LESSONS LEARNED: EVALUATING THE SAFETY AND EFFICACY OF COVID-19 VACCINES

Siri | Glimstad

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COVID-19 VACCINES FELL INTO AN EXISTING FRAMEWORK FOR VACCINES

PART I:
MARKET FORCES DRIVE PRODUCT SAFETY

MARKET FORCE DRIVING SAFETY ELIMINATED

HOW IS PRODUCT SAFETY ASSURED?

(1) Market Forces

(2) Regulators

MARKET FORCE DRIVING SAFETY ELIMINATED

3 Routine Vaccines in Early 1980s

TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s)†	Comments
2 mo.	DTP-1,§ OPV-1¶	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR††	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr.§§	DTP-5, OPV-4	Preferably at or before school entry
14-16. yr	Td¶¶	Repeat every 10 years throughout life

Bruesewitz v. Wyeth, 562 U.S. 223 ("the remaining manufacturer [of DTP] estimated that its potential tort liability exceeded its annual sales by a factor of 200")

Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, at 2 (1994) (By 1986, "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines.")

MARKET FORCE DRIVING SAFETY ELIMINATED

"No person may bring a civil action … against a vaccine administrator or manufacturer … for damages arising from a vaccine-related injury or death"

42 U.S.C. 300aa-11

"[The] Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers … for injury or death caused by a vaccine side effects."

Bruesewitz v. Wyeth, 562 U.S. 223

NO OTHER PRODUCT ENJOYS THIS DEGREE OF IMMUNITY

MARKET FORCE DRIVING SAFETY ELIMINATED

Covid-19 Vaccines: Market Forces Eliminated x2

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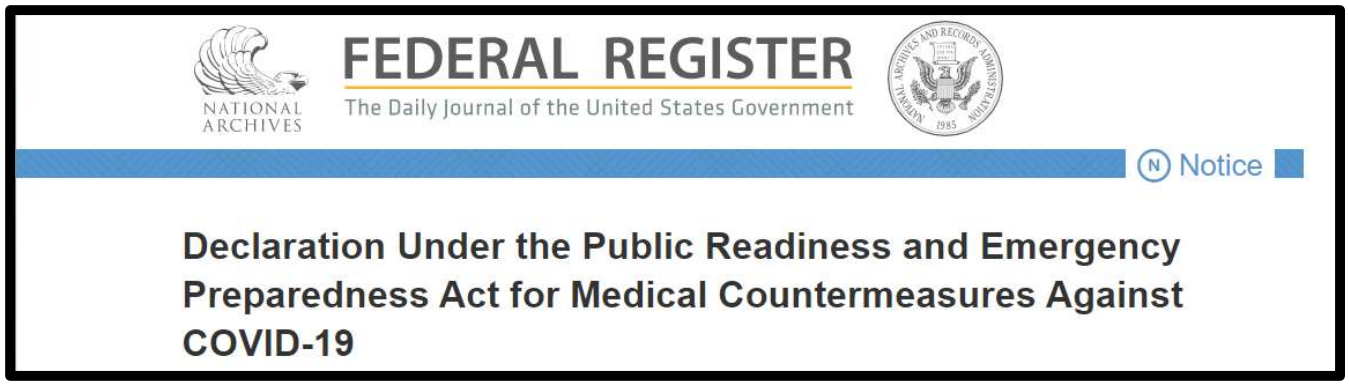

42 U.S.C. § 247d-6d: "[M]anufacturers" of "any vaccine, used to treat, … prevent or mitigate COVID-19" shall have "[l]iablity immunity ," including, "from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a [COVID-19 vaccine]."

MARKET FORCE DRIVING SAFETY ELIMINATED

Federal Gov't Pre-Guaranteed Immunity

Statement of Work
For
COVID-19 PANDEMIC–LARGE SCALE VACCINE MANUFACTURING DEMONSTRATION

RPP #: 20-11
Project Identifier: 2011-003

The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act declaration of equal or greater scope.

Copies of the gov't contracts available at:
https://aaronsiri.substack.com/p/prep-act-immunity-for-injuries-caused

PART II:
C-19 VACCINES:
CLINICAL TRIALS

CLINICAL TRIALS

Why are clinical trials critical?

CLINICAL TRIALS

Impact of Eliminating Market Forces

Pfizer's Top 5 Selling Drugs of All Time*		
DRUG	**SAFETY REVIEW PERIOD**	**CONTROL USED**
Enbrel (Pfizer)	6.6 years	Placebo
Eliquis (Pfizer)	7.4 years+	Placebo
PCV13 (Pfizer)	½ year	PCV7
Lyrica (Pfizer)	2 years+	Placebo
Lipitor (Pfizer)	4.9 years+	Placebo

Vaccines in First 6 Months of Life (3x Each)**		
VACCINE	**SAFETY REVIEW PERIOD**	**CONTROL USED**
Hep-B (Merck)	5 days	None
IPV (Sanofi)	3 days	None
Hib (Merck)	3 days	Hib
DTaP (GSK)	28 days	DTP
PCV13 (Pfizer)	6 months	PCV7

* https://moneyinc.com/the-five-highest-selling-pfizer-drugs-of-all-time/
** https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
Source for all data: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

CLINICAL TRIALS

Example: First Shot on CDC Schedule

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VACCINE	**SAFETY REVIEW PERIOD**	**CONTROL USED**
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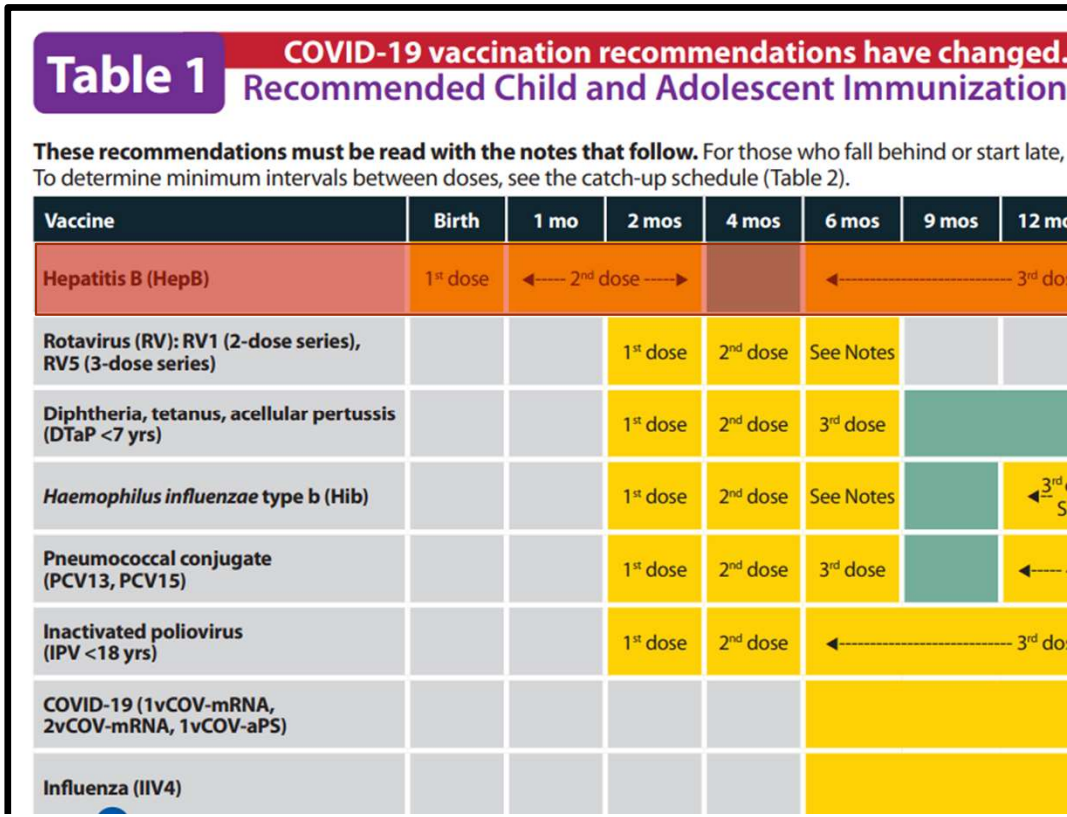

Table 1 COVID-19 vaccination recommendations have changed.
Recommended Child and Adolescent Immunization

These recommendations must be read with the notes that follow. For those who fall behind or start late, To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mo
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Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes		
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose		
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		◄-- 3rd S
Pneumococcal conjugate (PCV13, PCV15)			1st dose	2nd dose	3rd dose		◄----
Inactivated poliovirus (IPV <18 yrs)			1st dose	2nd dose	◄---------- 3rd do		
COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)							
Influenza (IIV4)							

CLINICAL TRIALS

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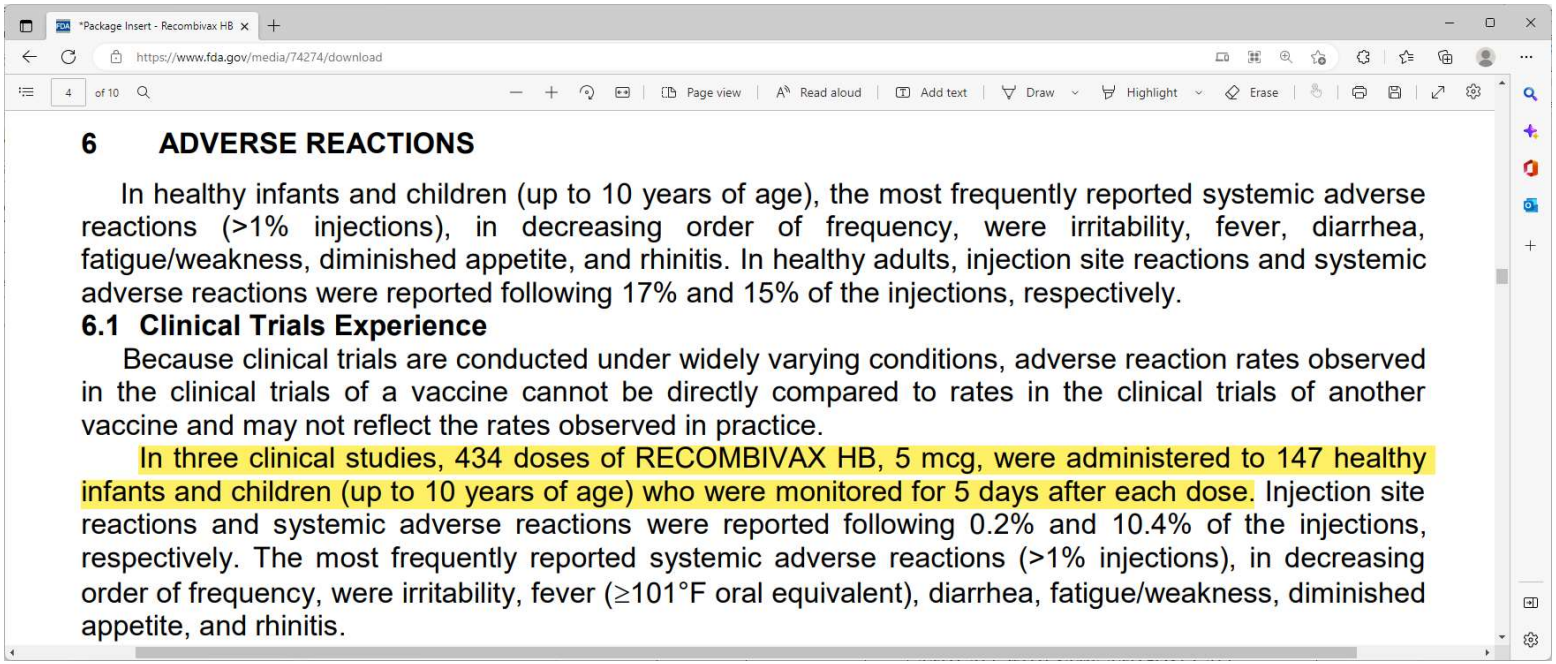
CLINICAL TRIALS

Clinical Trial for Hep B Vaccine



*Package Insert - Recombivax HB

https://www.fda.gov/media/74274/download

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6 ADVERSE REACTIONS

In healthy infants and children (up to 10 years of age), the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. 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.

Hep B Package Insert: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states
Hep B Clinical Trial Report: https://icandecide.org/wp-content/uploads/2020/09/COMBINED-02.pdf
Hep B Petition to FDA to Withdraw Licensure https://www.regulations.gov/document/FDA-2020-P-1857-0001

CLINICAL TRIALS

Another Example: Pfizer's PCV13

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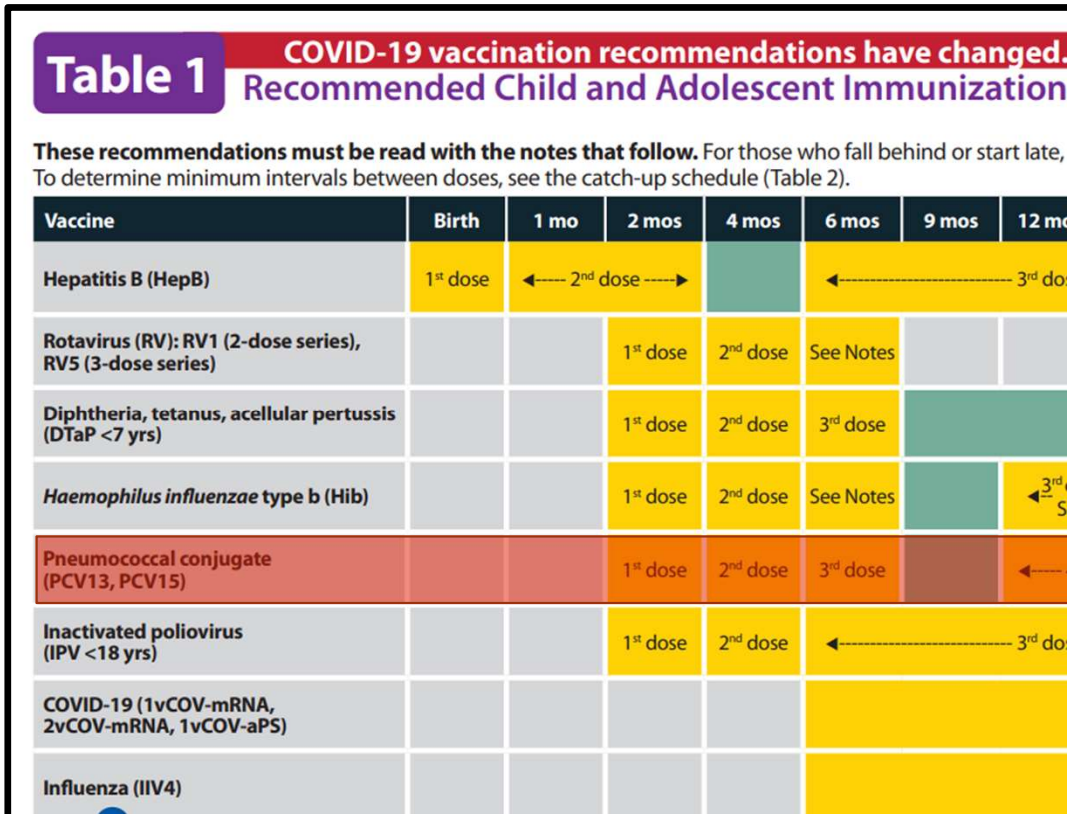
Hib (Merck)	3 days	Hib
DTaP (GSK)	28 days	DTP
PCV13 (Pfizer)	6 months	PCV7



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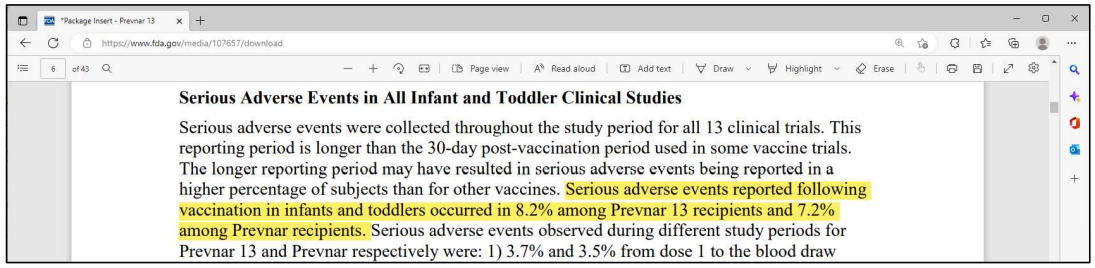
Inactivated poliovirus (IPV <18 yrs)			1st dose	2nd dose	◄---------- 3rd do		
COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)							
Influenza (IIV4)							

