

THE HHS IS LYING TO PREGNANT WOMEN

There is no evidence that "vaccinating" pregnant women for COVID-19 protects their babies, but the HHS is actively promoting this even though their own documents state there is no supporting evidence.



JAMES ROGUSKI

DEC 16, 2025



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BLACK BOX WARNING

**THE HHS, THE FDA AND THE CDC
HAVE BEEN LYING TO PREGNANT WOMEN
BY CLAIMING THAT COVID-19 "VACCINES"
WILL PROTECT THEIR BABIES FROM COVID-19.**

**THEY CONTINUE TO FUND AND PROVIDE ADVERTISING MATERIALS
THAT ARE IN DIRECT VIOLATION OF THEIR OWN DOCUMENTS
WHICH CLEARLY STATE THAT THERE IS NOT ENOUGH
INFORMATION TO RECOMMEND THE INJECTIONS FOR
PREGNANT OR BREASTFEEDING WOMEN.**

REVOKE THE LICENSES – TAKE ALL mRNA PRODUCTS OFF THE MARKET

Please watch the video below:



<https://rumble.com/v732ht2-the-hhs-is-lying-to-pregnant-women.html>

EXECUTIVE SUMMARY:

DESPITE THE CLEAR ACIP RECOMMENDATION AND ALL OF THE FACTS PRESENTED IN THIS ARTICLE, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IS STILL RECOMMENDING (AND PROVIDING MARKETING MATERIALS AND FUNDING TO ENCOURAGE) PREGNANT WOMEN TO GET "VACCINATED" FOR COVID-19 IN ORDER TO PROTECT THEIR UNBORN AND NEWBORN CHILDREN.

ACIP RECOMMENDATION

On September 19, 2025, the Advisory Committee on Immunization Practices (ACIP) voted 11-1 in favor of the following recommendations:

The safety and efficacy of COVID-19 vaccination during pregnancy have never been in appropriately powered randomized clinical trials. In one randomized trial there was observed numerical imbalance of higher number of babies with congenital malformations among those born to vaccinated women.

<https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/10-levi-COVID-508>

Vaccination in Pregnancy

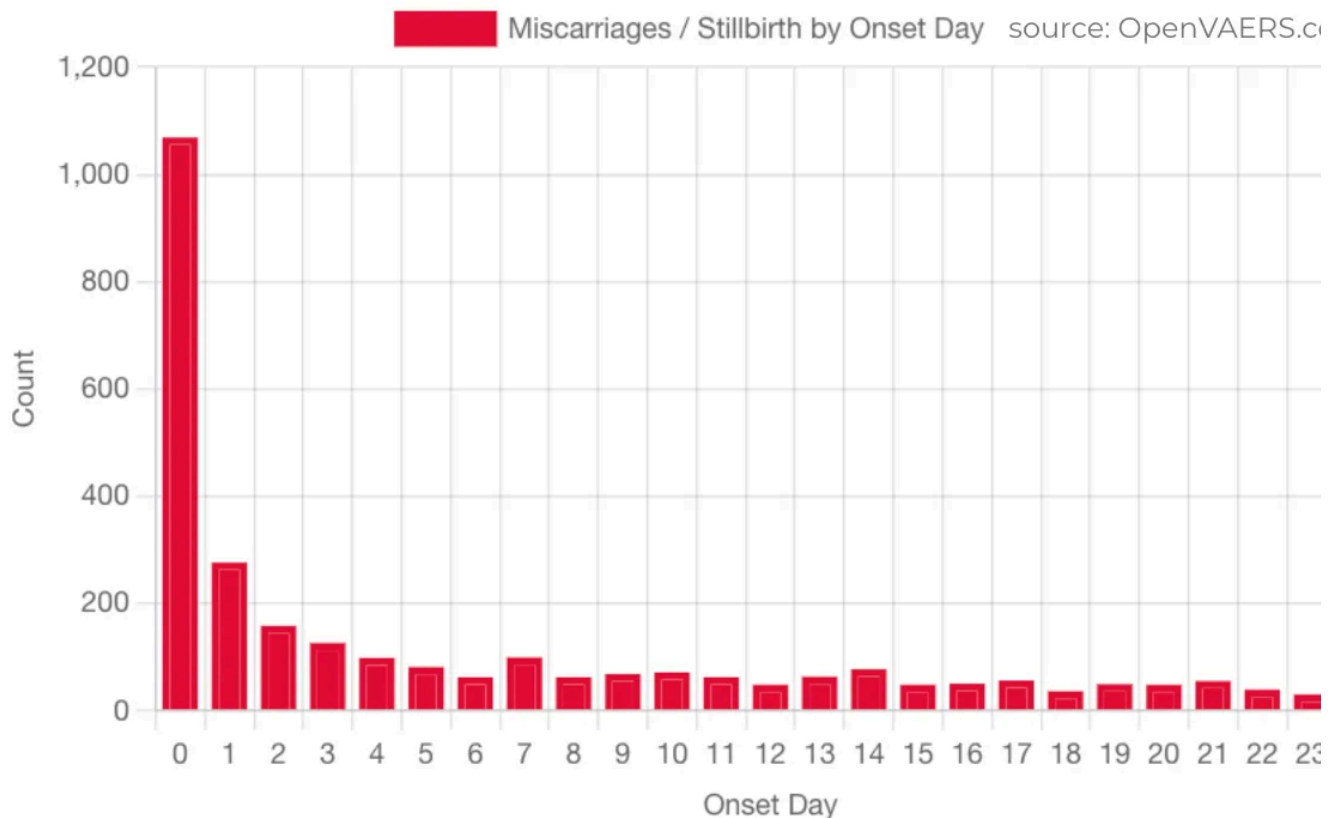
Most WG members felt that the current data not only do not support recommendation to vaccinate during pregnancy, but to the contrary support NOT to recommend:

- No appropriate randomized clinical trials to show efficacy and safety
- In the single (small) clinical trial (Pfizer) there was observed numerical imbalance of higher number of fetal anomalies among babies born to vaccinated women (8 vs

ACIP Meeting, CDC
September 19, 2025

VAERS REPORTS:

Reports of Miscarriages / Stillbirth Post Covid Vaccine



<https://openvaers.com/covid-data/reproductive-health>

Despite over one thousand VAERS reports of spontaneous abortion that occurred on the same day pregnant women received a COVID-injection and despite CLEARLY stating in the package inserts that...

