] Removing current financial incentives for physicians to vaccinate their patients could alleviate the severity of this problem.

Conclusion

The actions of public health agencies are out of balance with children's and parents' interests and with no check on the state interest, favoring lower aggregate disease burden over prudent caution. When Congress exempted vaccine producers from liability for harm through the 1986 National Vaccine Injury Act, the balance of power between parents and public health authorities was destroyed. If vaccine producers are held harmless for the ill effects of their products, parents should have greater freedom to exercise caution, not less. These commonsense recommendations, if adopted even in part, would go a long way toward restoring parents' trust in vaccines, in physicians, and in the nation's public health authorities.

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Endnotes

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16. Ibid.
17. Ibid.
18. Merck, "Highlights of Prescribing Information."
19. Ibid., Section 6.1. Emphasis added.
20. Ibid.
21. Ibid. Emphasis added.

22. "Injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively. The following adverse reactions were reported: *Incidence Equal To or Greater Than 1% of Injections* ¶ General Disorders and Administration Site Conditions ¶ Injection site reactions consisting principally of soreness, and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, and nodule formation. ¶ The most frequent systemic complaints include fatigue/weakness; headache; fever (≥100°F); malaise. ¶ Gastrointestinal Disorders ¶ Nausea; diarrhea ¶ Respiratory, Thoracic and Mediastinal Disorders ¶ Pharyngitis; upper respiratory infection ¶ *Incidence Less Than 1% of Injections* ¶ *General Disorders and Administration Site Conditions* ¶ Sweating; achiness; sensation of warmth; lightheadedness; chills; flushing. ¶ *Gastrointestinal Disorders* ¶ Vomiting; abdominal pains/cramps; dyspepsia; diminished appetite. ¶ *Respiratory, Thoracic and Mediastinal Disorders* ¶ Rhinitis; influenza; cough ¶ *Nervous System Disorders* ¶ Vertigo/dizziness; paresthesia ¶ *Skin and Subcutaneous Tissue Disorders* ¶ Pruritus; rash (non-specified); angioedema; urticaria ¶ *Musculoskeletal and Connective Tissue Disorders* ¶ Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffness ¶ *Blood and Lymphatic Disorders* ¶ Lymphadenopathy ¶ *Psychiatric Disorders* ¶ Insomnia/disturbed sleep ¶ *Ear and Labyrinth Disorders* ¶ Earache ¶ *Renal and Urinary Disorders* ¶ Dysuria ¶ *Cardiac Disorders* ¶ Hypotension." Ibid. Emphasis, capitalization, and punctuation as in original.
23. For a detailed breakdown, see Informed Consent Action Network, "None of the Vaccine Doses the CDC Recommends for Routine Injection into Children Were Licensed by the FDA Based on a Long-Term Placebo-Controlled Trial," updated October 18, 2023, https://icandecide.org/wp-content/uploads/2024/03/no-placebo-101823.pdf (accessed January 15, 2025).
24. Annette Rid et al., "Placebo Use in Vaccine Trials: Recommendations of a WHO Expert Panel," *Vaccine*, Vol. 32, No. 37 (August 20, 2014), pp. 4708–4712, https://www.sciencedirect.com/science/article/pii/S0264410X14005374?via%3Dihub (accessed February 27, 2025).
25. Anthony R. Mawson and Ashley M. Croft, "Multiple Vaccinations and the Enigma of Vaccine Injury," *Vaccines*, Vol. 8, No. 4 (November 2020), https://doi.org/10.3390/vaccines8040676 https://pmc.ncbi.nlm.nih.gov/articles/PMC7712358/ (accessed January 15, 2025).
26. Xiaowen Wang et al., "Prevalence and Trends of Polypharmacy in U.S. Adults, 1999–2018," *Global Health Research and Policy*, Vol. 8, No. 1 (July 12, 2023), https://pubmed.ncbi.nlm.nih.gov/37434230/ (accessed January 15, 2025).
27. The list includes Immune System Disorders ("Hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including: arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum.... Autoimmune diseases including systemic lupus erythematosus (SLE), lupus-like syndrome, vasculitis, and polyarteritis nodosa have also been reported."); Gastrointestinal Disorders ("Elevation of liver enzymes; constipation"); Nervous System Disorders ("Guillain-Barré syndrome; multiple sclerosis; exacerbation of multiple sclerosis; myelitis including transverse myelitis; seizure; febrile seizure; peripheral neuropathy including Bell's Palsy; radiculopathy; herpes zoster; migraine; muscle weakness; hypesthesia; encephalitis"); Skin and Subcutaneous Disorders ("Stevens–Johnson syndrome; alopecia; petechiae; eczema"); Musculoskeletal and Connective Tissue Disorders ("Arthritis; Pain in extremity"); Blood and Lymphatic System Disorders ("Increased erythrocyte sedimentation rate; thrombocytopenia"); Psychiatric Disorders ("Irritability; agitation; somnolence"); Eye Disorders ("Optic neuritis; tinnitus; conjunctivitis; visual disturbances; uveitis"); and Cardiac Disorders ("Syncope; tachycardia"). Merck, "Highlights of Prescribing Information," Section 6.2.
28. Ibid.
29. Ibid.
30. The vaccine is "indicated for prevention of infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB is approved for use in individuals of all ages." Ibid., Section 1. "The duration of the protective effect of RECOMBIVAX HB in healthy vaccinees is unknown at present and the need for booster doses is not yet defined." Ibid., Section 2.4. "RECOMBIVAX HB has been shown to elicit antibodies to hepatitis B virus as measured by ELISA. ¶ Antibody concentrations ≥10mIU/mL against HBsAg are recognized as conferring protection against hepatitis B infection. ¶ Infection with hepatitis B virus can have serious consequences including acute massive hepatic necrosis and chronic active hepatitis. Chronically infected persons are at increased risk for cirrhosis and hepatocellular carcinoma." Ibid., Section 12.1. "The protective efficacy of three 5 mcg doses of RECOMBIVAX HB has been demonstrated in neonates born of mothers positive for both HBsAg and HBeAg (a core-associated antigenic complex which correlates with high infectivity)." Ibid., Section 14.1. "Three 5 mcg doses of RECOMBIVAX HB induced a protective level of antibody in 100% of 92 infants, 99% of 129 children, and in 99% of 112 adolescents...." Ibid., Section 14.2. "For adolescents (11 through 15 years of age), the immunogenicity of a two-dose regimen (10 mcg at 0 and 4–6 months) was compared with that of the standard three-dose regimen (5 mcg at 0, 1, and 6 months) in an open, randomized, multicenter study. The proportion of adolescents receiving the two-dose regimen who developed a protective level of antibody one month after the last dose (99% of 255 subjects) appears similar to that among adolescents who received the three-dose regimen (98% of 121 subjects). After adolescents (11 through 15 years of age) received the first 10-mcg dose of the two-dose regimen, the proportion who developed a protective level of antibody was approximately 72%." Ibid., Section 14.3.
31. See Informed Consent Action Network, "None of the Vaccine Doses the CDC Recommends for Routine Injection into Children Were Licensed by the FDA Based on a Long-Term Placebo-Controlled Trial."
32. Sophia M. Connell, "Nurture and Parenting in Aristotelian Ethics," *Proceedings of the Aristotelian Society*, Vol. 119, No. 2 (July 2019), pp. 179–200, https://eprints.bbk.ac.uk/id/eprint/26839/1/26839.pdf (accessed January 15, 2025). Connell also cross references the passage in the Nichomachean Ethics: "'[T]he parent regards their children as their own more than the product regards the maker as its own' (*EN* VIII.11.1161b 22-24)."
33. The research supporting this claim is too voluminous to list here, but one representative work is Lawrence M. Berger, Christina Paxson, and Jane Waldfogel, "Mothers, Men, and Child Protective Services Involvement," *Child Maltreatment*, Vol. 14, No. 3 (August 2009), pp. 263–276, https://pmc.ncbi.nlm.nih.gov/articles/PMC2845296/pdf/nihms177236.pdf (accessed January 15, 2025).