CLINICAL TRIALS

Clinical Trial for Pfizer's PCV13 (Prevnar) Vaccine



Serious Adverse Events in All Infant and Toddler Clinical Studies

Serious adverse events were collected throughout the study period for all 13 clinical trials. This reporting period is longer than the 30-day post-vaccination period used in some vaccine trials. The longer reporting period may have resulted in serious adverse events being reported in a higher percentage of subjects than for other vaccines. Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients. Serious adverse events observed during different study periods for Prevnar 13 and Prevnar respectively were: 1) 3.7% and 3.5% from dose 1 to the blood draw

https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

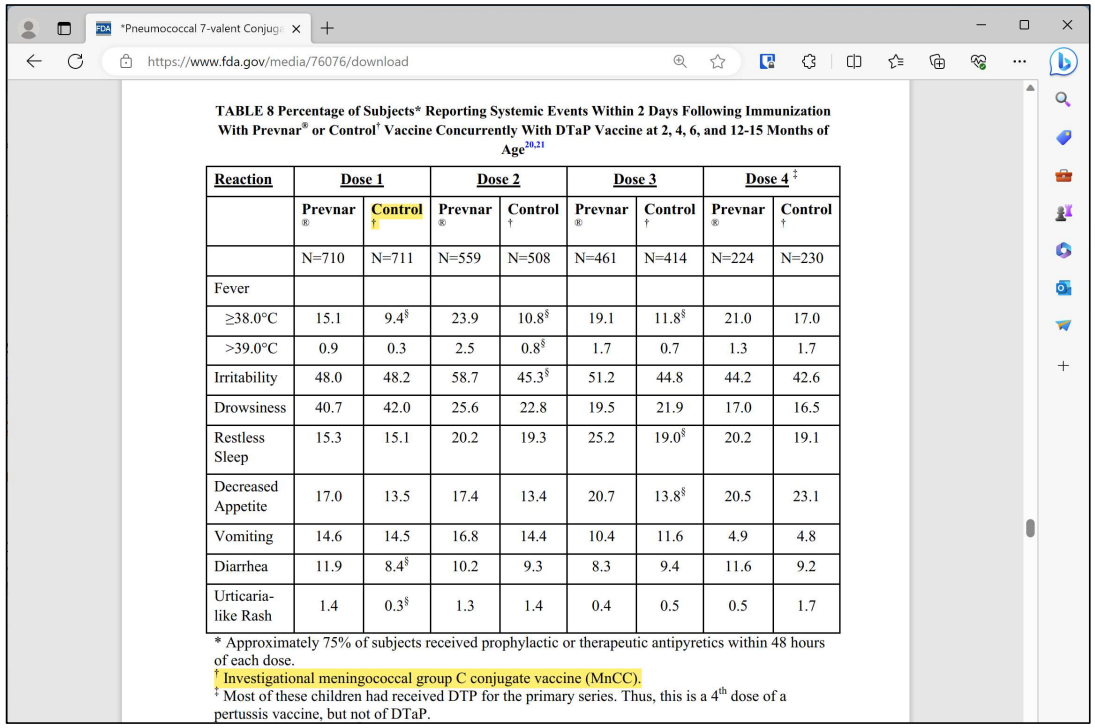


TABLE 8 Percentage of Subjects* Reporting Systemic Events Within 2 Days Following Immunization With Prevnar® or Control† Vaccine Concurrently With DTaP Vaccine at 2, 4, 6, and 12-15 Months of Age[20,21]

Reaction	Dose 1		Dose 2		Dose 3		Dose 4 ‡	
	Prevnar ®	Control †	Prevnar ®	Control †	Prevnar ®	Control †	Prevnar ®	Control †
	N=710	N=711	N=559	N=508	N=461	N=414	N=224	N=230
Fever								
≥38.0°C	15.1	9.4§	23.9	10.8§	19.1	11.8§	21.0	17.0
>39.0°C	0.9	0.3	2.5	0.8§	1.7	0.7	1.3	1.7
Irritability	48.0	48.2	58.7	45.3§	51.2	44.8	44.2	42.6
Drowsiness	40.7	42.0	25.6	22.8	19.5	21.9	17.0	16.5
Restless Sleep	15.3	15.1	20.2	19.3	25.2	19.0§	20.2	19.1
Decreased Appetite	17.0	13.5	17.4	13.4	20.7	13.8§	20.5	23.1
Vomiting	14.6	14.5	16.8	14.4	10.4	11.6	4.9	4.8
Diarrhea	11.9	8.4§	10.2	9.3	8.3	9.4	11.6	9.2
Urticaria-like Rash	1.4	0.3§	1.3	1.4	0.4	0.5	0.5	1.7

* Approximately 75% of subjects received prophylactic or therapeutic antipyretics within 48 hours of each dose.

† Investigational meningococcal group C conjugate vaccine (MnCC).

‡ Most of these children had received DTP for the primary series. Thus, this is a 4th dose of a pertussis vaccine, but not of DTaP.

CLINICAL TRIALS

Final Example: DTaP

Vaccines in First 6 Months of Life (3x Each)**		
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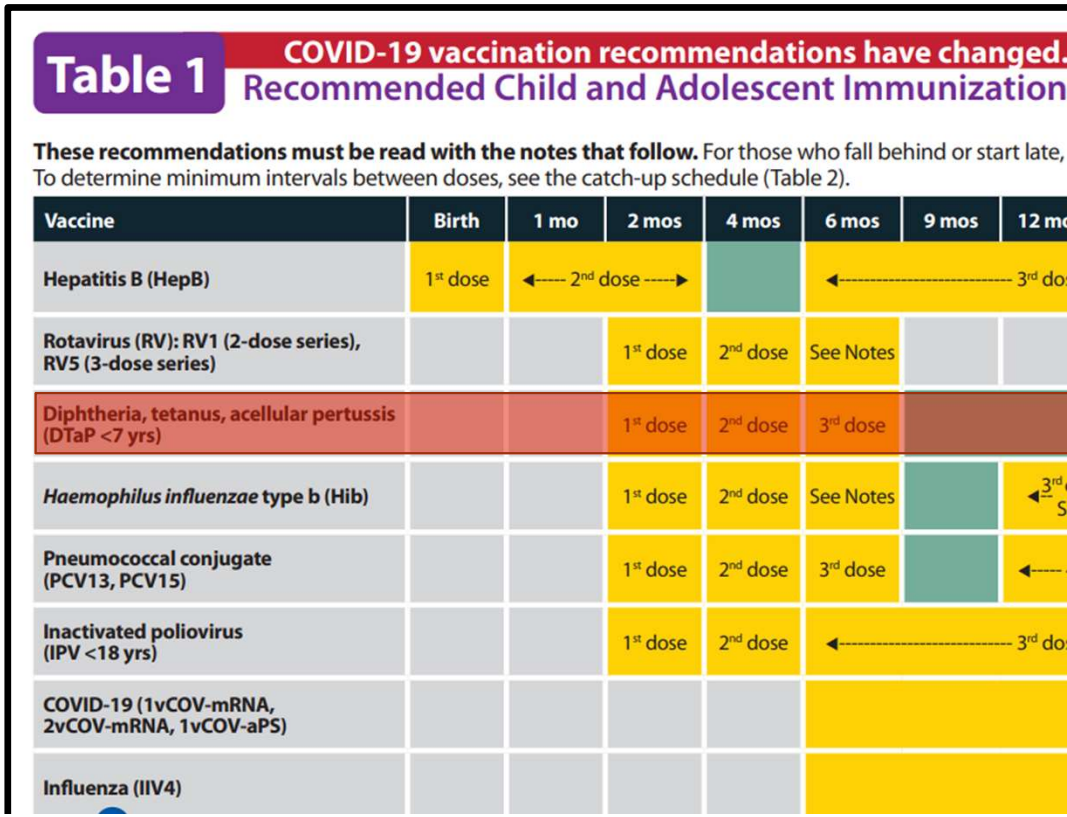

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Influenza (IIV4)							

CLINICAL TRIALS

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The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment

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Measles vaccine
Non-specific effects of vaccines
Oral polio vaccine

ABSTRACT

Background: We examined the introduction of diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau in the early 1980s.
Methods: The child population had been followed with 3-monthly nutritional weighing sessions since 1978. From June 1981 DTP and OPV were offered from 3 months of age at these sessions. Due to the 3-monthly intervals be-ildren were allocated by birthday in a 'natural experiment' to receive vaccinations early or nonths of age. We included children who were <6 months of age when vaccinations started til the end of December 1983. We compared mortality between 3 and 5 months of age of ot-yet-DTP-vaccinated children in Cox proportional hazard models.
Results: Among 3–5-month-old children, having received DTP (±OPV) was associated with a mortality hazard ratio (HR) of 5.00 (95% CI 1.53–16.3) compared with not-yet-DTP-vaccinated children. Differences in background factors did not explain the effect. The negative effect was particularly strong for children who had received DTP-only and no OPV (HR = 10.0 (2.61–38.6)). All-cause infant mortality after 3 months of age increased after the introduction of these vaccines (HR = 2.12 (1.07–4.19)).
Conclusion: DTP was associated with increased mortality; OPV may modify the effect of DTP.

1. Introduction

Individually randomized studies to measure impact on child survival of different vaccines were not conducted when the Expanded Program on Immunization (EPI) was introduced in low-income countries in the 1970s. The disease-protective effects were well documented, so the main issue was at which age to introduce the vaccine most effectively (The Expanded Programme on Immunization, 1982). Except for measles to other infections (Aaby et al., 1995). WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs of BCG, diphtheria-tetanus-pertussis (DTP) and MV and recommended further research (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014).

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies

5. Conclusions

DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections.

The recently published SAGE review called for rand

Vaccination with the DPT vaccine the first 3-5 months of age was associated with a 10 fold higher mortality rate compared to unvaccinated infants.

All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.

longed, the present study may remain the closest we will ever come to a RCT of the NSEs of DTP.

10x

Table 3
Mortality rate and hazard rate (HR) for children from 3 months of age until first examination without vaccination or 6 months of age. Natural experiment.

Age group 3–5 months	Mortality rate (deaths/person-years)			HR (95% CI) DTP vs unvaccinated
All				
Unvaccinated (N = 651)	4.5 (5/111.4)	DTP (±OPV) (N = 462)	17.4 (11/63.1)	5.00 (1.53–16.3)
		DTP only (N = 101)	35.2 (5/14.2)	10.0 (2.61–38.6)

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icandecide.org/no-placebo/

Type	Doses	Age Injected	Brand	Company[3]	Control	Placebo?	Safety Review After Injection[2]	Long	Source	Note
HepB	3	Birth 1M 6M	Recombivax HB	M	None	NO	5 days	NO	Package insert at § 6.1	Note that to license a vaccine for children, the FDA relies upon the clinical trial conducte with children, not adults, because as the FDA explains, "It's important that the publi recognize that, because young children are still growing and developing, it's critical tha thorough and robust clinical trials of adequate size are completed to evaluate the safety an the immune response to a ... vaccine in this population. Children are not small adults[.]"
			Engerix B	G	None	NO	4 days	NO	Package insert at § 6.1	
DTaP	15	2M 4M6M 15M 4Y	Infanrix	G	DTP	NO	30 days		Package insert at § 6.1	DTP was also not licensed based on a placebo controlled trial and it increases mortality.
			Daptacel	S	DT or DTP	NO	Up to 2 months + 1 trial 6 months	NO	Package insert at § 6.1	The 6-month Daptacel trial had no control, 1,454 children and "[w]ithin 30 days following an dose of DAPTACEL, 3.9% subjects reported at least one serious adverse event."
PCV	4	2M 4M 6M 12M	Prevnar 13, PCV-13	P	Prevnar 7	NO	6 months	NO	Package insert at § 6.1	Prevnar 7 trial's control was an "[i]nvestigational meningococcal group C conjugate vaccine." I Prevnar 13 trial, "[s]erious adverse events reported following vaccination in infants and toddler occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar 7 recipients." I
			Vaxneuvance PCV-15	M	Prevnar 13	NO	6 months	NO	Package insert at § 6.1	Vaxneuvance trial, "serious adverse events...were reported by 9.6% of VAXNEUVANCE recipient and by 8.9% of Prevnar 13 recipients" but deemed "safe" because "no notable patterns o numerical imbalances between vaccination groups." Prevnar 20 had similar result split int "serious adverse events" and "newly diagnosed chronic medical conditions."
			Prevnar 20, PCV-20	P	Prevnar 13	NO	6 months	NO	Package insert at § 6.1; Clinical Review	
IPV	4	2M4M 6M 4Y	IPOL	S	None	NO	3 days	NO	Package insert at 14-17	IPOL is very different than the polio vaccine created by Jonas Salk in the 1950s (used unt 1960s). Hence, trials of Salk's vaccine from the 1950s were not relied upon to license IPOL.
Hib	3 or 4	2M 4M 6M 12M	ActHIB	S	HepB	NO	30 days	NO	Package insert at § 6.1; Basis of Approval at 8	Within 30 days of injection in the ActHIB trial, 3.4% experienced a serious adverse event bu "[n]one was assessed by the investigators [Sonafi] as related to the study of vaccines."
			Hiberix	G	HibTITER or other vaccine	NO	31 days	NO	Package insert at § 6.1; Clinical review at 20-21	
			Liquid PedvaxHIB	M	Lyophilized PedvaxHIB	NO	3 days	NO	Package insert at 6-8	Lyophilized PedvaxHIB vaccine, used as the control for Liquid PedvaxHIB, was tested in a tria in which controls were given placebo, OPV, and DTP but there is no indication Lyophilize PedvaxHIB was ever licensed.
RV[3]	2 or 3	2M 4M 6M	Rotarix	G	Dextran, Sorbitol, Amino Acids, Dulbecco's Modified Eagle Medium, and Xanthan	NO	31 days + 1 year for intussusception	NO	Package insert at § 6.1; Clinical review at 23-24	"[T]here were 68 (0.19%) deaths following...ROTARIX...and 50 (0.15%) deaths followin placebo.... The most common...cause...was pneumonia...observed in 19 (0.05%) recipients o ROTARIX and 10 (0.03%) placebo recipients." Its clinical review admits "[t]he placebo consiste
			RotaTeq	M	Polysorbate-80, Tissue Culture Medium, Fetal Bovine Serum, and Sodium Phosphate	NO	42 days + 1 year for intussusception	NO	Package insert at § 6.1; Clinical reports at 445 etc	of all components of Rotarix, but without any RV particles." The package insert for RotaTe similarly admits its "placebo" contains multiple ingredients as seen to the left.
Covid19	3	6M 7M 10M	Comirnaty	P	Placebo	YES	6 months	NO	Package insert at § 6.1	Comirnaty licensed for only 12+ (Spikevax, Moderna, only 18+). Placebo controls unblinde and most vaccinated during the trial. All data 16+ is combined but 12-15 data is separate, ha 1,131 vaccinated children, and one participant shows how this trial was conducted.
Flu	19	6M 7M Yearly	Various	[VARIOUS]	Flu shots change annually without any clinical trial	NO	Flu shots change annually without any clinical trial	NO	CDC 22-23 Flu Shots; FDA Flu Shots	The trials of the original flu shot formulations for children also did not have a placebo contro (see pp. 13-14) even though some adult trials did. The one inhaled influenza vaccine had placebo but, again, it changes every year and is not safety tested in any trial.
MMR	6	12M 4Y	M-M-R-II	M	None	NO	42 days	NO	Clinical reports	M-M-R-II trials totaled only 834 children and a third developed gastrointestinal issues and third respiratory issues. In Priorix trial, both vaccine groups had high rate of serious adverse
			Priorix	G	M-M-R-II	NO	6 months	NO	Package insert at § 6.1; Sup materials at 12	events, emergency room visits, and new chronic diseases (e.g., autoimmune disorders asthma, type I diabetes, celiac, and allergies). See Table 6 of the Supplementary Materials.
VAR	2	12M 4Y	Varivax	M	45 mg of neomycin per milliliter	NO	70 days	NO	Package insert at § 6.1; Merck study at 2; Clinical reports	One controlled trial with 956 children, half Varivax and half neomycin, and one trial with 3 vaccinated and another 29 vaccinated 8 weeks later, during which the first group had doubl the ear infections and 50% more respiratory infections.
HepA	2	12M 18M	Havrix	G	Engerix-B	NO	6 months	NO	Package insert at § 6.1	Trials for both occurred at the same time when there was no licensed Hep A vaccine an hence no excuse for not using a placebo control. It is also startling Engerix-B, see above, wa
			Vaqta	M	AAHS and Thimerosal	NO	42 days	NO	Package insert at § 6.1; Merck study at 454	the control for Havrix, and an injection of cyto-and-neuro toxic substances, AAHS an thimerosal, were used as a control for Vaqta instead of a saline injection.
Tdap	3	11Y	Adacel	S	Td, for adults	NO	6 months	NO	Package insert at § 6.1	Due to reactions, Tdap (Adacel) given at 11Y has 12.5 times less diphtheria toxoid (25Lf v 2Lf
			Boostrix	G	Decavac or Adacel	NO	6 months	NO	Package insert at § 6.1	and 10 times less pertussis toxin (25mcg v 2.5mcg) than DTaP (Infanrix) given to babies.
	2	9Y			Gardasil 4		1 month in five trials, 6 months			Gardasil 9 trial gave 306 people placebo after full series of Gardasil 4. In Gardasil 4's trial, control received aluminum adjuvant, AAHS, except 320 people labeled "Saline Placebo" that actuall

CLINICAL TRIALS

Covid-19 Vaccine Clinical Trials

VACCINE	AGE	SAFETY REVIEW PERIOD	# RECEIVING VACCINE	# RECEIVING CONTROL	CONTROL USED
C19 (Pfizer)	16 years+	6 months+	21,926	21,921	Placebo ≈ 2 months
C19 (Moderna)	18 years+	6 months+	15,184	15,162	Placebo ≈ 2 months
Hep-B (Merck)	1 day+	5 days	147	0	None
IPV (Sanofi)	2 months+	3 days	1,300	0	None
Hib (Merck)	2 months+	3 days	678	225	Hib
DTaP (GSK)	2 months+	28 days	29,243	4,678	DTP
PCV13 (Pfizer)	2 months+	6 months	4,729	2,760	PCV7

https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

CLINICAL TRIALS

Should be a statistical comparison. Should not let Pfizer inject its bias.

CLINICAL TRIALS

Deaths

Pfizer Report: Covid-19 Vaccine

July 2021

Vaccinated (15 Deaths) v.
Placebo (14 deaths)

Study:
https://www.nejm.org/doi/full/10.1056/NEJMoa2110345

Supplemental Data:
https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110345/suppl_file/nejmoa2110345_appendix.pdf

Reported Cause of Death[a]	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

Note: 5 additional deaths in vaccinated group after unblinding (Pfizer FOIA docs):
https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf

CLINICAL TRIALS

Deaths in Pfizer's C-19 Vaccine Clinical Trial

FDA Report: November 2021
Vaccinated Group (21 Deaths) v. Placebo Group (17 deaths)

"From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the COMIRNATY group and 17 in the placebo group. None of the deaths were considered related to vaccination."

https://www.fda.gov/media/151733/download

Shouldn't this statistical result have been the end of this experimental product?