Available data on [mRNA “vaccines”] administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

It is not known whether [mRNA “vaccine”] is excreted in human milk. Data are not available to assess the effects of [mRNA “vaccine”] on the breastfed infant or on milk production/excretion.

The Department of Health and Human Services is actively LYING to American public by encouraging and funding the promotion of false and misleading advertising that advocates the injection of pregnant women with the COVID-19 “vaccines” in order to protect their newborn infants during the first 6 months of life.

The RISK LESS, DO MORE marketing campaign from the Department of Health and Human Services specifically targets pregnant women with MISINFORMATION.

<https://www.hhs.gov/risk-less-do-more/campaign-ads/pregnant-women/index.htm>

Watch the all of the videos below.

I encourage you to download and save the videos below - I expect them to disappear



<https://www.youtube.com/watch?v=11wweHsb1YE>



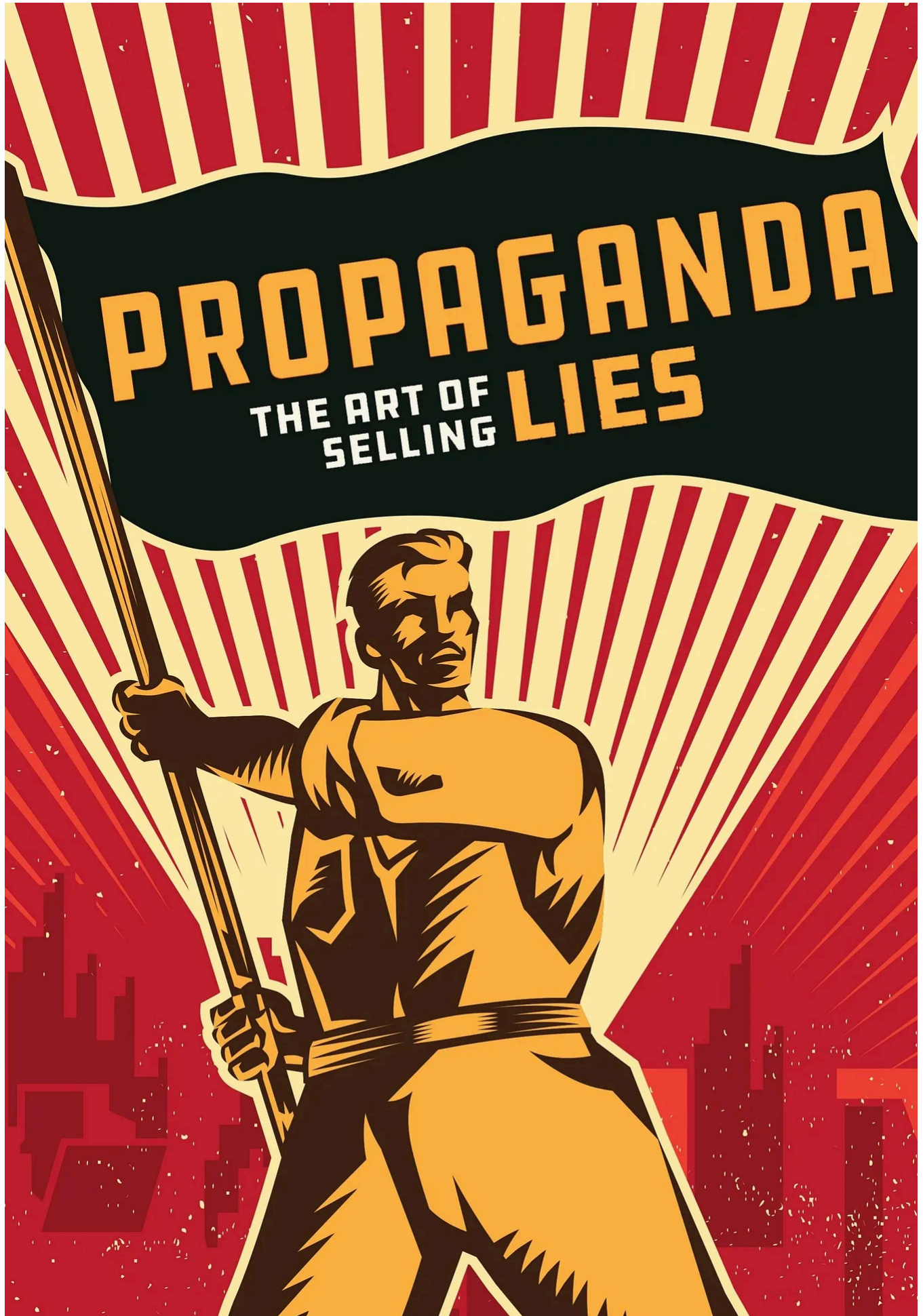
<https://www.youtube.com/watch?v=CKHs-m2YCxc>



<https://www.youtube.com/watch?v=yZauKKh9rwA>



https://www.youtube.com/watch?v=m3_nZomSGig



Is the mRNA COVID vaccine safe for me and my baby? | A Nurse Midwife Res



The New York State Department of Health and the New York City Department of Health and Mental Hygiene appear to be run by psychopaths.

HEALTH ADVISORY:

2025-2026 COVID-19 IMMUNIZATION GUIDANCE

FOR PREGNANT PEOPLE

New York State Recommendations for Pregnant PEOPLE

September 5, 2025

*The New York State Department of Health and New York City Health Department are issuing COVID-19 immunization recommendations for **pregnant and postpartum people** for the 2025–2026 respiratory virus season.*

- *Vaccination against COVID-19 remains the most effective defense to prevent severe COVID19 disease outcomes, including in **pregnant people**.*

- We urge providers to discuss COVID-19 vaccination with people who are pregnant, postpartum, lactating, or planning pregnancy.
- This guidance applies to all available COVID-19 vaccines (i.e. Pfizer, Moderna, Novavax)

COVID-19 RECOMMENDATIONS FOR PREGNANT PEOPLE

All pregnant people should be vaccinated against COVID-19.