34. Neil Chandra Murthy et al., "Disparities in First Dose COVID-19 Vaccination Coverage Among Children 5–11 Years of Age, United States," Emerging Infectious Diseases, Vol. 28, No. 5 (May 2022), pp. 986–989, https://pmc.ncbi.nlm.nih.gov/articles/PMC9045440/pdf/22-0166.pdf (accessed January 15, 2025).
35. Daniel Romer et al., "Misinformation About Vaccine Safety and Uptake of COVID-19 Vaccines Among Adults and 5–11-Year-Olds in the United States," *Vaccine*, Vol. 40, No. 45 (October 26, 2022), pp. 6463–6470, https://pmc.ncbi.nlm.nih.gov/articles/PMC9492517/pdf/main.pdf (accessed January 15, 2025).
36. Vinay Prasad, "A Simple Litmus Test for RFK Jr.'s Ideas," *The Free Press*, November 18, 2024, https://www.thefp.com/p/rfk-jr-health-human-services-flouride-vaccines-covid-trump-europe (accessed February 27, 2025).
37. Mawson and Jacob, "Vaccination and Neurodevelopmental Disorders: A Study of Nine-Year-Old Children Enrolled in Medicaid."
38. Riley Brennan, "PREP Act Immunity Supersedes Parental Rights, Says Kansas Appeals Court in COVID-19 Vaccine Debate," Law.com, May 2, 2023, https://www.law.com/2023/05/02/prep-act-immunity-supersedes-parental-rights-says-kansas-appeals-court-in-covid-19-vaccine-debate/?slreturn=20241129155153 (accessed January 15, 2025).
39. Gerry Fairbrother et al., "The Impact of Physician Bonuses, Enhanced Fees, and Feedback on Childhood Immunization Coverage Rates," *American Journal of Public Health*, Vol. 89, No. 2 (February 1999), pp. 171–175, https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.89.2.171 (accessed February 27, 2025); Tianyan Hu et al., "Medicaid Pay for Performance Programs and Childhood Immunization Status," *American Journal of Preventive Medicine*, Vol. 50, No. 5 (May 2016), pp. S51–S57, https://www.researchgate.net/publication/301571866_Medicaid_Pay_for_Performance_Programs_and_Childhood_Immunization_Status (accessed February 27, 2025); Roshanak Benabbas et al., "The Effect of Pay-for-Performance Compensation Model Implementation on Vaccination Rate: A Systematic Review," *Quality Management in Health Care*, Vol. 28, No. 3 (July/September 2019), pp. 155–162, https://journals.lww.com/qmhcjournal/abstract/2019/07000/the_effect_of_pay_for_performance_compensation.5.aspx (accessed February 27, 2025).
40. Tamara B. Garcia and Sean T. O'Leary, "Dismissal Policies for Vaccine Refusal Among US Physicians: A Literature Review," *Human Vaccines and Immunotherapeutics*, Vol. 16, No. 5 (2020), pp. 1189–1193, https://www.tandfonline.com/doi/10.1080/21645515.2020.1724742?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed (accessed February 27, 2025).