CLINICAL TRIALS

Deaths in Pfizer's C-19 Vaccine Clinical Trial

Asked the FDA that precise question:

"Why are the death data from a randomized controlled trial ("RCT") treated like a clinical case-series rather than an RCT when it comes to assessing causality?"

https://icandecide.org/wp-content/uploads/2022/02/Ltr-re-Pfizer-death-discrepancies_2021_11_16.pdf

FDA's response:

"We are unable to respond substantively at this time due to resource constraints and the ongoing pandemic response."

https://icandecide.org/wp-content/uploads/2022/07/Pfizer-death-discrepancy-email.pdf

CLINICAL TRIALS

Why conduct a clinical trial if:

statistical comparison when supports desired conclusion

but

individual assessment when doesn't?

CLINICAL TRIALS

Data Reliability:

Example of one clinical trial participant

CLINICAL TRIALS

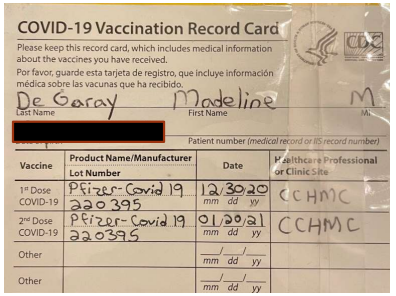
Maddie de Garay

1 of only 1,131 vaccinated in Pfizer 12–15-Year-Old Trial

October 20, 2020

January 16, 2021

January 20, 2021
(2nd Pfizer Dose)



COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.
Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

De Garay — Last Name
Madeline — First Name
M — MI
[redacted]
Patient number (medical record or IIS record number)

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19	Pfizer-Covid 19 220395	12/30/20 mm dd yy	CCHMC
2nd Dose COVID-19	Pfizer-Covid 19 220395	01/20/21 mm dd yy	CCHMC
Other		__/__/__ mm dd yy	
Other		__/__/__ mm dd yy	

CLINICAL TRIALS

Maddie de Garay

1 of only 1,131 vaccinated in Pfizer 12–15-Year-Old Trial

CLINICAL TRIALS

Maddie de Garay

1 of only 1,131 vaccinated in Pfizer 12-15 Year-Old Trial

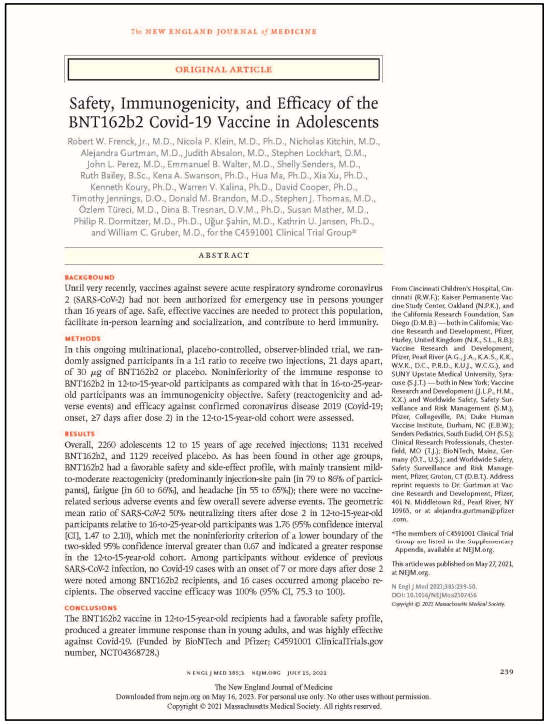
Pfizer reported Maddie's serious harm to FDA as stomach pain

> "The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. she reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. she subsequently had SAEs of abdominal pain and constipation. she had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

https://sirillp.com/degaray (obtained via FOIA litigation in federal court)

CLINICAL TRIALS

Maddie de Garay



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents

Robert W. Frenck, Jr., M.D., Nicola P. Klein, M.D., Ph.D., Nicholas Kitchin, M.D., Alejandra Gurtman, M.D., Judith Absalon, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Emmanuel B. Walter, M.D., Shelly Senders, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Hua Ma, Ph.D., Xia Xu, Ph.D., Kenneth Koury, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Timothy Jennings, D.O., Donald M. Brandon, M.D., Stephen J. Thomas, M.D., Özlem Türeci, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

ABSTRACT

BACKGROUND

Until very recently, vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) had not been authorized for emergency use in persons younger than 16 years of age. Safe, effective vaccines are needed to protect this population, facilitate in-person learning and socialization, and contribute to herd immunity.

METHODS

In this ongoing multinational, placebo-controlled, observer-blinded trial, we randomly assigned participants in a 1:1 ratio to receive two injections, 21 days apart, of 30 μg of BNT162b2 or placebo. Noninferiority of the immune response to BNT162b2 in 12-to-15-year-old participants as compared with that in 16-to-25-year-old participants was an immunogenicity objective. Safety (reactogenicity and adverse events) and efficacy against confirmed coronavirus disease 2019 (Covid-19; onset, ≥7 days after dose 2) in the 12-to-15-year-old cohort were assessed.

RESULTS

Overall, 2260 adolescents 12 to 15 years of age received injections; 1131 received BNT162b2, and 1129 received placebo. As has been found in other age groups, BNT162b2 had a favorable safety and side-effect profile, with mainly transient mild-to-moderate reactogenicity (predominantly injection-site pain [in 79 to 86% of participants], fatigue [in 60 to 66%], and headache [in 55 to 65%]); there were no vaccine-related serious adverse events and few overall severe adverse events. The geometric mean ratio of SARS-CoV-2 50% neutralizing titers after dose 2 in 12-to-15-year-old participants relative to 16-to-25-year-old participants was 1.76 (95% confidence interval [CI], 1.47 to 2.10), which met the noninferiority criterion of a lower boundary of the two-sided 95% confidence interval greater than 0.67 and indicated a greater response in the 12-to-15-year-old cohort. Among participants without evidence of previous SARS-CoV-2 infection, no Covid-19 cases with an onset of 7 or more days after dose 2 were noted among BNT162b2 recipients, and 16 cases occurred among placebo recipients. The observed vaccine efficacy was 100% (95% CI, 75.3 to 100).

CONCLUSIONS

The BNT162b2 vaccine in 12-to-15-year-old recipients had a favorable safety profile, produced a greater immune response than in young adults, and was highly effective against Covid-19. (Funded by BioNTech and Pfizer; C4591001 ClinicalTrials.gov number, NCT04368728.)

From Cincinnati Children's Hospital, Cincinnati (R.W.F.); Kaiser Permanente Vaccine Study Center, Oakland (N.P.K.), and the California Research Foundation, San Diego (D.M.B.) — both in California; Vaccine Research and Development, Pfizer, Hurley, United Kingdom (N.K., S.L., R.B.); Vaccine Research and Development, Pfizer, Pearl River (A.G., J.A., K.A.S., K.K., W.V.K., D.C., P.R.D., K.U.J., W.C.G.), and SUNY Upstate Medical University, Syracuse (S.J.T.) — both in New York; Vaccine Research and Development (J.L.P., H.M., X.X.) and Worldwide Safety, Safety Surveillance and Risk Management (S.M.), Pfizer, Collegeville, PA; Duke Human Vaccine Institute, Durham, NC (E.B.W.); Senders Pediatrics, South Euclid, OH (S.S.); Clinical Research Professionals, Chesterfield, MO (T.J.); BioNTech, Mainz, Germany (Ö.T., U.Ş.); and Worldwide Safety, Safety Surveillance and Risk Management, Pfizer, Groton, CT (D.B.T.). Address reprint requests to Dr. Gurtman at Vaccine Research and Development, Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965, or at alejandra.gurtman@pfizer.com.

*The members of C4591001 Clinical Trial Group are listed in the Supplementary Appendix, available at NEJM.org.

This article was published on May 27, 2021, at NEJM.org.

N Engl J Med 2021;385:239-50.
DOI: 10.1056/NEJMoa2107456

What Pfizer told the public about its 12-15-year-old trial on May 27, 2021:

"there were no vaccine related serious adverse events"

https://pubmed.ncbi.nlm.nih.gov/34043894/

CLINICAL TRIALS

Maddie de Garay

1 of only 1,131 vaccinated in Pfizer 12–15-Year-Old Trial

Our firm sent numerous detailed letters, with access to medical records, to FDA about Maddie and the false reporting by Pfizer.

https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-3-Jan-3-2022-Dr.-Peter-Mark-Letter_2022_01_03-41fe80ff1853909f2e9b5e329a55934e.pdf

The FDA finally responded on February 26, 2022 and told us that Maddie should file a VAERS report!

https://www.sirillp.com/wp-content/uploads/2022/03/Paul-Richards-email-response_2022_02_26_Redacted-33b881e4534f7fc2af8e5872c01984ea.pdf

CLINICAL TRIALS

Maddie de Garay

1 of only 1,131 vaccinated in Pfizer 12–15-Year-Old Trial

RESULT OF FOIA LAWSUIT AGAINST THE FDA:

By June 2021, FDA cannot ignore public inquiries and asks Pfizer about Maddie.
Did FDA get upset Pfizer didn't disclose Maddie's injuries? No!
Did they punish Pfizer for withholding evidence of harm? No!

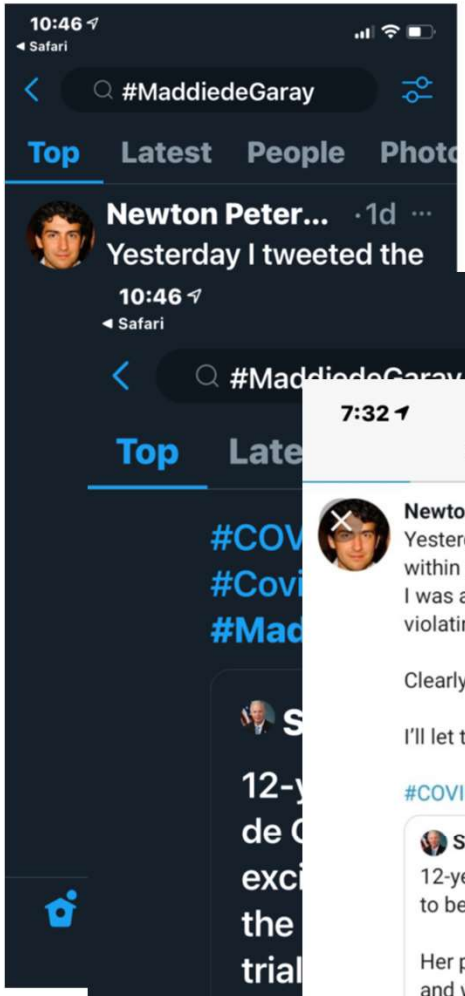
Instead, FDA blindly accepts Pfizer's conclusion that:
"The PI [principal investigator paid by Pfizer] did not feel that the subject's symptology [sic] was consistent with a vaccine related adverse event."

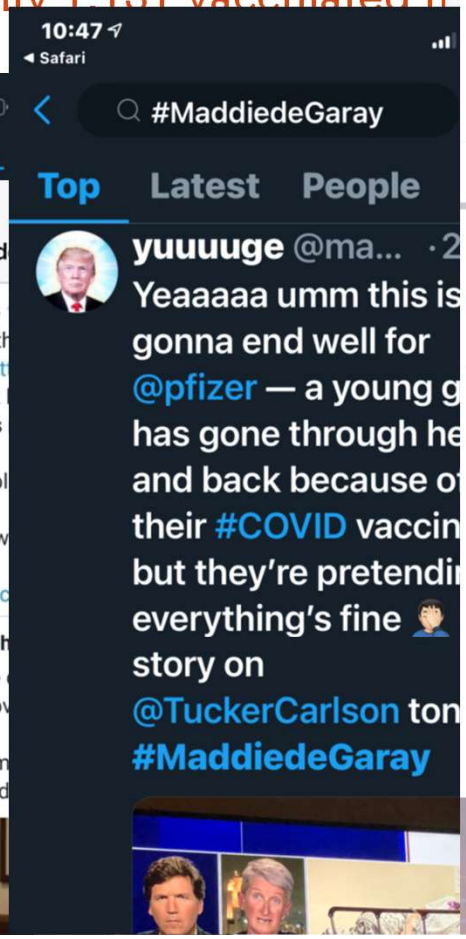
Must read emails: https://www.sirillp.com/wp-content/uploads/2024/04/FDA-emails-with-Pfizer-about-M.-deGaray-c6f24607aa9781481eae01d0d073b684.pdf