- Vaccination may occur in any trimester.
- All individuals in the postpartum period should be vaccinated against COVID-19.
- All **lactating individuals** should be vaccinated against COVID-19. There is no need to stop or delay breastfeeding.
- All individuals contemplating pregnancy or actively trying to conceive should be vaccinated against COVID-19. There is no need to delay pregnancy following a COVID-19 vaccine.

Our recommendations are based on the following evidence-based conclusions: Pregnancy is an independent risk factor for severe illness due to COVID-19.

- There is benefit to COVID-19 vaccination for all people who are pregnant during any trimester, 1 postpartum, 2 lactating, 3 or planning pregnancy.⁴
- COVID-19 vaccination during any trimester protects both the **pregnant person** and their infant under 6 months of age from severe illness due to COVID-19.
- These recommendations are aligned with the COVID-19 vaccination recommendations issued by the American College of Obstetricians and Gynecologists in August 2025, a nationally recognized authority on health care for adults, including **pregnant people**. Additional information, about the American College of Obstetricians and Gynecologists' recommendations and relevant clinical considerations can be found [here](https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care).

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care>

VACCINE EFFECTIVENESS AND SAFETY

Studies have demonstrated COVID-19 vaccine effectiveness in pregnancy 5,6,7 and is robust literature demonstrating that vaccination helps prevent poor maternal and fetal outcomes such as severe COVID-19 illness, hospitalization, intensive care unit admission, perinatal disease, and death. 8,9,10,11,12,13

- COVID-19 vaccination during pregnancy has been shown to reduce COVID-19-related emergency department and urgent care visits by 52%.¹⁴
- Vaccinating **pregnant people** confers antibodies to their infants; a population segment at increased risk for severe COVID-19 and for whom no COVID-19 vaccine is recommended until 6 months of age. 15, 16, 17
- COVID-19 vaccination during pregnancy reduces the risk that an infant will develop symptomatic or severe illness leading to hospitalization within the first six months of life. Completion of a two-dose COVID-19 mRNA series during pregnancy was shown to be 61% effective at preventing hospitalization in infants under 6 months of age.
- A 2023 meta-analysis incorporating 862,272 individuals found that infants whose **mothers** received an mRNA COVID-19 vaccine during pregnancy were 15% less likely to be born prematurely and 20% less likely to be admitted to a neonatal intensive care unit than infants of unvaccinated **mothers**. 19
- Vaccination prior to becoming pregnant during family planning has been associated with reduced adverse birth outcomes and with no negative effects on fertility. 20
- Vaccination mitigates the risk of post-COVID-19 conditions, often termed Long COVID. 22,23

COVID-19 vaccination safety during pregnancy is well documented. The safety profiles of these vaccines have been evaluated in clinical trials and continue to be monitored through postmarketing surveillance systems.

- Side effects of COVID-19 vaccination in **pregnant people** are generally similar to those in **non-pregnant people**. The most common side effects reported after COVID-19 vaccination are mild and include soreness in the area where the vaccine was administered, fatigue, headache, muscle aches, arthralgias, fever, and nausea. 24

- **Pregnant people** do not experience higher rates of side effects. 26, 27
- No association has been found between COVID-19 vaccination and pregnancy i whether through miscarriage or stillbirth. 28, 29, 30
- Receipt of a messenger RNA COVID-19 vaccine during pregnancy was not linke preterm birth, small-for-gestational-age infants, gestational diabetes, hypertensi preeclampsia, eclampsia, or HELLP syndrome (hemolysis, elevated liver functio and low platelet counts). 31, 32
- The risk of birth defects is not elevated among **pregnant people** vaccinated with messenger RNA COVID-19 vaccine.33, 34, 35
- COVID-19 vaccination had no measurable effect on fertility (fecundability reme similar among vaccinated and unvaccinated individuals).36
- Providers are advised to check the FDA Package Insert for product specific contraindications.

UNITED STATES COVID 19 DATA

COVID-19 continues to cause significant morbidity and mortality in pregnant people supporting vaccination of this population group.

- Pregnancy is a well-established factor for severe COVID-19 regardless of whether pregnancy is considered high-risk or healthy.37,38,39,40
- COVID-19 vaccination coverage among **pregnant people** is suboptimal; less than of **pregnant people** received the COVID-19 vaccine during the 2022-2023 season according to Vaccine Safety Datalink data. 41, 42
- **Pregnant people** are at increased risk of severe disease and adverse pregnancy outcomes from COVID-19 (e.g., intensive care unit admission, mechanical venti death, preterm birth).43
- Between April 2024 and March 2025, 28.5% of all women ages 15-49 years hospitalized with laboratory-confirmed COVID-19 in the U.S. were pregnant. 44
- Half of the **pregnant people** admitted to the hospital with COVID-19 between A 2024 and March 2025 in the U.S. had no underlying conditions, and 92% had no

record of COVID-19 vaccination since July 1, 2023, highlighting missed opportunities for prevention.⁴⁵

*No COVID-19 vaccines are currently approved for infants under 6 months of age, meaning any protection must come from **maternal** antibody transfer through vaccination during pregnancy, or from prior infection.⁴⁶*

- Between April 2024 and March 2025, only 3.5% of hospitalized infants 0-6 months of age had any documentation of maternal COVID-19 vaccination during pregnancy.⁴⁷*
- Between July 2024 and May 2025, infants under 6 months of age had the highest rate of COVID-19-associated hospitalization among all pediatric age groups at 268 per 100,000, surpassing even adults aged 65-74 years.⁴⁸*
- Between April 2024 and March 2025, 71% of infants hospitalized for COVID-19 had no underlying medical conditions; 22% of those infants hospitalized required intensive care, demonstrating that even healthy infants can experience severe COVID-19 impacts.⁴⁹*
- Infants under 6 months of age had a hospitalization rate 1.4 times higher for COVID-19 compared to influenza. ⁵⁰*

<https://coronavirus.health.ny.gov/system/files/documents/2025/09/doh-pregnancy-vaccination-recommendation-2025-26.pdf>

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Comment and criticism:

In the documents below, the “esteemed” American College of Obstetricians and Gynecologists (ACOG) makes claims that are not permitted and far exceed the permissible language in the official package inserts that are available above in the article. The ACOP should be ashamed of themselves.