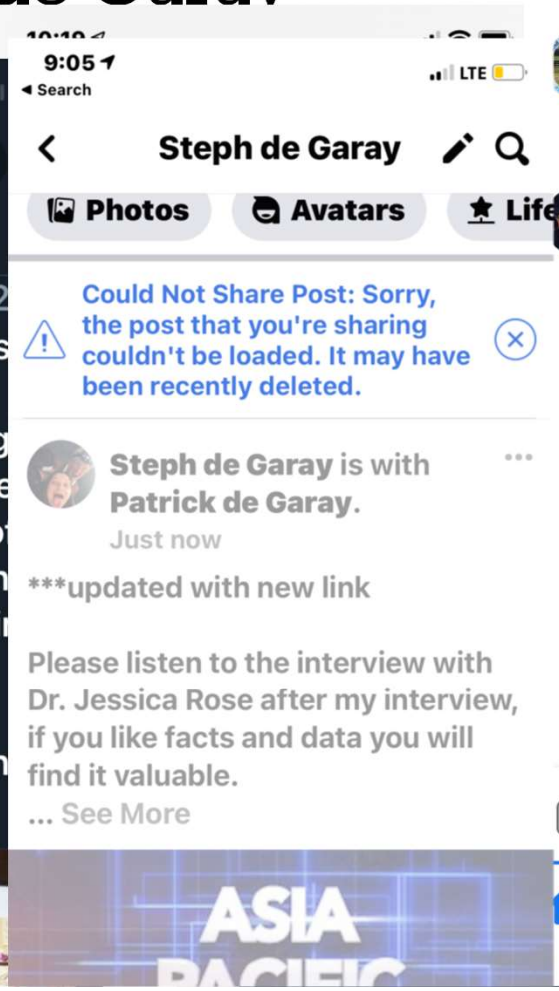
CLINICAL TRIALS

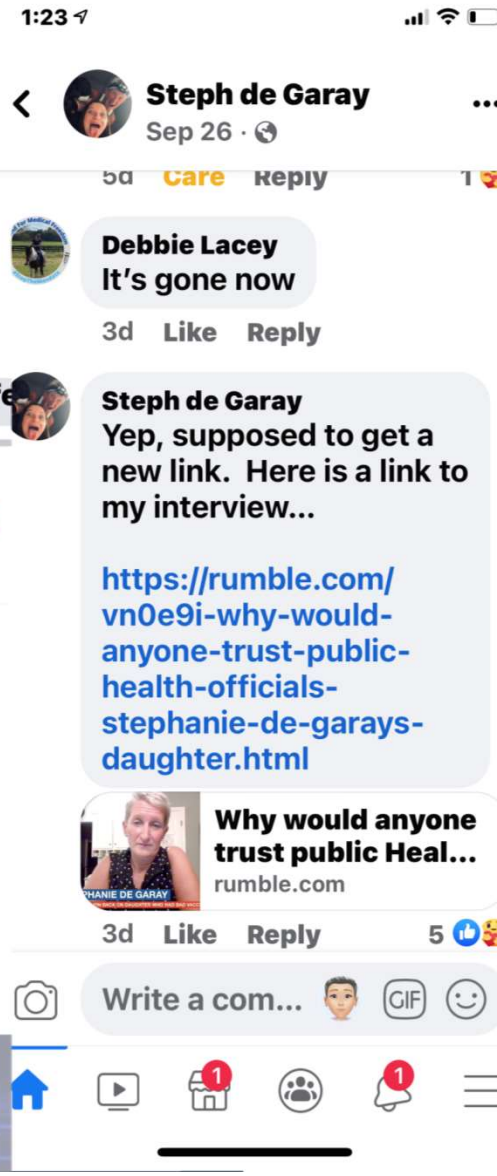
Maddie de Garay

1 of only 1,131 vaccinated ju

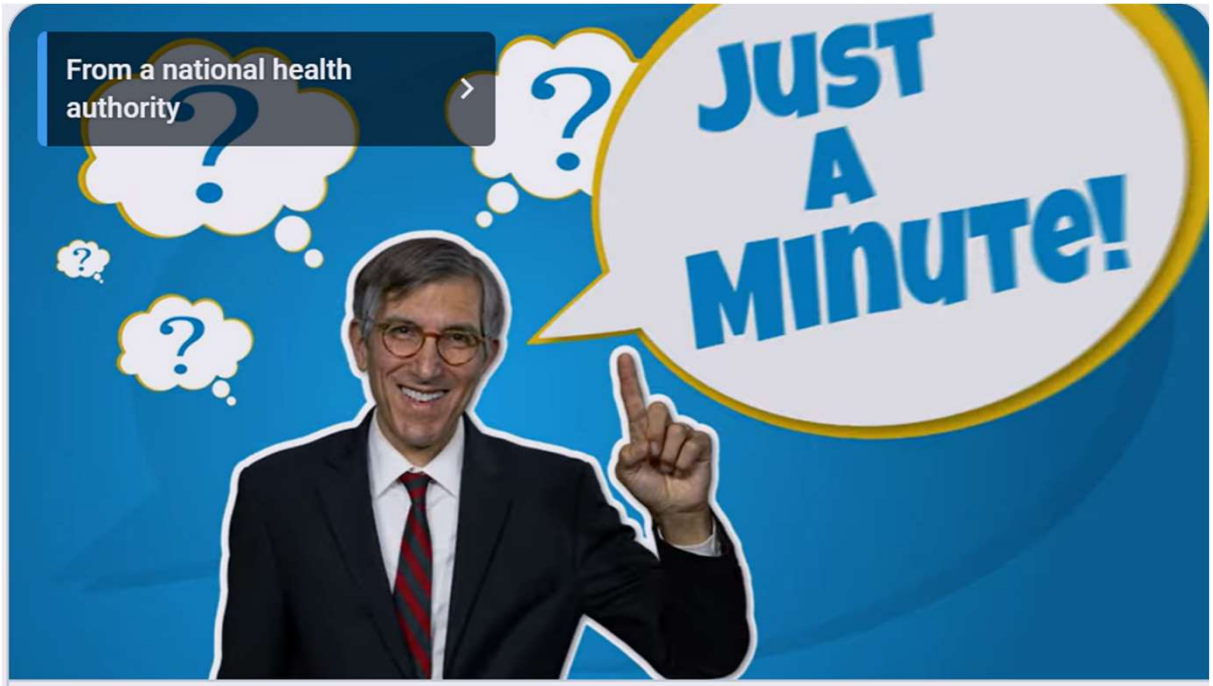








CLINICAL TRIALS

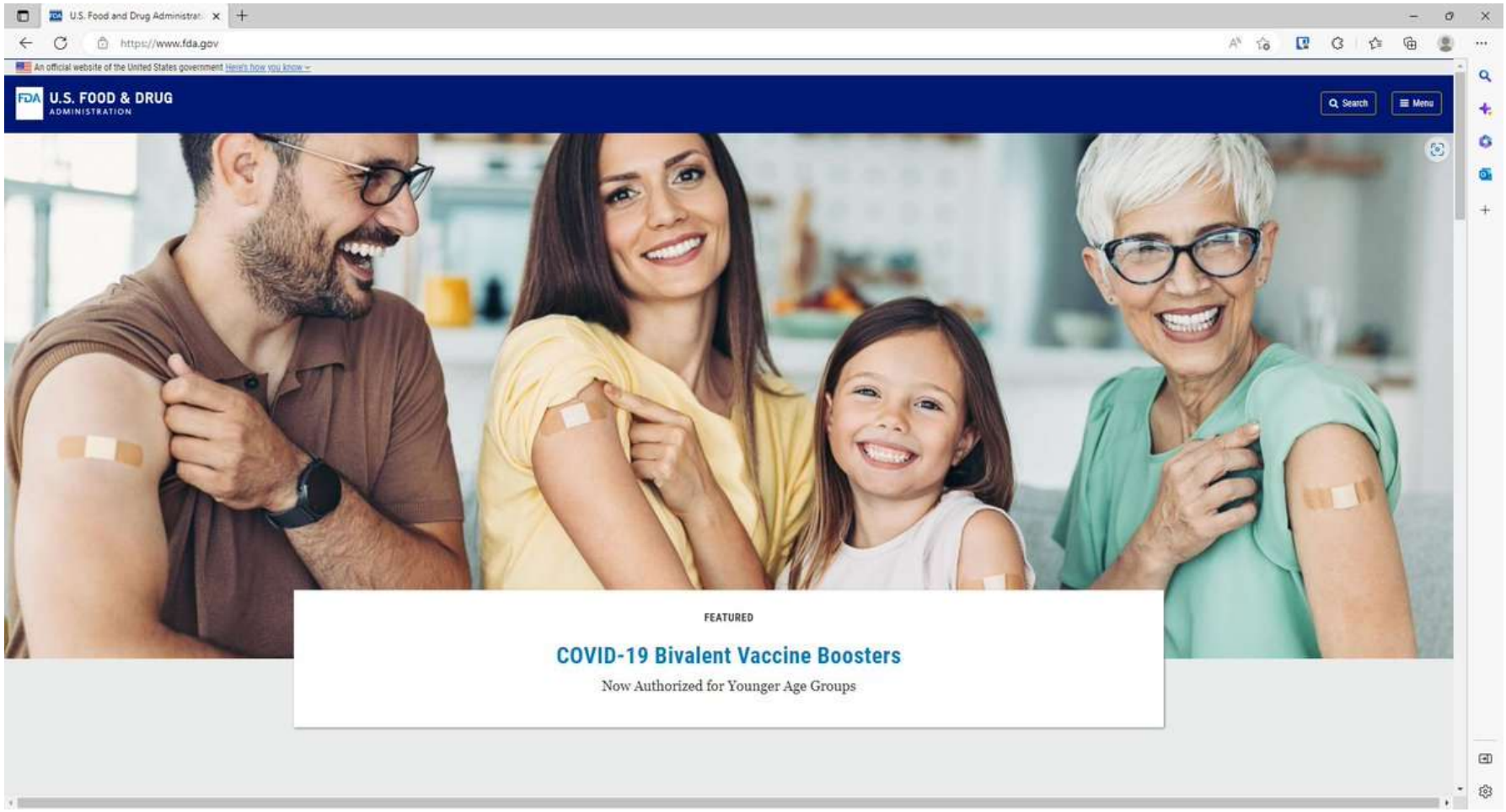


youtube.com

Why should I get the updated COVID-19 vaccine now? – Just a Minut...

There's a pretty good reason why you should get the updated COVID-19 vaccine now. Here's Dr. Peter Marks with more... #JustAMinute

CLINICAL TRIALS



CLINICAL TRIALS

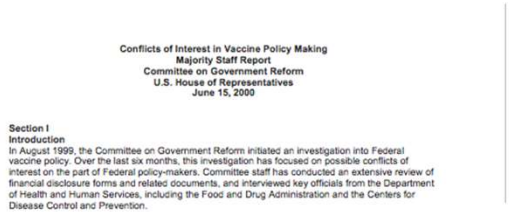
FDA Vaccine Advisory Committee

U.S. House Report (June 2000)

> **"The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."**

HHS Inspector General (December 2009)

> **"CDC had a systemic lack of oversight of the ethics program" including finding that "58 percent of [committee members] had potential conflicts of interest that CDC did not identify" and "32 percent … had potential conflicts of intertest that CDC identified but did not resolve."**



Conflicts of Interest in Vaccine Policy Making
Majority Staff Report
Committee on Government Reform
U.S. House of Representatives
June 15, 2000

Section I
Introduction
In August 1999, the Committee on Government Reform initiated an investigation into Federal vaccine policy. Over the last six months, this investigation has focused on possible conflicts of interest on the part of Federal policy-makers. Committee staff has conducted an extensive review of financial disclosure forms and related documents, and interviewed key officials from the Department of Health and Human Services, including the Food and Drug Administration and the Centers for Disease Control and Prevention.

This staff report focuses on two influential advisory committees ut
provide expert advice on vaccine policy:
1. The FDA's Vaccines and Related Biological Products Advisory
2. The CDC's Advisory Committee on Immunizations Practices (A

The VRBPAC advises the FDA on the licensing of new vaccines,
on guidelines to be issued to doctors and the states for the appro

Members of the advisory committees are required to disclose any
recuse themselves from participating in decisions in which they ha
investigation has determined that conflict of interest rules employe
been weak, enforcement has been lax, and committee members
pharmaceutical companies have been given waivers to participate
Among the specific problems identified in this staff report:

§ The CDC routinely grants waivers from conflict of interest rules
committee.

§ CDC Advisory Committee members who are not allowed to vote
to financial conflicts of interest are allowed to participate in commi
specific positions.

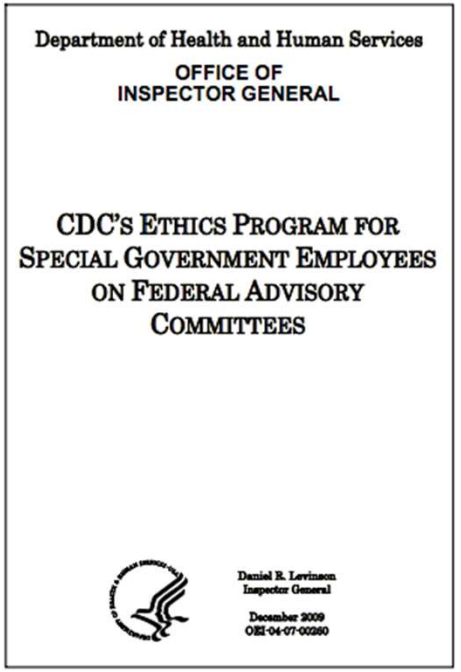
§ The Chairman of the CDC's advisory committee until very recen
Merck, a pharmaceutical company with an active vaccine division.

§ Members of the CDC's advisory Committee often fill out incompl
statements, and are not required to provide the missing informatio

§ Four out of eight CDC advisory committee members who voted
rotavirus vaccine in June 1998 had financial ties to pharmaceutica
different versions of the vaccine.

§ 3 out of 5 FDA advisory committee members who voted to appr
December 1997 had financial ties to pharmaceutical companies th
versions of the vaccine.

A more complete discussion of specific conflict of interest problem



Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

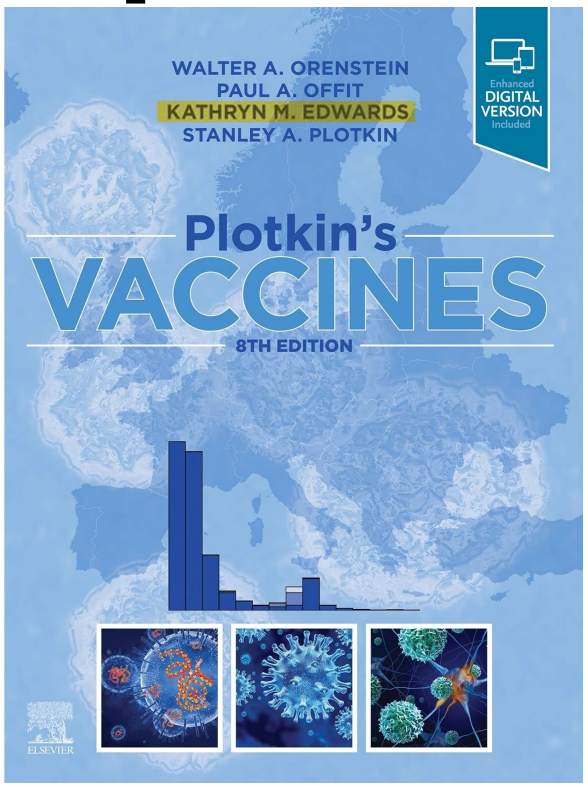
CDC'S ETHICS PROGRAM FOR SPECIAL GOVERNMENT EMPLOYEES ON FEDERAL ADVISORY COMMITTEES

Daniel R. Levinson
Inspector General

December 2009
OEI-04-07-00260

CLINICAL TRIALS

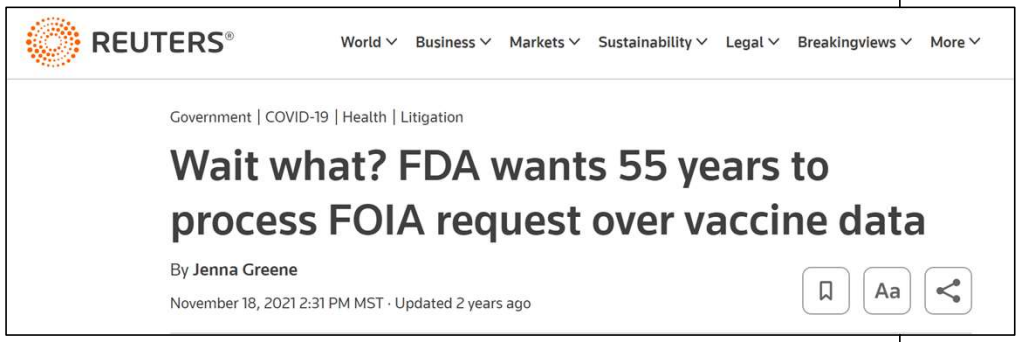
Independent Data Safety Monitoring Board for Pfizer C-19 Trial



Full Deposition: https://thehighwire.com/videos/the-deposition-of-the-godmother-of-vaccines-dr-kathryn-edwards/

CLINICAL TRIALS

FDA Wanted Decades to Release Clinical Trial Data



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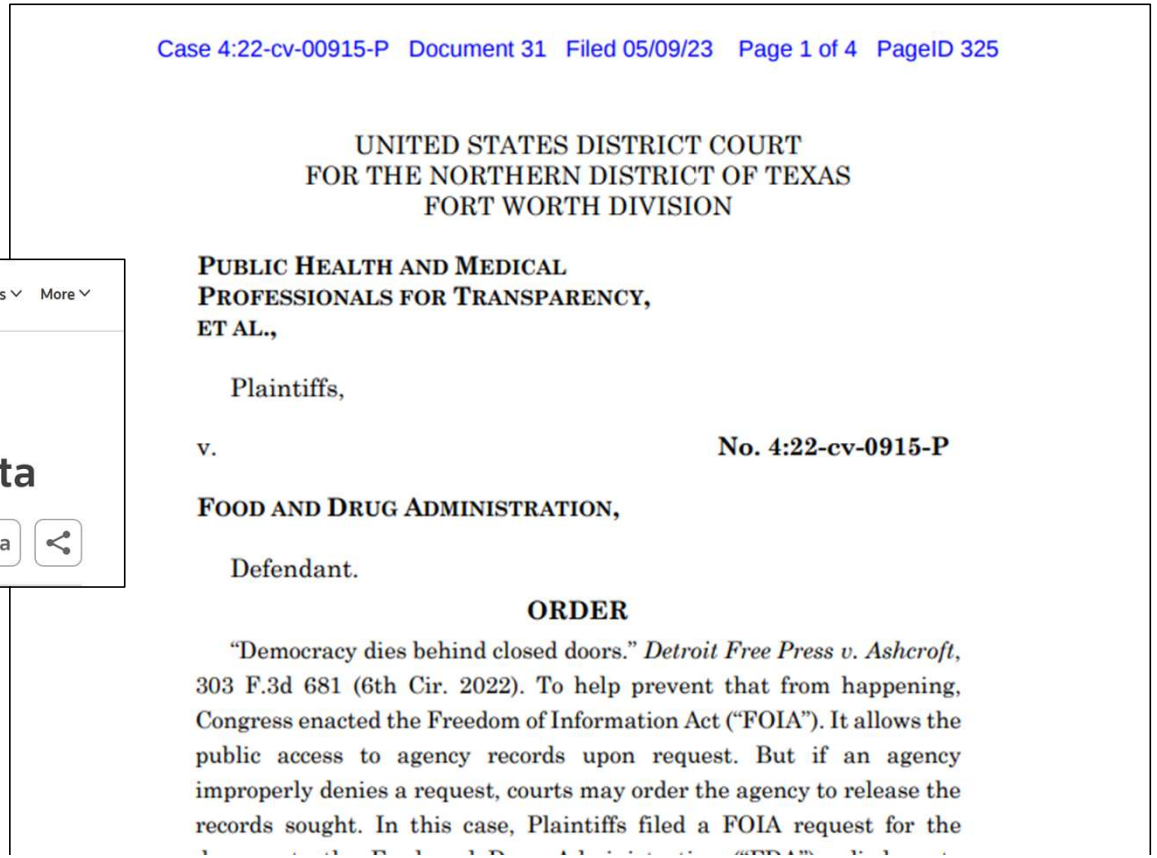
Wait what? FDA wants 55 years to process FOIA request over vaccine data

By Jenna Greene

November 18, 2021 2:31 PM MST · Updated 2 years ago



Case 4:22-cv-00915-P Document 31 Filed 05/09/23 Page 1 of 4 PageID 325

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, ET AL.,

Plaintiffs,

v. **No. 4:22-cv-0915-P**

FOOD AND DRUG ADMINISTRATION,

Defendant.

ORDER

"Democracy dies behind closed doors." *Detroit Free Press v. Ashcroft*, 303 F.3d 681 (6th Cir. 2022). To help prevent that from happening, Congress enacted the Freedom of Information Act ("FOIA"). It allows the public access to agency records upon request. But if an agency improperly denies a request, courts may order the agency to release the records sought. In this case, Plaintiffs filed a FOIA request for the

PART III:
COVID-19 VACCINES POST-LICENSURE SAFETY

POST-LICENSURE SAFETY

Maybe trials not great, but after licensure definitely studied, right?

POST-LICENSURE SAFETY

VAERS (Vaccine Adverse Events Reporting System)

CDC's Proportional Reporting Ratio (PRR) Analysis of VAERS's Data

2.3 Signal detection methods and data analyses

The analyses for COVID-19 vaccine safety signals will focus on identifying deviations from preliminary safety data, and possibly from other vaccines, using disproportionality analyses and comparisons of reporting rates.