I guess \$500,000 from the government does that to people.

American College of Obstetricians and Gynecologists

Pregnant? Top 3 Reasons Why You Need a COVID-19 Vaccine



1 **COVID-19 illness can be more serious during pregnancy.** The virus can make you very sick and affect your pregnancy.

2 **COVID-19 vaccines work.** They can prevent infection, severe illness, and death from COVID-19, including from new variants.

3 **COVID-19 vaccines are safe** for both you and your fetus.

Get a COVID-19 vaccine to protect yourself and your pregnancy. You can get the vaccine during any trimester.

Learn more at [acog.org/Vaccine-Resources](https://www.acog.org/Vaccine-Resources)

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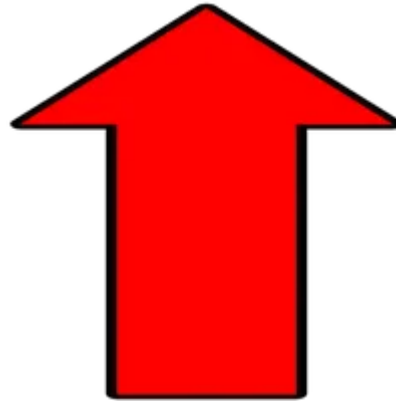
This resource was supported by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS) as a part of a financial assistance award totaling \$500,000 with 100 percent funded by CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government.



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<https://www.acog.org/womens-health/infographics/pregnant-top-3-reasons-why-you-need-a-covid-vaccine>





Why should I get the COVID-19 vaccine while I'm pregnant?

If you're pregnant, you have a higher risk of more severe illness from COVID-19 than people who are not pregnant. Getting vaccinated may protect you from severe illness. Vaccination during pregnancy also helps protect your fetus.

ACOG strongly recommends COVID-19 vaccination for all people, including anyone who is pregnant. If you are pregnant and want to know more about the vaccines, talk with your obstetrician–gynecologist (ob-gyn).

Risks of COVID-19 infection

Pregnant women who get sick with COVID-19 are more likely than nonpregnant women to..



need care in an
intensive care
unit (ICU)



need a ventilator
for breathing
support



die from
the illness

Certain health conditions, such as diabetes or high blood pressure, may also increase your risk. You and your ob-gyn should talk about your risk of severe illness if you get sick.

Benefits to getting vaccinated

The COVID-19 vaccines available in the United States are effective at protecting against severe illness, hospitalization, and death from COVID-19.



Getting vaccinated during pregnancy may help protect...



you



your fetus



your family



your
commun

Safety and fertility facts



The vaccines cannot give you COVID-19.

The vaccines do not use the live virus that causes COVID-19



COVID-19 vaccines are safe to get during pregnancy.

Scientists have compared the pregnancies of women who have received COVID-19 vaccines and women who have not. The reports show that these women have had similar pregnancy outcomes. Data do not show any safety concerns.



After you get vaccinated, the antibodies made by your body may be passed through breastmilk and may help protect your baby from the virus. ACOG recommends that breastfeeding women be vaccinated against COVID-19.



There is no evidence that the COVID-19 vaccines affect fertility. ACOG recommends vaccination for anyone who may consider getting pregnant in the future

future.



How will I feel after getting the vaccine?

Side effects vary from person to person. Some people develop a fever and arm pain for a short time.

Remember:



If you have a fever or other discomfort after getting a shot, you can take acetaminophen. This over-the-counter medication is safe during pregnancy.



If your discomfort lasts more than a couple of days or if you have questions, talk with your ob-gyn.

If you have had a severe allergic reaction to a vaccine in the past, talk with your ob-gyn before getting the COVID-19 vaccine.

Other things to consider

- The vaccine is updated regularly to protect against the most common COVID-19 variants. Make sure to stay up to date on recommended vaccines.
- You may choose to wear a mask in crowded areas even after being vaccinated. Masks are most important for people at increased risk of severe illness from COVID-19.

More information

- Other questions about COVID-19, pregnancy, and breastfeeding: www.acog.org/COVID-Pregnancy
- More vaccine information for people who are pregnant and breastfeeding: www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
- Other COVID-19 vaccine questions: www.cdc.gov/coronavirus/2019-ncov/vaccines

PFSI029: This information is designed as an educational aid for the public. It offers current information and opinions related to women's health. It is not intended as a statement of the standard of care. It does not explain all of the proper treatments or methods of care. It is not a substitute for the advice of a physician. For ACOG's complete disclaimer, visit www.acog.org/WomensHealth-Disclaimer.

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<https://www.acog.org/-/media/project/acog/acogorg/womens-health/files/infographics/why-should-i-get-the-covid-19-vaccine-while-im-pregnant.pdf>

The American Academy of Pediatrics

The American Academy of Pediatrics recommends the COVID vaccine for all young children age 6 months through 23 months. Children younger than 2 years old are at h risk for severe COVID-19 and hospitalization.

Beyond that age, it recommends the vaccine for children and teens with risk factors for COVID.

The vaccine also should be available for children ages 2-18 who do not fall into these groups, but whose parent wants them to have COVID vaccine protection.