Two main approaches to data mining are Proportional Reporting Ratios (PRRs) and Empirical Bayesian Geometric Means [11–13]. Both have published literature suggesting criteria for detecting "signals" [14]. PRR will be used at CDC for potential signal detection; Empirical Bayesian data mining will be performed by FDA.

https://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-4-Dec-2020-508.pdf (Dec 4, 2020)

POST-LICENSURE SAFETY

VAERS (Vaccine Adverse Events Reporting System)

When CDC's PRR data finally released:

2.3.1 Proportional Reporting Ratio (PRR)

CDC will perform PRR data mining on a weekly basis or as needed. PRRs compare the proportion of a specific AE following a specific vaccine versus the proportion of the same AE following receipt of another vaccine (see equation below Table 4). A safety signal is defined as a PRR of at least 2, chi-squared statistic of at least 4, and 3 or more cases of the AE following receipt of the specific vaccine of interest.

https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

N>=3 (Current Week), PRR>=2.00 (Ratio of

MedDRA Codes ALL Reports (18+)	12/14/2020-05/06/2022 COVID19 mRN N=632725	12/14-05/06 Chi-Square	12/14-05/06 PRR
CEREBRAL THROMBOSIS	194	69.78	73.46
INTERMENSTRUAL BLEEDING	1323	481.57	62.62
CEREBRAL VENOUS SINUS THROMBOSIS	155	55.02	58.69
HEAVY MENSTRUAL BLEEDING	4246	1543.71	53.59
INTENTIONAL PRODUCT USE ISSUE	141	49.72	53.39
POSITIVE AIRWAY PRESSURE THERAPY	789	283.64	49.79
PULMONARY THROMBOSIS	610	218.11	46.20
DISEASE RECURRENCE	227	79.98	42.98
HYPERPYREXIA	111	38.38	42.03
POSTMENOPAUSAL HAEMORRHAGE	521	184.41	39.46
POLYMENORRHOEA	684	241.57	37.00
RIGHT VENTRICULAR DYSFUNCTION	96	32.71	36.35
INTENTIONAL DOSE OMISSION	94	31.96	35.59
ABNORMAL UTERINE BLEEDING	82	27.43	31.05
OLIGOMENORRHOEA	564	196.16	30.51
CEREBELLAR STROKE	80	26.68	30.29
SUSPECTED COVID-19	550	190.86	29.75
CEREBRAL MASS EFFECT	75	24.79	28.40
RIGHT VENTRICULAR DILATATION	73	24.04	27.64
DYSMENORRHOEA	1821	631.80	27.58

2.3.1 Proportional Reporting Ratio (PRR)

CDC will perform PRR data mining on a weekly basis or as needed. PRRs compare the proportion of a specific AE following a specific vaccine versus the proportion of the same AE following receipt of another vaccine (see equation below Table 4). A safety signal is defined as a PRR of at least 2, chi-squared statistic of at least 4, and 3 or more cases of the AE following receipt of the specific vaccine of interest.

https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

MYOCARDIAL STRAIN	64	20.65	24.23
HAEMOFILTRATION	62	19.90	23.48
IMPLANTABLE CARDIAC MONITOR INSERTION	61	19.52	23.10
TRANSVERSE SINUS THROMBOSIS	60	19.15	22.72
MATERNAL EXPOSURE DURING BREAST FEEDING	292	97.84	22.11
BODY HEIGHT DECREASED	57	18.02	21.58
MENSTRUAL DISORDER	2435	822.34	20.96
MENSTRUATION IRREGULAR	3240	1094.66	20.79
MESENTERIC VEIN THROMBOSIS	54	16.90	20.45
NIH STROKE SCALE ABNORMAL	54	16.90	20.45
NIH STROKE SCALE	53	16.52	20.07
CORONARY ARTERY DISSECTION	52	16.15	19.69
JUGULAR VEIN THROMBOSIS	52	16.15	19.69
LEFT VENTRICULAR DILATATION	51	15.77	19.31
ANOSMIA	3546	1186.66	19.18
NEUROLOGIC NEGLECT SYNDROME	50	15.40	18.93
CEREBRAL ARTERY OCCLUSION	98	31.29	18.55
VITAL SIGNS MEASUREMENT	146	47.19	18.43
ILLNESS	4279	1423.54	18.21
INTRACARDIAC THROMBUS	95	30.16	17.99
LYMPHOPENIA	94	29.79	17.80
THROMBOEMBOLECTOMY	47	14.28	17.80
VACCINATION SITE URTICARIA	322	104.80	17.42
COR PULMONALE ACUTE	46	13.90	17.42
HEPATIC MASS	46	13.90	17.42
WRONG PATIENT	45	13.53	17.04
PREMENSTRUAL PAIN	44	13.16	16.66
PRODUCT RECONSTITUTION QUALITY ISSUE	44	13.16	16.66
TOTAL LUNG CAPACITY DECREASED	44	13.16	16.66
PERIPHERAL ARTERY OCCLUSION	43	12.78	16.28
ANTICOAGULANT THERAPY	3684	1204.20	16.22
COLON CANCER	41	12.04	15.53
SYMPTOM RECURRENCE	163	51.45	15.43
ACUTE CARDIAC EVENT	40	11.67	15.15
PERIPHERAL ARTERY THROMBOSIS	78	23.79	14.77
CARDIOVASCULAR SYMPTOM	39	11.29	14.77

POST-LICENSURE SAFETY

VAERS (Vaccine Adverse Events Reporting System)

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

September 5, 2023

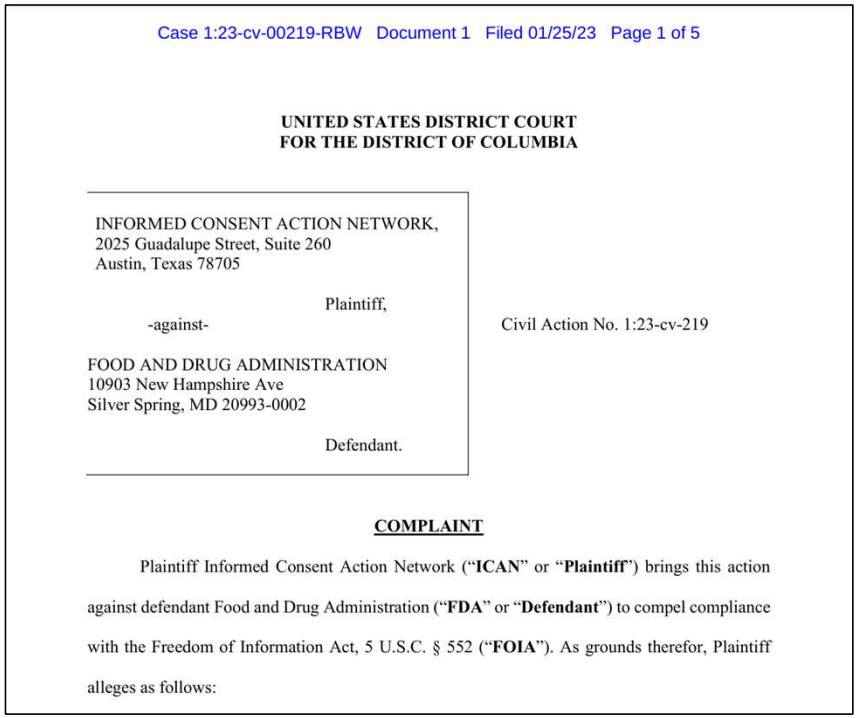
The January 2021 SOP described the types of data mining analyses CDC and FDA would conduct to identify potential safety concerns linked to the COVID-19 vaccines.[5] These analyses included Proportional Reporting Ratio (PRR) and empirical Bayesian (EB) data mining.[6] In a September 2, 2022 response to my requests, CDC Director Rochelle Walensky informed my office that:

> "CDC and the Food and Drug Administration (FDA) chose to rely on Empirical Bayesian (EB) data mining—a more robust technique used to analyze disproportionate reporting—rather than PRR calculations to mitigate potential false signals. . . . Given the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data mining moving forward."[7]

https://www.documentcloud.org/documents/23940343-sen-johnson-letter-to-fda-on-eb-data-mining

POST-LICENSURE SAFETY

VAERS (Vaccine Adverse Events Reporting System)



Case 1:23-cv-00219-RBW Document 1 Filed 01/25/23 Page 1 of 5

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK,
2025 Guadalupe Street, Suite 260
Austin, Texas 78705

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

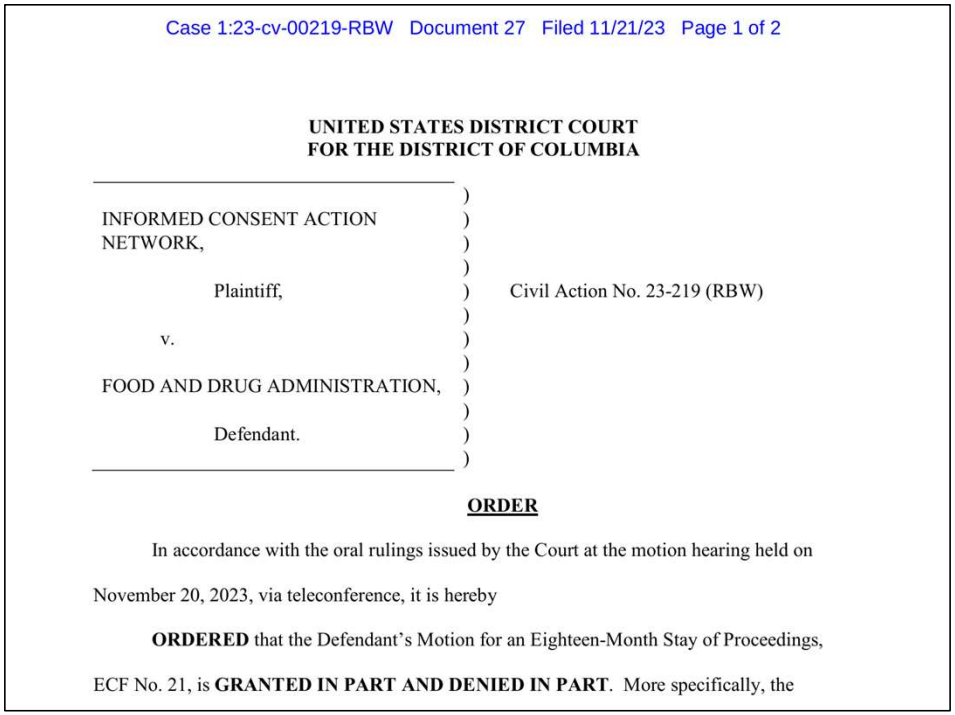
Defendant.

Civil Action No. 1:23-cv-219

COMPLAINT

Plaintiff Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") brings this action against defendant Food and Drug Administration ("**FDA**" or "**Defendant**") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("**FOIA**"). As grounds therefor, Plaintiff alleges as follows:

https://www.sirillp.com/wp-content/uploads/2024/05/Complaint-v-FDA-EB-data-mining-1be65fe02850d0112b041c8598f07daf.pdf



Case 1:23-cv-00219-RBW Document 27 Filed 11/21/23 Page 1 of 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 23-219 (RBW)

ORDER

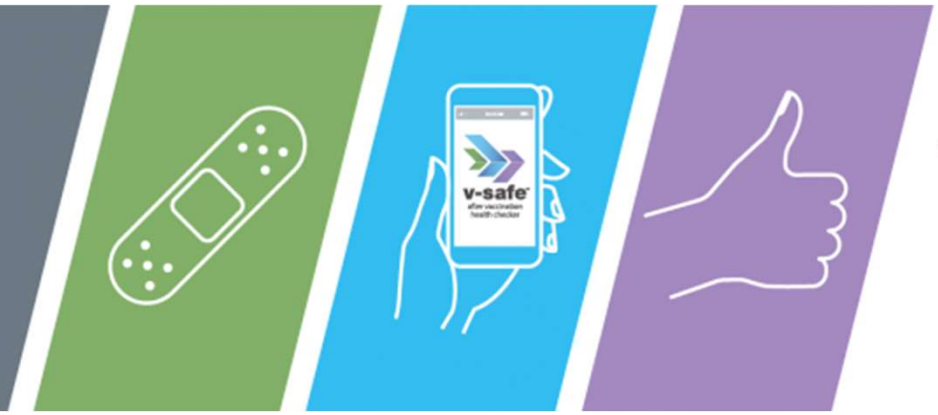
In accordance with the oral rulings issued by the Court at the motion hearing held on November 20, 2023, via teleconference, it is hereby

ORDERED that the Defendant's Motion for an Eighteen-Month Stay of Proceedings, ECF No. 21, is **GRANTED IN PART AND DENIED IN PART**. More specifically, the

https://www.sirillp.com/wp-content/uploads/2024/05/Court-Decision-and-Order-on-Stay-a277998ce28b0f644bf0dcd033f65e2a.pdf

POST-LICENSURE SAFETY

CDC

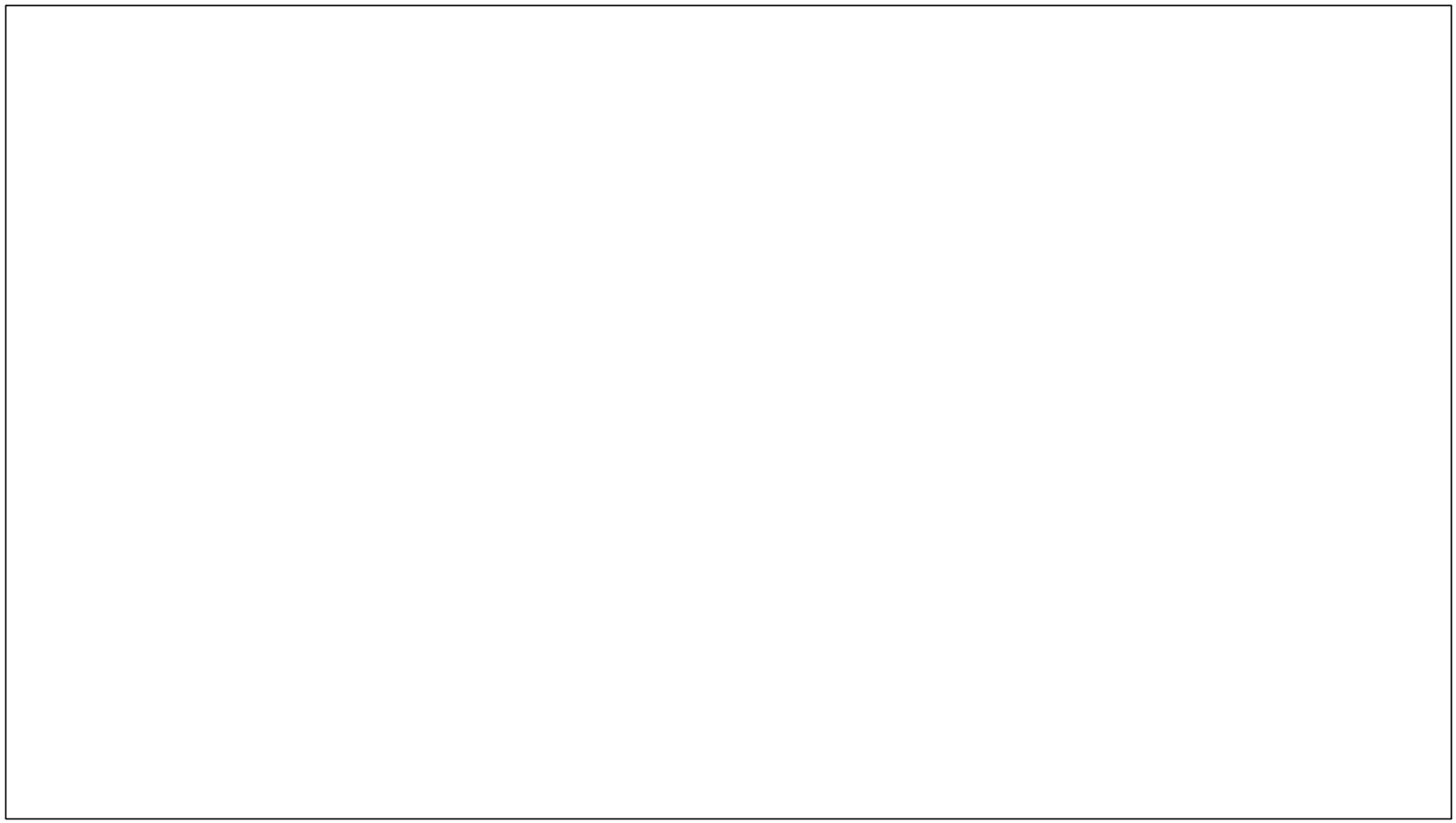


v-safe℠
after vaccination
health checker

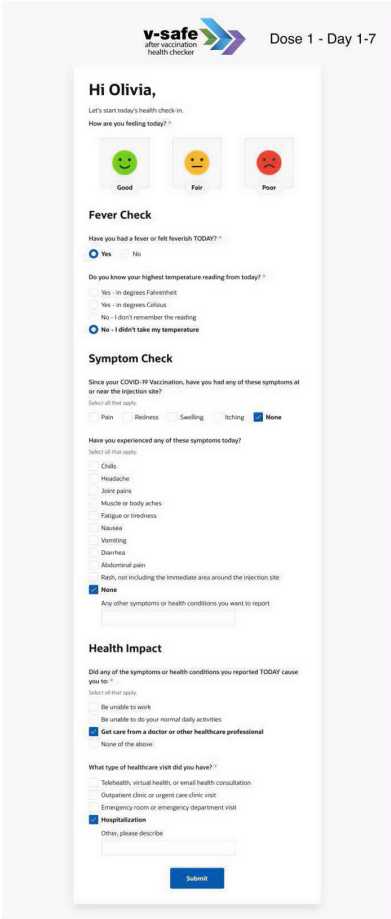
10,000,000+ Users

Benefits over VAERS and Clinical Trial Data

POST-LICENSURE SAFETY



POST-LICENSURE SAFETY



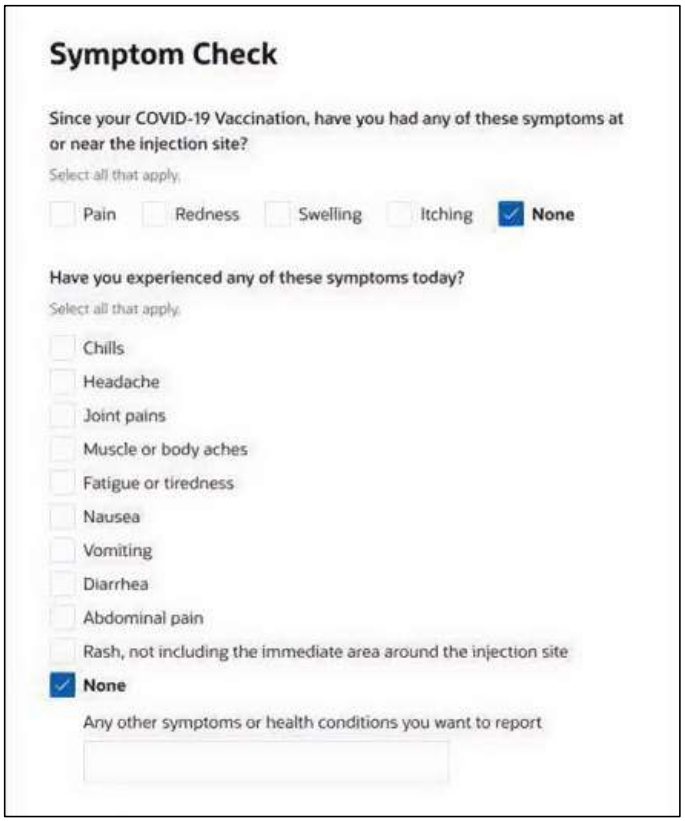
POST-LICENSURE SAFETY

v-safe℠ after vaccination health checker

Director of CDC Immunization Safety Office, Tom Shimabukuro:

"It's [v-safe] just not designed to directly monitor specific adverse events outside of reactogenic AEs [adverse events]."