<https://www.healthychildren.org/English/health-issues/conditions/COVID-19/Pages/default.aspx>

- [COVID Vaccine Checklist for Kids](#)
 - [When Should Kids Get the COVID Vaccine?](#)
 - [COVID-19: What Families Need to Know](#)
 - [Breastfeeding & COVID-19: What Parents Need to Know](#)
 - [The Science Behind COVID Vaccines: Parent FAQs](#)
 - [Getting My COVID Vaccine: A Picture Story for Kids](#)
 - [COVID-19 Vaccines During Pregnancy & Breastfeeding: Parent FAQs](#)
 - [RSV, Flu & COVID: How Are These Respiratory Illnesses Different?](#)
 - [Do Healthy Young People Need the COVID-19 Vaccine?](#)
-

**IF YOU'RE NOT
OUTRAGED
YOU'RE NOT
PAYING
ATTENTION**

STUDIES:

Are COVID-19 Vaccines in Pregnancy as Safe and Effective as the Medical Industrial Complex Claim? Part I

The CDC/FDA's safety signals were breached for all 37 AEs following COVID-19 vaccination in pregnancy including miscarriage, chromosomal abnormalities, fetal malformations, cervical insufficiency, fetal arrhythmia, hemorrhage in pregnancy, premature labor/delivery, preeclampsia, preterm rupture of membranes, placental abnormalities, fetal growth restriction, stillbirth, newborn asphyxia and newborn dea

We found unacceptably high breaches in safety signals for 37 AEs after COVID-19 vaccination in pregnant women. An immediate global moratorium on COVID-19 vaccination during pregnancy is warranted. The United States government, medical organizations, hospitals, and pharmaceutical companies have misled and/or deceived public regarding the safety of COVID-19 vaccination in pregnancy. The promotion of COVID-19 vaccines in pregnancy by The American College of Obstetricians and Gynecologists (ACOG), The American Board of Obstetrics & Gynecology (ABOG), and Society for Maternal Fetal Medicine (SMFM) must cease immediately.

<https://publichealthpolicyjournal.com/are-covid-19-vaccines-in-pregnancy-as-effective-as-the-medical-industrial-complex-claim-part-i/>

Overall Health Effects of mRNA COVID-19 Vaccines in Children and Adolescents A Systematic Review and Meta-Analysis

*mRNA vaccines... were associated with an **increased risk of severe adverse events in children** (In a combined analysis, the RR was **3.77** (1.56-9.13)[0.4% vs 0.1% in vaccine placebo recipients]) in above 5 year-olds,*

*In the younger children, mRNA vaccines were associated with **higher risk of lower respiratory tract infection (LRTI)** (RR=**2.80** (1.32-5.94)[0.6% vs 0.3%]) including a **high risk of RSV infections** (RR=**2.78** (1.09-7.06)[0.4% vs 0.2%]).*

<https://www.medrxiv.org/content/10.1101/2023.12.07.23298573v3>

The phase 2/3 clinical trial for the Pfizer-BioNTech COVID-19 vaccine in children 6 months through 4 years of age included 4,526 participants. The study, which was randomized, placebo-controlled trial, recruited children from various countries including the U.S., Finland, Poland, Spain, and Brazil. Participants were divided into two age-based groups for analysis: 6 to 23 months and 2 to 4 years.

<https://investors.biontech.de/news-releases/news-release-details/pfizer-biontech-covid-19-vaccine-receives-fda-emergency-use>

May 27, 2025

RFK Jr. takes COVID vaccine off 'recommended list' for healthy kids and preg



Dr. Clare Craig



<https://www.bitchute.com/video/6aCHlFXMIDas>

mRNA and pregnant women



COVID-19 mRNA Vaccination of Pregnant Women Temporally Associated wit



COVID-19 Vaccines Not Safe For Pregnant Woman or Baby: Synthetic mRNA



I strongly encourage you to watch Professor Retsef Levi's 25 minute presentation.

COVID-19 Vaccine Discussion Framing, 2025-2026

Professor Retsef Levi, PhD, MIT

ACIP Meeting, CDC
September 19, 2025



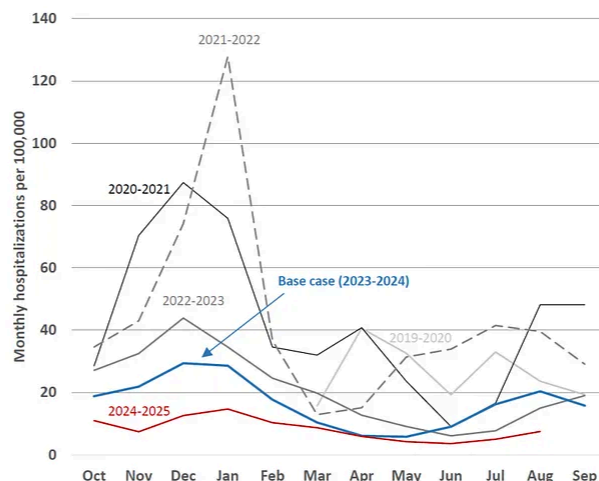
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https://www.youtube.com/watch?v=_9ChY9SpPlY&t=16500s

COVID-19 Burden Decreases

Weekly rates of
COVID-19
associated
hospitalizations
by season, all
ages

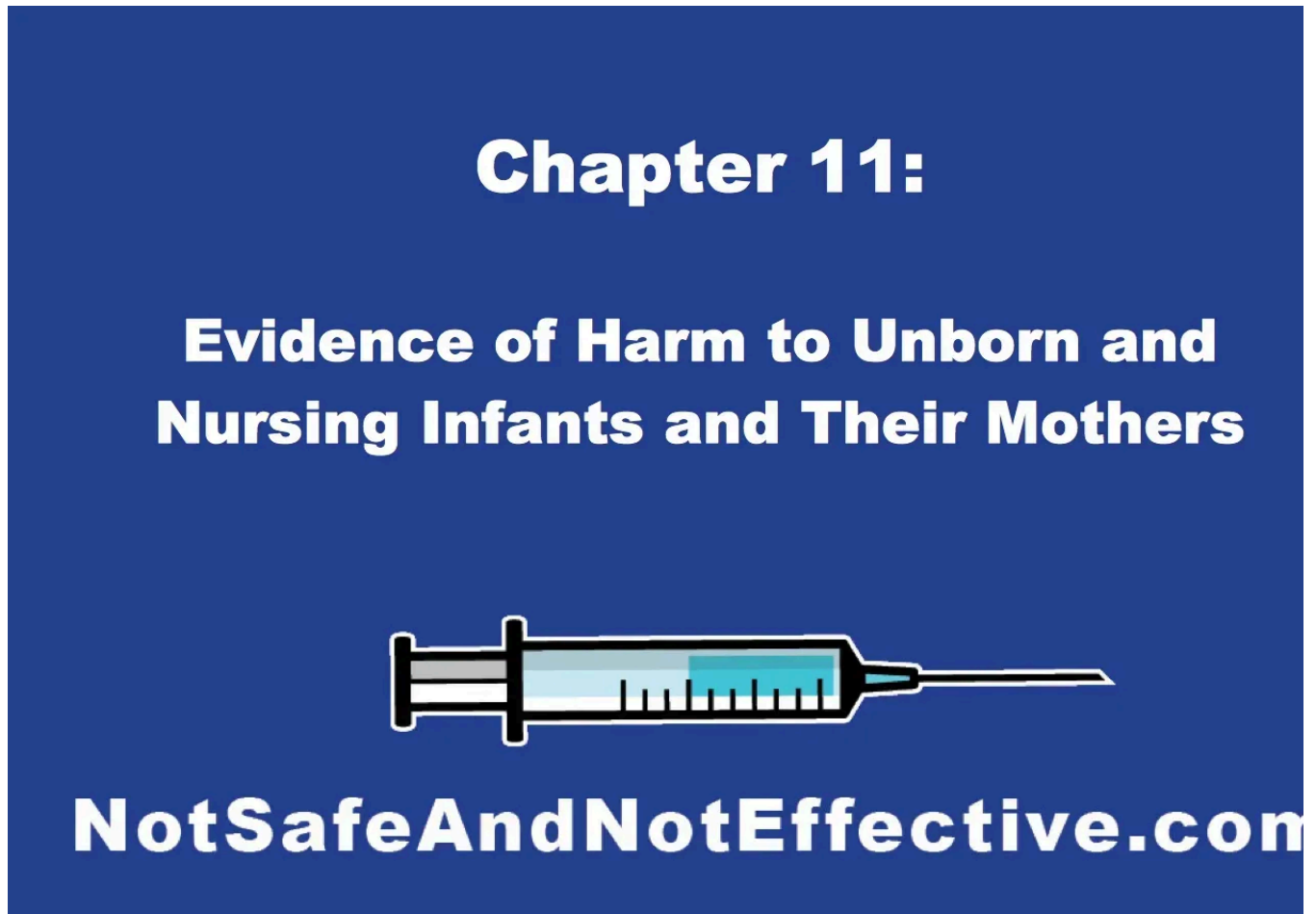


Source: COVID-NET

Presentation to COVID-19 Work Group September 12, 2025 by the University of Michigan

ACIP Meeting, CDC
September 19, 2025

Nearly a year ago I wrote the article below:



<https://jamesroguski.substack.com/p/evidence-of-harm-to-unborn-and-nursing>

Please take the time to read the above article.

The package inserts state that there is not enough information to determine safety or effectiveness in pregnant or breastfeeding women.

The information below is the most up-to-date information that is available:

COMIRNATY (Package Insert - August 2025)

COMIRNATY is approved for use in individuals who are:

- *65 years of age and older, or*
- *5 years through 64 years of age with at least one underlying condition that puts i at high risk for severe outcomes from COVID-19.*

NOT APPROVED FOR CHILDREN YOUNGER THAN 5 YEARS OLD

Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. (page 25)

It is not known whether COMIRNATY is excreted in human milk. Data are not avail assess the effects of COMIRNATY on the breastfed infant or on milk production/exc (page 25)

The safety and effectiveness of COMIRNATY in individuals younger than 5 years of have not been established. Evidence from clinical studies in individuals 6 months thr years of age strongly suggests that a single dose of COMIRNATY would be ineffectiv individuals younger than 6 months of age. (page 26)

<https://www.fda.gov/media/151707/download>

SPIKEVAX (Package Insert August/2025)

SPIKEVAX is approved for use in individuals who are:

- *65 years of age and older, or*
- *6 months through 64 years of age with at least one underlying condition that put at high risk for severe outcomes from COVID-19.*

Available data on SPIKEVAX administered to pregnant women are insufficient to in vaccine-associated risks in pregnancy. (page 48)

It is not known whether SPIKEVAX is excreted in human milk. Data are not available to assess the effects of SPIKEVAX on the breastfed infant or on milk production/excretion (page 49)

Safety and effectiveness of SPIKEVAX have not been established in individuals less than 6 months of age. (page 49)

<https://www.fda.gov/media/155675/download>

ONLY MODERNA'S SPIKEVAX HAS BEEN FDA APPROVED FOR CHILDREN 6 MONTHS THROUGH 4 YEARS OF AGE.

Should Healthy Children Be Given Moderna's Spikevax Covid 19 Injections? No

[Download](#)



Should Healthy Children Be Given Moderna's Spikevax Covid 19 Injections? No
49.3KB · PDF file

Download

Download

Should healthy children (6 months through 11 years of age) be given Moderna's SPIKEVAX COVID-19 Injections?

Is there substantial certainty of a net clinical benefit (benefits outweigh harms) to vaccinating healthy children with this mRNA vaccine?

The answer, at the present time, with best available information, is NO.

COVID-19 severe disease, hospitalization and death is extremely low at pediatric ages and has fallen, according to US CDC data from 2021-22 to the present. These rates are lower for healthy kids than kids with risk factors.

Moderna has never shown a reduction in severe COVID-19, hospitalization, ICU stay or death in a randomized study in children.

Moderna has not shown that COVID-19 vaccination reduces long covid or transmiss any setting at any age with high quality data.