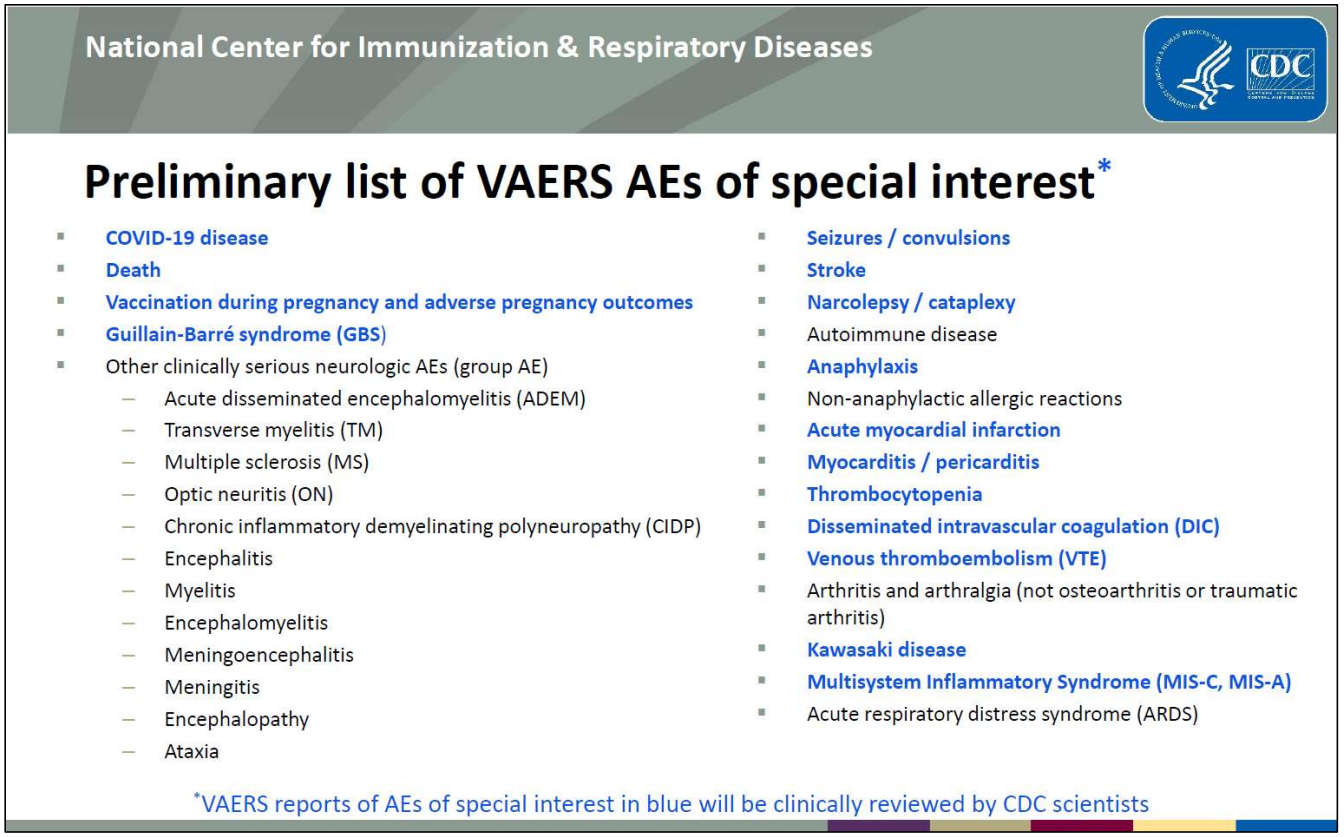
https://icandecide.org/wp-content/uploads/2023/05/IR0960C-2.pdf



Collect for 1 week after shot. ***What is it not asking?***

POST-LICENSURE SAFETY

October 2020
CDC Presentation



POST-LICENSURE SAFETY

November 19, 2020

CDC V-Safe Protocol

Version 1

Attachment 2: Adverse Events of Special Interest

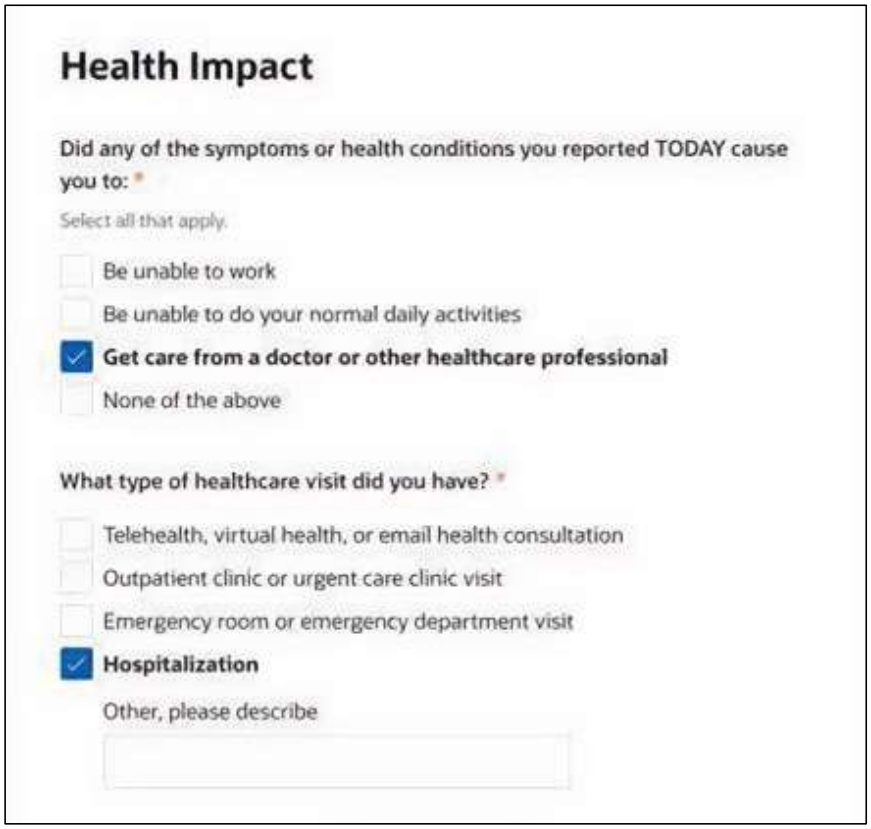
Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

https://icandecide.org/wp-content/uploads/2023/01/V-safe-Protocol-508-V1.pdf

POST-LICENSURE SAFETY

v-safe℠
after vaccination
health checker



Health Impact

Did any of the symptoms or health conditions you reported TODAY cause you to: *

Select all that apply.

- [ ] Be unable to work
- [ ] Be unable to do your normal daily activities
- [x] **Get care from a doctor or other healthcare professional**
- [ ] None of the above

What type of healthcare visit did you have? *

- [ ] Telehealth, virtual health, or email health consultation
- [ ] Outpatient clinic or urgent care clinic visit
- [ ] Emergency room or emergency department visit
- [x] **Hospitalization**

Other, please describe

POST-LICENSURE SAFETY

	Study Title	Link
1	Safety Monitoring of an Additional Dose of COVID-19 Vaccine - United States, August 12-September 19, 2021	https://pubmed.ncbi.nlm.nih.gov/34591835/
2	Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine - United States, March-April 2021	https://pubmed.ncbi.nlm.nih.gov/33956784/
3	Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines	https://pubmed.ncbi.nlm.nih.gov/33818592/
4	First Month of COVID-19 Vaccine Safety Monitoring - United States, December 14, 2020-January 13, 2021	https://pubmed.ncbi.nlm.nih.gov/33630816/
5	COVID-19 Vaccine Safety in Children Ages 5-11 years - United States, November 3-December 19, 2021.	https://pubmed.ncbi.nlm.nih.gov/34968370/
6	COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years - United States, December 14, 2020-July 16, 2021	https://pubmed.ncbi.nlm.nih.gov/34351881/
7	Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults - United States, September 22, 2021-February 6, 2022	https://pubmed.ncbi.nlm.nih.gov/35176008/
8	Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8901181/
9	Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9706403/
10	Safety Monitoring of COVID-19 mRNA Vaccine First Booster Doses Among Persons Aged =12 Years with Presumed Immunocompromise Status —	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9290389/
11	Safety Monitoring of COVID-19 Vaccine Booster Doses Among Persons Aged 12–17 Years — United States, December 9, 2021–February 20, 2022	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8893335/
12	Safety Monitoring of COVID-19 mRNA Vaccine Second Booster Doses Among Adults Aged =50 Years — United States, March 29, 2022–July 10, 2	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9345177/
13	Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 202	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9400528/
14	Association between history of SARS-CoV-2 infection and severe systemic adverse events after mRNA COVID-19 vaccination among U.S. adults	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9622386/
15	Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9287747/
16	Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9287747/
17	COVID-19 vaccine safety updateAdvisory Committee on Immunization Practices (ACIP)January 27, 2021	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf
18	COVID-19 vaccine safety update:Advisory Committee on Immunization Practices (ACIP)March 1, 2021	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
19	COVID-19 Vaccine safety updates: Advisory Committee on Immunization Practices (ACIP)	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf
20	Early safety monitoring for additional COVID-19 vaccine doses: Reports to VAERS and v-safe Advisory Committee on Immunization Practices Octo	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf
21	Safety monitoring of COVID-19 vaccine among children and young adults in v-safe Advisory Committee on Immunization Practices January 5, 2021	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/03-COVID-Hause-508.pdf
22	Safety update of 1st booster mRNA COVID-19 vaccination Advisory Committee on Immunization Practices (ACIP) April 20, 2022	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/03-COVID-Klein-Shimabukuro-508.pdf
23	COVID-19 vaccine safety updates: Primary series in children ages 5–11 years Advisory Committee on Immunization Practices (ACIP) May 19, 2022	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/03-COVID-Shimabukuro-508.pdf
24	COVID-19 vaccine safety update: Primary series in young children and booster doses in older children and adults	https://stacks.cdc.gov/view/cdc/120824
25	Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Persons Aged =12 Years — United States, August 31–October 23, 2	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9639436/
26	Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1,	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9869731/
27	Reactogenicity within 2 weeks after mRNA COVID-19 vaccines: Findings from the CDC v-safe surveillance system.	https://pubmed.ncbi.nlm.nih.gov/34763946/
28	Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	https://pubmed.ncbi.nlm.nih.gov/33882218/
29	Menstrual irregularities and vaginal bleeding after COVID-19 vaccination reported to v-safe active surveillance, USA in December, 2020–January, 202	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9363036/
30	Current Data on COVID-19 mRNA-Vaccine Safety during Pregnancy Might Be Subject to Selection Bias. Reply to Stroobandt, S.; Stroobandt, R. Dat	https://pubmed.ncbi.nlm.nih.gov/34452411/
31	Monitoring the safety of COVID-19 vaccines in pregnancy in the US	https://pubmed.ncbi.nlm.nih.gov/34756131/
32	Primer of COVID-19 Vaccines for the Perioperative Physician	https://pubmed.ncbi.nlm.nih.gov/34870630/
33	Readability of COVID-19 vaccine information for the general public	https://pubmed.ncbi.nlm.nih.gov/35534313/
34	The v-safe after vaccination health checker: Active vaccine safety monitoring during CDC's COVID-19 pandemic response	https://pubmed.ncbi.nlm.nih.gov/36697313/
35	Data of the COVID-19 mRNA-Vaccine V-Safe Surveillance System and Pregnancy Registry Reveals Poor Embryonic and Second Trimester Fetal Surv	https://pubmed.ncbi.nlm.nih.gov/34452410/
36	Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization	https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm
37	Update on myocarditis following mRNA COVID-19 vaccination Advisory Committee on Immunization Practices (ACIP) June 23, 2022	https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/03-covid-shimabukuro-508.pdf
38	CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion	https://pubmed.ncbi.nlm.nih.gov/34496196/
39	COVID-19 vaccine safety in pregnancy : updates from the v-safe COVID-19 vaccine pregnancy registry	https://stacks.cdc.gov/view/cdc/110034
40	Receipt of mRNA COVID-19 vaccines preconception and during pregnancy and risk of self-reported spontaneous abortions, CDC v-safe COVID-19	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8366802/

POST-LICENSURE SAFETY

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

CENTERS FOR DISEASE CONTROL AND PREVENTION AND HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 1:22-cv-481

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, as for its Complaint regarding a Freedom of Information Act request against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. Between December 2020 and February 2021, the Food and Drug Administration ("**FDA**") issued Emergency Use Authorizations for three COVID-19 vaccines,[1] one of which subsequently received FDA approval in August 2021 and another on January 31, 2022.[2] While the FDA approved these vaccines, the Centers for Disease Control and Prevention ("**CDC**"), an agency within the Department of Health and Human Services ("**HHS**"), is charged with

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

CENTERS FOR DISEASE CONTROL AND PREVENTION AND HEALTH AND HUMAN SERVICES,

Defendants.

Civil Action No. 1:21-cv-1179

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, as for its Complaint regarding Freedom of Information Act requests against the above-captioned Defendants, alleges as follows:

INTRODUCTION

1. Between December 2020 and February 2021, the Food and Drug Administration ("**FDA**") issued Emergency Use Authorizations for three COVID-19 vaccines,[1] one of which subsequently received FDA approval in August 2021.[2] While the FDA approved these vaccines,

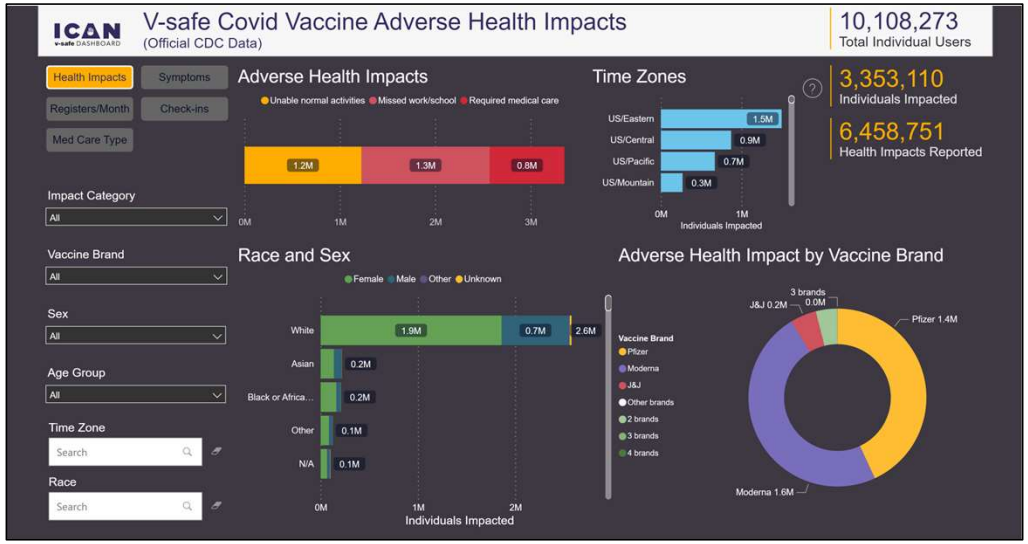
POST-LICENSURE SAFETY

7.7% Needed Medical Care

-4.2% in First 6 Weeks

-3 in 4 were hospitalized or needed emergency room or urgent care

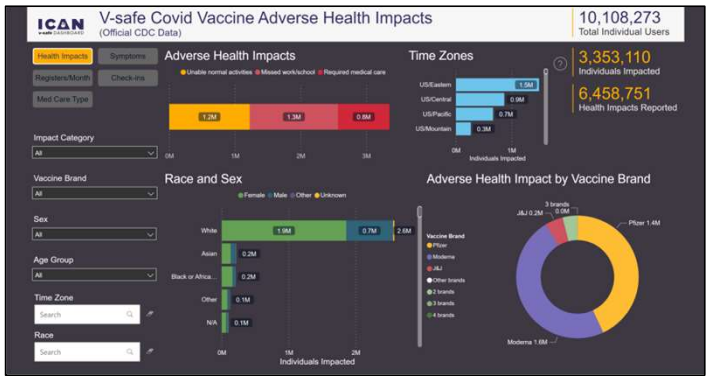
32% Missed School/Work or were Unable to Perform Normal Daily Activities



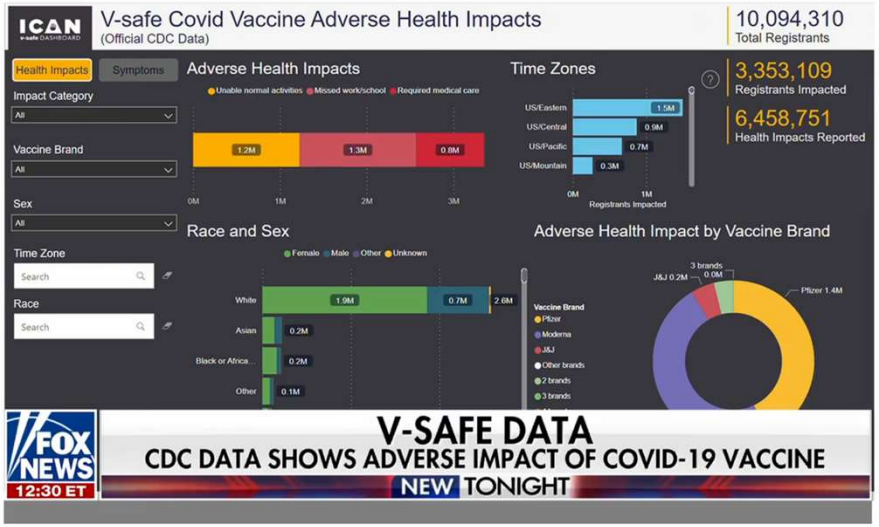
icandecide.org/v-safe-data

POST-LICENSURE SAFETY

icandecide.org/v-safe-data



POST-LICENSURE SAFETY



REUTERS®

https://aaronsiri.substack.com/p/v-safe-part-8-cdc-falsely-claims

POST-LICENSURE SAFETY

Percent of v-safe users 3 years and older reporting seeking medical care after first dose of Pfizer covid vaccine in succeeding time intervals:

Time Interval	Percentage Reported Seeking Medical Care
Days 1 to 7	.32%
Days 8 to 14	.67%
Days 15 to 21	1.06%
Days 22 to 28	2.88%
Days 29 to 35	4.96%
Days 36 to 42	6.93%

POST-LICENSURE SAFETY

One group alone has 36,000+ Americans seriously injured from Covid-19 vaccines

PART IV:
COVID-19 VACCINES: TRANSMISSION

TRANSMISSION

THE ARGUMENT MADE FOR WHY GOV'T CAN CRUSH CIVIL & INDIVIDUAL RIGHTS AND MANDATE VACCINES IS THEY….