The potential upper bound absolute benefit to a kid who had and recovered from CO lower than one that has not been exposed to the virus.

Kids have broadly returned to normal life, and many more will encounter COVID-19 circulates year-round, from the moment of their birth. Vaccinating these individuals (healthy kids with natural immunity) carries massive uncertainty as to whether benefi outweigh risks.

Although COVID-19 vaccines have been given to billions of individuals and the harm been studied in depth, no one knows if these products have harms that only materiali or 20 years later, as such is a necessary limit of time. It is ignorant to claim that unkn longterm risks are not possible.

Make no mistake—antibody titers are a surrogate endpoint.

Antibodies are not gold standard science, and one cannot be certain of net clinical be merely because antibodies are increased. The human body does not actively manufac all antibodies it is capable of producing at all times. Instead, it mobilizes antibody production from memory cells when appropriate. Vaccine doses can increase antibod but fail to further improve clinical outcomes.

No European peer nation advises healthy children to undergo COVID-19 vaccination the US has been a global outlier with its push to vaccinate healthy children with a no mRNA product.

The estimated efficacy of the vaccine is based primarily on three clinical studies whic insufficient to characterize the current clinical benefit of the SPIKEVAX vaccine in t population of children without high-risk conditions.

In addition to the limitations of the original pediatric clinical trials, the amount of protection conferred by an increase in neutralizing antibodies, used as surrogate endp in the second two studies, is unclear.²

Protection against future severe COVID-19 may predominantly come from other factors of the immune system, such as innate immunity or cell mediated immunity.^{3,4}

Additionally, the risk of severe outcomes from COVID-19 has decreased dramatically in the last four years.⁵

Hospitalizations from COVID-19 have declined even in the age group 6 months to 2 years between 2021 and 2025.⁶

The infection fatality rate is estimated to have decreased approximately 10-fold with the emergence of the Omicron subvariants.⁵

Individuals who were previously at low risk of severe outcomes from COVID-19 now face even lower risks of death, hospitalization and severe disease due to COVID-19. The infection fatality rate in non-high-risk children is challenging to calculate as death due to COVID-19 in this group is extremely rare.^{5,7}

Due to this decrease in disease severity, any vaccination-related harms have a greater potential of outweighing potential benefits in low-risk populations.

It is important to acknowledge circumstances in which the potential for benefit from vaccination among non-high-risk individuals is small and poorly defined. Although millions of COVID-19 vaccines have been given to hundreds of millions, if not billions of individuals, the long-term safety profile of these products remains unknown.

The decrease in the chance of developing severe COVID-19, means that the potential absolute benefit from vaccination has simultaneously decreased.

The absolute potential for benefit among non-high-risk children is, at best, marginal because there is substantial uncertainty about vaccine efficacy against omicron variants coupled with higher rates of some adverse events among vaccine recipients¹ and, although rare, the possibility of serious harms from mRNA vaccination in this age group⁸, including unknown long term risks,

FDA has a regulatory duty to only grant marketing authorization in settings where with substantial certainty the benefits outweigh the risks. For healthy children that stand

not met

REFERENCES

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The above is a collection of excerpts adapted from

CENTER DIRECTOR DECISIONAL MEMO - 7/9/2025

by Vinayak Prasad, M.D., MPH.,

Director, Center for Biologics Evaluation and Research (CBER), FDA

<https://www.fda.gov/media/187542/download>

mNEXSPIKE (Package Insert - August 2025)

MNEXSPIKE is approved for use in individuals who are:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

NOT APPROVED FOR CHILDREN YOUNGER THAN 12 YEARS OLD

Available data on MNEXSPIKE administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. (page 18)

It is not known whether MNEXSPIKE is excreted in human milk. Data are not available to assess the effects of MNEXSPIKE on the breastfed infant or on milk production/excretion. (page 19)

The safety and effectiveness of MNEXSPIKE have not been established in individuals younger than 12 years of age. (page 19)

<https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/publications/published/2025/08/Package-Insert-MNEXSPIKE.pdf>

NUVAXOVID (Package Insert - X 2025)

NUVAXOVID is approved for use in individuals who are:

- *65 years of age and older, or*
- *12 years through 64 years of age with at least one underlying condition that puts at high risk for severe outcomes from COVID-19.*

NOT APPROVED FOR CHILDREN YOUNGER THAN 12 YEARS OLD

Available data on NUVAXOVID administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy (page 30)

It is not known whether NUVAXOVID is excreted in human milk. Data are not available to assess the effects of NUVAXOVID on the breastfed infant or on milk production/excretion (page 30)

The safety and effectiveness of NUVAXOVID in individuals younger than 12 years of age have not been established. (page 31)

<https://www.fda.gov/media/186544/download>

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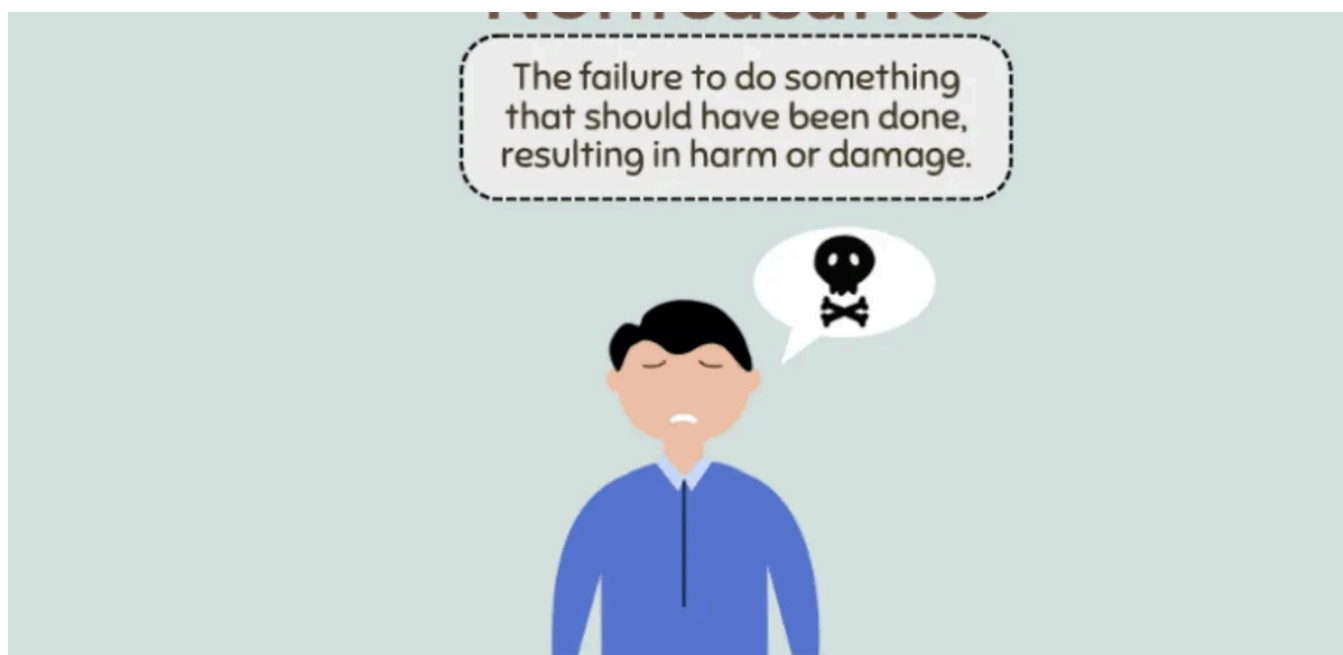


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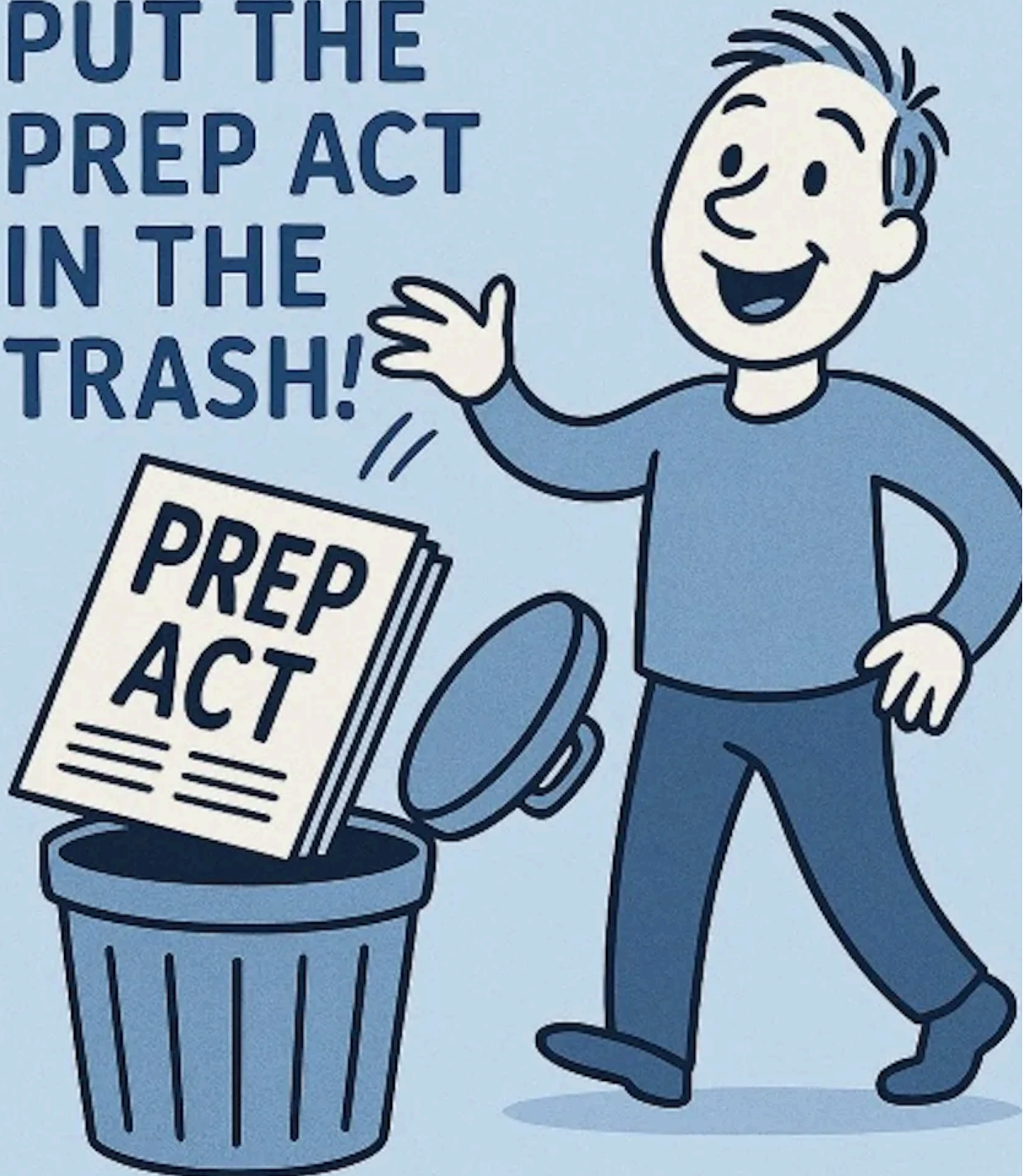
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Janet Hofbauer Janet Hofbauer 6h

♥ Liked by James Roguski

Well written stack today. I remember years ago they did not want any pregnant woman or br child to take any vaccinations due to the child well being unknown risks. Today seems to be n by lusty greed never satisfied. Profit over human life horrible no honor. Bravo! Please keep yo works. Blessings always.

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John Roberts John Roberts 7h

What ever the government suggests, the opposite is probably the correct choice !!!

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