PREVENT TRANSMISSION!

TRANSMISSION

Regulators acted surprised that Covid-19 vaccines did not prevent transmission

Should they have been?

TRANSMISSION

AGAIN, THE VACCINES PRECEDING COVID ARE INSTRUCTIVE.

Utah Department of Health & Human Services

Immunization Requirements
Kindergarten Entry 2024-2025

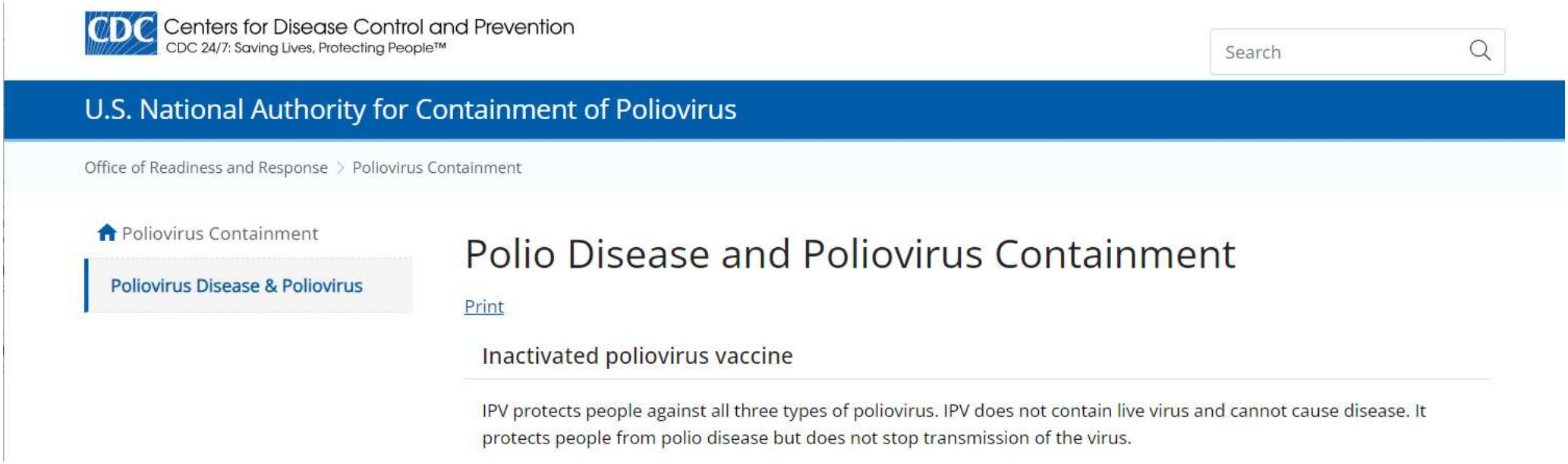
To attend kindergarten, a student *must have written proof* of receiving the following immunizations:

- **5 DTaP/DT**
- **4 Polio**
- **2 Measles, Mumps, Rubella (MMR)**
- **3 Hepatitis B**
- **2 Hepatitis A**
- **2 Varicella (chickenpox)**

Recommended for children 5 years and older but not required for school entry in Utah:

- **Influenza**
- **COVID-19**

TRANSMISSION



https://www.cdc.gov/orr/polioviruscontainment/diseaseandvirus.htm

TRANSMISSION

Disadvantages

- IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the faeces, risking continued circulation.

  IPV does not stop transmission of the virus

https://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/

TRANSMISSION

Diphtheria Immunization

Effect Upon Carriers and the Control of Outbreaks

Louis W. Miller, MD; J. Justin Older, MD; James Drake; and Sherwood Zimmerman, Austin, Tex

A diphtheria epidemic in a small central Texas community centered in the elementary school. Epidemiological investigation at the school included throat cultures and immunization histories of 306 of the 310 students and staff. Of these, 104 (34%) had culture-proven diphtheria infections; 15 were symptomatic cases and 89 were carriers. There was no statistical difference in the risk of diphtheria infection among those with full, lapsed, inadequate, or no previous diphtheria immunizations. However, the risk of symptomatic diphtheria was 30 times as great for those with none, and 11.5 times as great for those with inadequate immunizations as for those fully immunized. Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection. Identifying, isolating, and treating carriers are very important aspects in the control of diphtheria outbreaks.

With the increase in the number of cases of diphtheria in the United States during the past few years, the effect of immunization on the control of outbreaks has become an important question. In the Austin, Tex, diphtheria epidemic of 1967-1969[1] cases continued to occur despite the administration of 155,200 doses of diphtheria toxoid and the concomitant rise in immunization levels of school age children from 68% to 89%. Data from the Austin outbreak suggested that a large reservoir of carriers was important in the continued transmission of *Corynebacterium diphtheriae*. Other diphtheria outbreaks have shown that epidemics occur in populations with high immunization levels.[2-4] A diphtheria outbreak in an elementary school in Elgin, Tex, in the spring of 1970 provided an opportunity to study the effects of immunization on carriers and on the control of an epidemic situation.

Table 1.—Definitions of Immunization Status*

Status	Definition
Full	Primary series (three or more injections), or a primary series plus a booster, completed within ten years.
Lapsed	Primary series, or a primary series plus booster, completed more than ten years ago.
Inadequate	Uncompleted primary series (less than three injections) at any time.
None	No diphtheria toxoid ever received.

* Adapted from the Center for Disease Control.[5]

Materials and Methods

When it became obvious in the Elgin diphtheria epidemic (Older JJ et al, unpublished data) that cases were clustered in the elementary school, a special throat culture and immunization survey was begun there. Throat cultures were obtained from and immunization status was determined for 306 of 310 students and staff. Throat swabs were taken on three separate occasions from each person: April 7, April 17, and May 4. These were streaked on Loeffler blood serum or Pai medium and incubated overnight. Cystine tellurite blood agar and Tinsdale medium were used for isolation, Elek-King agar diffusion plates were used for toxigenicity determination.

Immunization status information was

Received for publication Oct 11, 1971; accepted Dec 6.

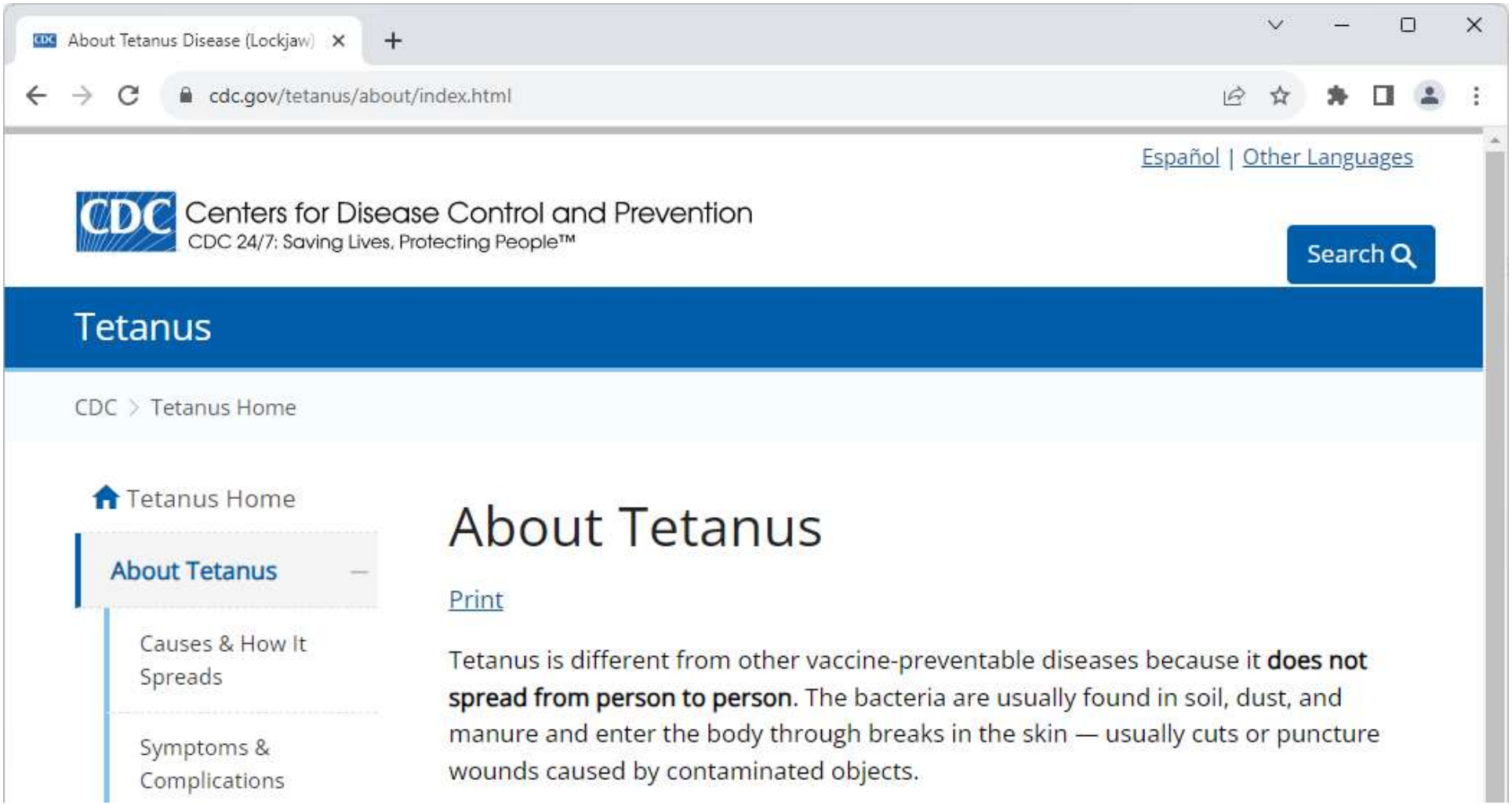
From the Epidemiology Program Center for Disease Control, Atlanta (Drs. Miller, Older, Drake, and Zimmerman); the Communicable Disease Services, Texas State Department of Health, Austin (Drs. Miller, Older, Drake, and Zimmerman); and the Department of Preventive Medicine, University of Maryland School of Medicine, Baltimore (Dr. Miller).

Reprint requests to Epidemiology Program, Center for Disease Control, Atlanta 30333.

"Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection … [T]he known importance of carriers in the spread of diphtheria, and the demonstrated failure of toxoid to prevent the carrier state lead us to conclude that the concept of herd immunity is not applicable in the prevention of diphtheria."

https://www.ncbi.nlm.nih.gov/pubmed/5026197

TRANSMISSION



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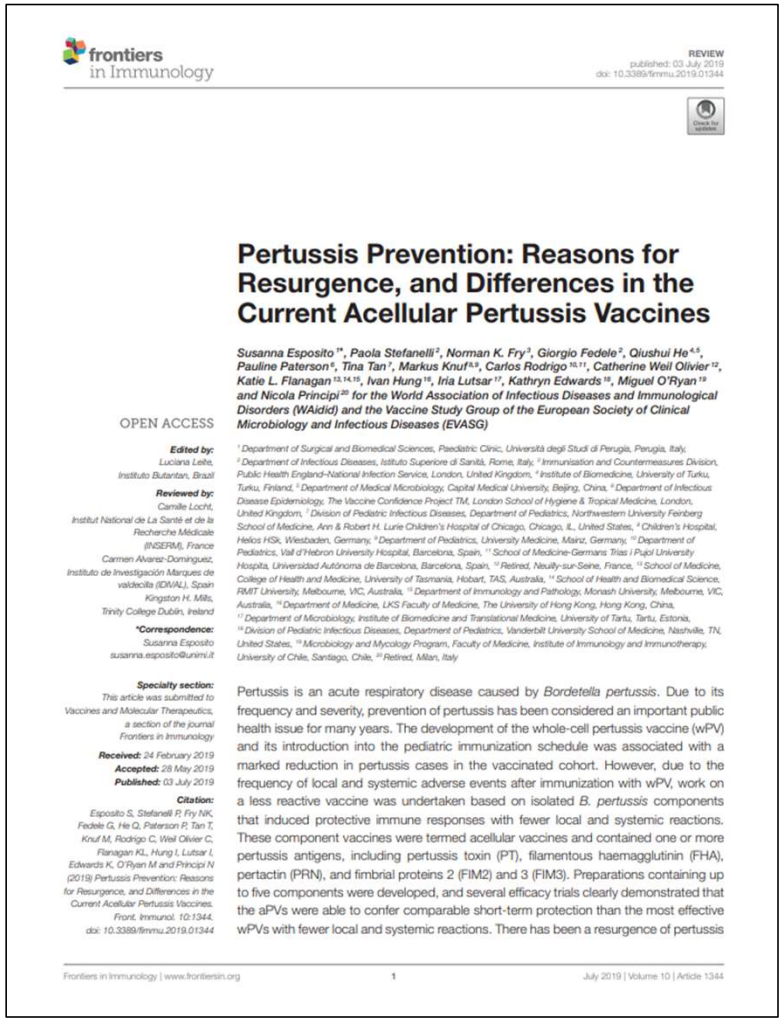

frontiers in Immunology

REVIEW
published: 03 July 2019
doi: 10.3389/fimmu.2019.01344

Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines

Susanna Esposito[1], Paola Stefanelli[2], Norman K. Fry[3], Giorgio Fedele[2], Qiushui He[4,5], Pauline Paterson[6], Tina Tan[7], Markus Knuf[8,9], Carlos Rodrigo[10,11], Catherine Weil Olivier[12], Katie L. Flanagan[13,14,15], Ivan Hung[16], Iria Lutsar[17], Kathryn Edwards[18], Miguel O'Ryan[19] and Nicola Principi[20] for the World Association of Infectious Diseases and Immunological Disorders (WAidid) and the Vaccine Study Group of the European Society of Clinical Microbiology and Infectious Diseases (EVASG)*

OPEN ACCESS

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Esposito S, Stefanelli P, Fry NK, Fedele G, He Q, Paterson P, Tan T, Knuf M, Rodrigo C, Weil Olivier C, Flanagan KL, Hung I, Lutsar I, Edwards K, O'Ryan M and Principi N (2019) Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines. Front. Immunol. 10:1344. doi: 10.3389/fimmu.2019.01344

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Pertussis is an acute respiratory disease caused by *Bordetella pertussis*. Due to its frequency and severity, prevention of pertussis has been considered an important public health issue for many years. The development of the whole-cell pertussis vaccine (wPV) and its introduction into the pediatric immunization schedule was associated with a marked reduction in pertussis cases in the vaccinated cohort. However, due to the frequency of local and systemic adverse events after immunization with wPV, work on a less reactive vaccine was undertaken based on isolated *B. pertussis* components that induced protective immune responses with fewer local and systemic reactions. These component vaccines were termed acellular vaccines and contained one or more pertussis antigens, including pertussis toxin (PT), filamentous haemagglutinin (FHA), pertactin (PRN), and fimbrial proteins 2 (FIM2) and 3 (FIM3). Preparations containing up to five components were developed, and several efficacy trials clearly demonstrated that the aPVs were able to confer comparable short-term protection than the most effective wPVs with fewer local and systemic reactions. There has been a resurgence of pertussis

"aPVs [pertussis vaccine] … cannot avoid infection and transmission. … aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect."

https://pubmed.ncbi.nlm.nih.gov/31333640/

TRANSMISSION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

December 30, 2021

Elizabeth Brehm
Siri & Glimstad
200 Park Ave, 17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Brehm:

This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of September 28, 2020, assigned #20-02418-FOIA, for:

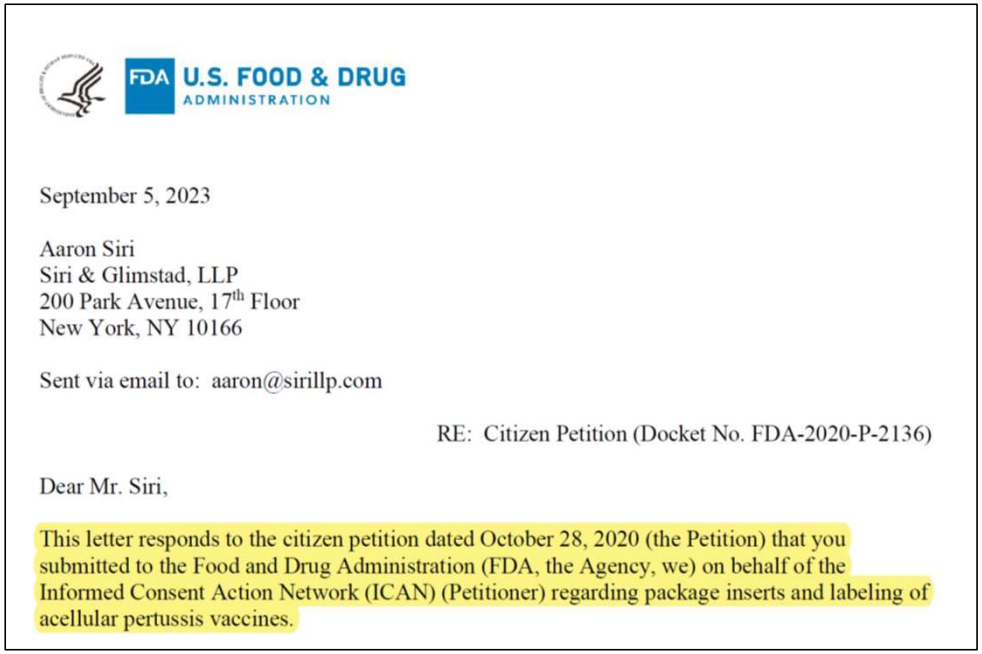
> *"Documents sufficient to reflect that acellular pertussis vaccines, while reducing symptoms from pertussis, do not prevent infection and transmission."*

Published scientific literature was used to inform the sentence in question ("Acellular pertussis vaccines may not prevent colonization (carrying the bacteria in your body without getting sick or spread of the bacteria."). For administrative convenience and to fully respond to your request, program staff have provided examples of literature that support the content of this sentence below.

Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model.
https://pubmed.ncbi.nlm.nih.gov/24277828/

Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines
https://pubmed.ncbi.nlm.nih.gov/31333640/

TRANSMISSION



FDA U.S. FOOD & DRUG ADMINISTRATION

September 5, 2023

Aaron Siri
Siri & Glimstad, LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Sent via email to: aaron@sirillp.com

RE: Citizen Petition (Docket No. FDA-2020-P-2136)

Dear Mr. Siri,

This letter responds to the citizen petition dated October 28, 2020 (the Petition) that you submitted to the Food and Drug Administration (FDA, the Agency, we) on behalf of the Informed Consent Action Network (ICAN) (Petitioner) regarding package inserts and labeling of acellular pertussis vaccines.

https://icandecide.org/wp-content/uploads/2023/10/Highlighted-FDA-Response-Pertussis-Vaccine-Not-Prevent-Infection-and-Transmission.pdf

TRANSMISSION

Reducing symptoms while remaining able to transmit makes one more likely to transmit.

TRANSMISSION

Do we exclude those vaccinated for pertussis from work/school/military?

OF COURSE NOT!

TRANSMISSION

Could have tested whether Covid-19 vaccines prevent transmission in the clinical trials – but didn't.

Asked millions of Americans to test regularly but couldn't have the clinical trial participants do the same?

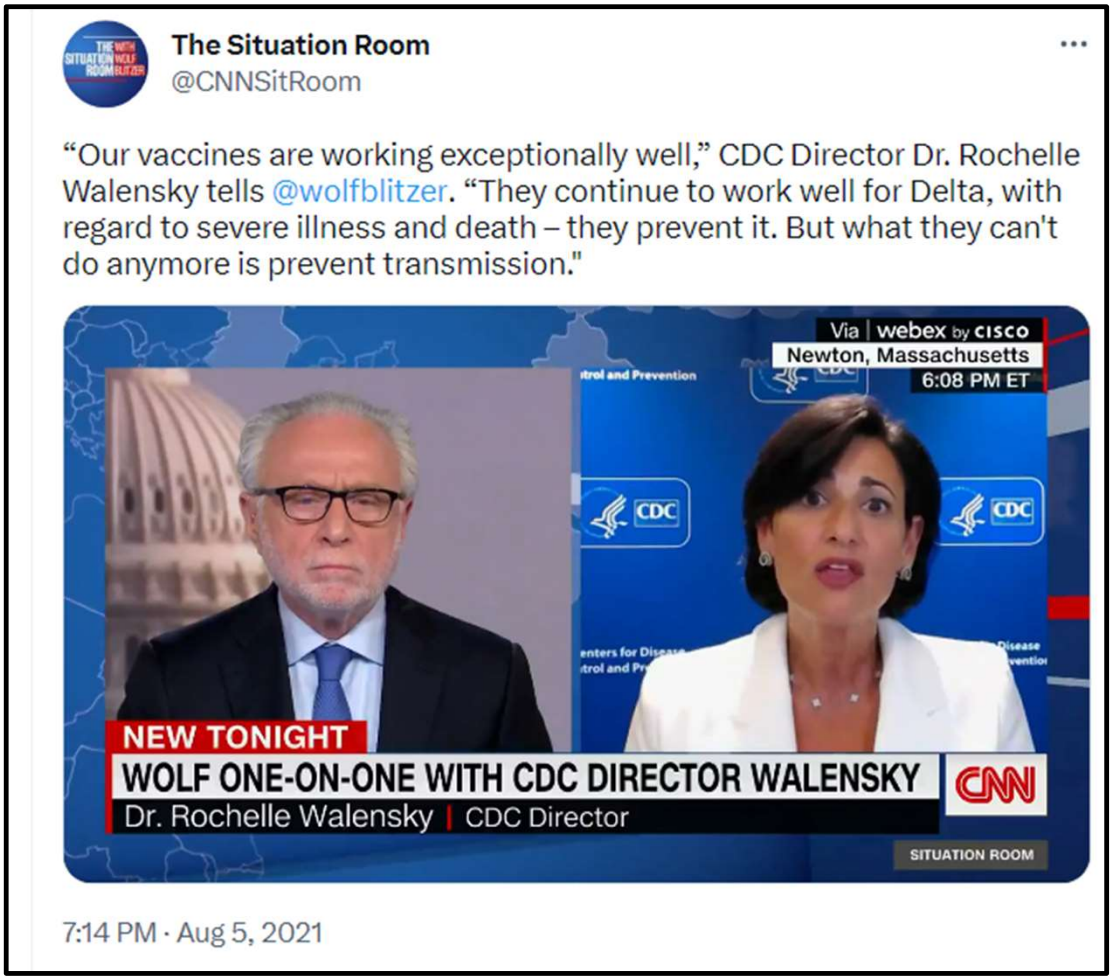
TRANSMISSION

"FDA's authorization and licensure standards for vaccines do not require demonstration of the prevention of infection or transmission"
https://www.regulations.gov/docket/FDA-2023-P-0360/document

FDA's authorizations and licensures for Covid-19 vaccines never said prevent transmission.

TRANSMISSION

AUGUST 5, 2021



https://twitter.com/CNNSitRoom/status/1423422301882748929

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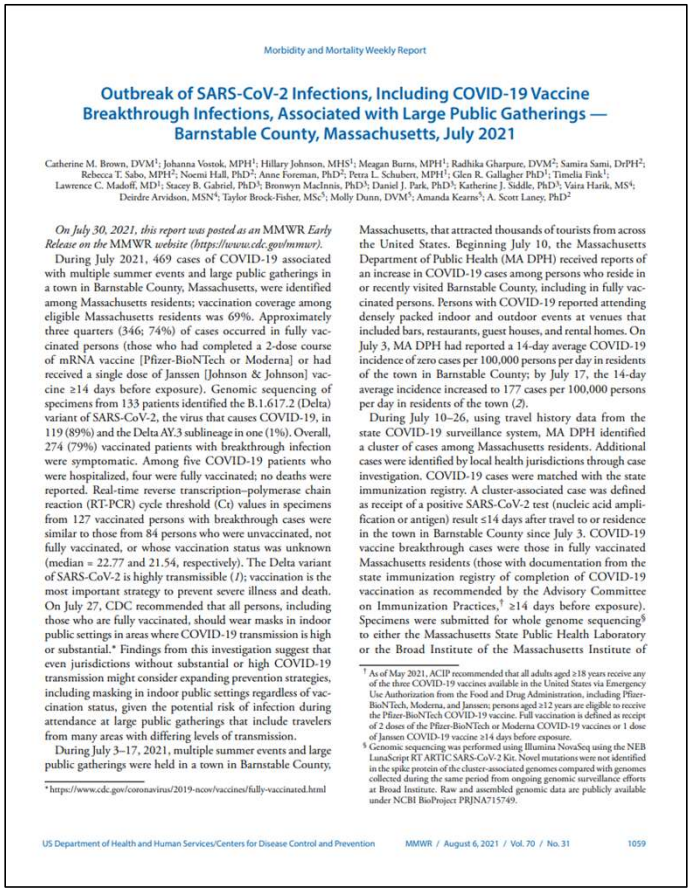


Morbidity and Mortality Weekly Report

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

Catherine M. Brown, DVM[1]; Johanna Vostok, MPH[1]; Hillary Johnson, MHS[1]; Meagan Burns, MPH[1]; Radhika Gharpure, DVM[2]; Samira Sami, DrPH[2]; Rebecca T. Sabo, MPH[2]; Noemi Hall, PhD[2]; Anne Foreman, PhD[2]; Petra L. Schubert, MPH[1]; Glen R. Gallagher PhD[1]; Timelia Fink[1]; Lawrence C. Madoff, MD[1]; Stacey B. Gabriel, PhD[3]; Bronwyn MacInnis, PhD[3]; Daniel J. Park, PhD[3]; Katherine J. Siddle, PhD[3]; Vaira Harik, MS[4]; Deirdre Arvidson, MSN[4]; Taylor Brock-Fisher, MSc[5]; Molly Dunn, DVM[5]; Amanda Kearns[5]; A. Scott Laney, PhD[2]

On July 30, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts, were identified among Massachusetts residents; vaccination coverage among eligible Massachusetts residents was 69%. Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons (those who had completed a 2-dose course of mRNA vaccine [Pfizer-BioNTech or Moderna] or had received a single dose of Janssen [Johnson & Johnson] vaccine ≥14 days before exposure). Genomic sequencing of specimens from 133 patients identified the B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, in 119 (89%) and the Delta AY.3 sublineage in one (1%). Overall, 274 (79%) vaccinated patients with breakthrough infection were symptomatic. Among five COVID-19 patients who were hospitalized, four were fully vaccinated; no deaths were reported. Real-time reverse transcription–polymerase chain reaction (RT-PCR) cycle threshold (Ct) values in specimens from 127 vaccinated persons with breakthrough cases were similar to those from 84 persons who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median = 22.77 and 21.54, respectively). The Delta variant of SARS-CoV-2 is highly transmissible (*1*); vaccination is the most important strategy to prevent severe illness and death. On July 27, CDC recommended that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial.* Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

During July 3–17, 2021, multiple summer events and large public gatherings were held in a town in Barnstable County, Massachusetts, that attracted thousands of tourists from across the United States. Beginning July 10, the Massachusetts Department of Public Health (MA DPH) received reports of an increase in COVID-19 cases among persons who reside in or recently visited Barnstable County, including in fully vaccinated persons. Persons with COVID-19 reported attending densely packed indoor and outdoor events at venues that included bars, restaurants, guest houses, and rental homes. On July 3, MA DPH had reported a 14-day average COVID-19 incidence of zero cases per 100,000 persons per day in residents of the town in Barnstable County; by July 17, the 14-day average incidence increased to 177 cases per 100,000 persons per day in residents of the town (*2*).

During July 10–26, using travel history data from the state COVID-19 surveillance system, MA DPH identified a cluster of cases among Massachusetts residents. Additional cases were identified by local health jurisdictions through case investigation. COVID-19 cases were matched with the state immunization registry. A cluster-associated case was defined as receipt of a positive SARS-CoV-2 test (nucleic acid amplification or antigen) result ≤14 days after travel to or residence in the town in Barnstable County since July 3. COVID-19 vaccine breakthrough cases were those in fully vaccinated Massachusetts residents (those with documentation from the state immunization registry of completion of COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices,† ≥14 days before exposure). Specimens were submitted for whole genome sequencing§ to either the Massachusetts State Public Health Laboratory or the Broad Institute of the Massachusetts Institute of

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html

† As of May 2021, ACIP recommended that all adults aged ≥18 years receive any of the three COVID-19 vaccines available in the United States via Emergency Use Authorization from the Food and Drug Administration, including Pfizer-BioNTech, Moderna, and Janssen; persons aged ≥12 years are eligible to receive the Pfizer-BioNTech COVID-19 vaccine. Full vaccination is defined as receipt of 2 doses of the Pfizer-BioNTech or Moderna COVID-19 vaccines or 1 dose of Janssen COVID-19 vaccine ≥14 days before exposure.

§ Genomic sequencing was performed using Illumina NovaSeq using the NEB LunaScript RT ARTIC SARS-CoV-2 Kit. Novel mutations were not identified in the spike protein of the cluster-associated genomes compared with genomes collected during the same period from ongoing genomic surveillance efforts at Broad Institute. Raw and assembled genomic data are publicly available under NCBI BioProject PRJNA715749.

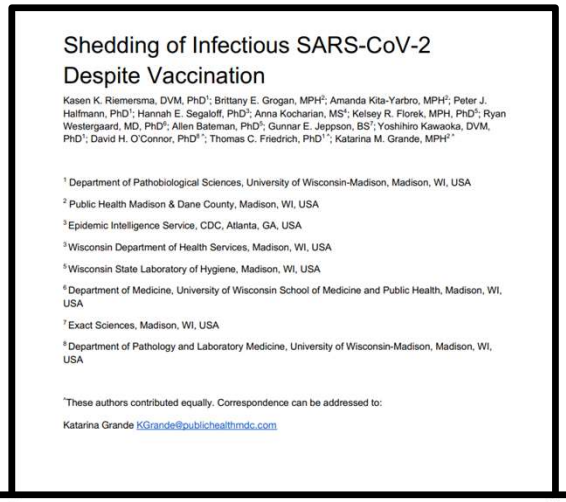
August 6, 2021 – CDC Study

- CDC carefully studied an outbreak in Barnstable County, MA which had a 69% vaccination rate among eligible residents.

- CDC found:
  - 74% of those infected in the outbreak were fully vaccinated Covid-19 and
  - the vaccinated had on average more virus in their nasal cavity than the unvaccinated that were infected.

https://pubmed.ncbi.nlm.nih.gov/34351882/

TRANSMISSION



Shedding of Infectious SARS-CoV-2 Despite Vaccination

Kasen K. Riemersma, DVM, PhD[1]; Brittany E. Grogan, MPH[2]; Amanda Kita-Yarbro, MPH[2]; Peter J. Halfmann, PhD[1]; Hannah E. Segaloff, PhD[3]; Anna Kocharian, MS[4]; Kelsey R. Florek, MPH, PhD[5]; Ryan Westergaard, MD, PhD[6]; Allen Bateman, PhD[5]; Gunnar E. Jeppson, BS[7]; Yoshihiro Kawaoka, DVM, PhD[1]; David H. O'Connor, PhD[8,*]; Thomas C. Friedrich, PhD[1,*]; Katarina M. Grande, MPH[2,*]

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[2] Public Health Madison & Dane County, Madison, WI, USA

[3] Epidemic Intelligence Service, CDC, Atlanta, GA, USA

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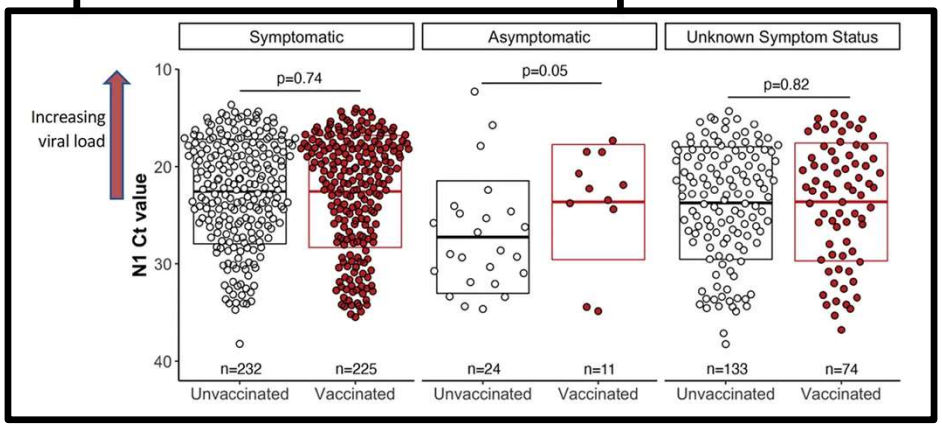
[8] Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA

[*] These authors contributed equally. Correspondence can be addressed to:

Katarina Grande KGrande@publichealthmdc.com



August 24, 2021 – WI DOH/CDC Study

- Reviewed swab specimens in 24 counties.
- High viral load in "158 of 232 unvaccinated (68%…) and 156 of 225 fully vaccinated (69%…) symptomatic individuals."
- High viral loads in "7 of 24 unvaccinated (29%…) and 9 of 11 fully vaccinated asymptomatic individuals (82%…)."

https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf

TRANSMISSION

Dozens of large studies followed all showing the same thing: Covid vaccines do not prevent transmission.

This was also clear in the infection rate between highly vaccination and low vaccination countries.

TRANSMISSION

Reducing symptoms while remaining able to transmit makes one more likely to transmit.

TRANSMISSION

Should states have crushed the rights of those who refused this medical procedure?

TRANSMISSION

PART V:
COVID-19 VACCINES: INFORMED CONSENT

WHAT IS
INFORMED CONSENT?

YOU GET INFORMED,
THEN YOU DECIDE WHETHER TO CONSENT

FOR COVID VACCINES:
7 BASIC QUESTIONS

FIRST QUESTION:
DOES THE MANUFACTURER STAND BEHIND ITS PRODUCT?

Vaccines Pharma Won't Stand Behind per the 1986 Act:
https://www.hrsa.gov/vaccine-compensation/covered-vaccines

Vaccines Pharma Won't Stand Behind per the PREP Act:
https://www.hrsa.gov/cicp/covered-countermeasures

Form Letter Asking Pharma to Stand Behind a Vaccine Product:
https://icandecide.org/Form-Letter-to-Pharma-to-Stand-Behind-Their-Product

SECOND QUESTION:
DID ITS CLINICAL TRIAL PROVE IT WAS SAFE?

THIRD QUESTION:
DO POST-LICENSURE STUDIES PROVE IT IS SAFE?

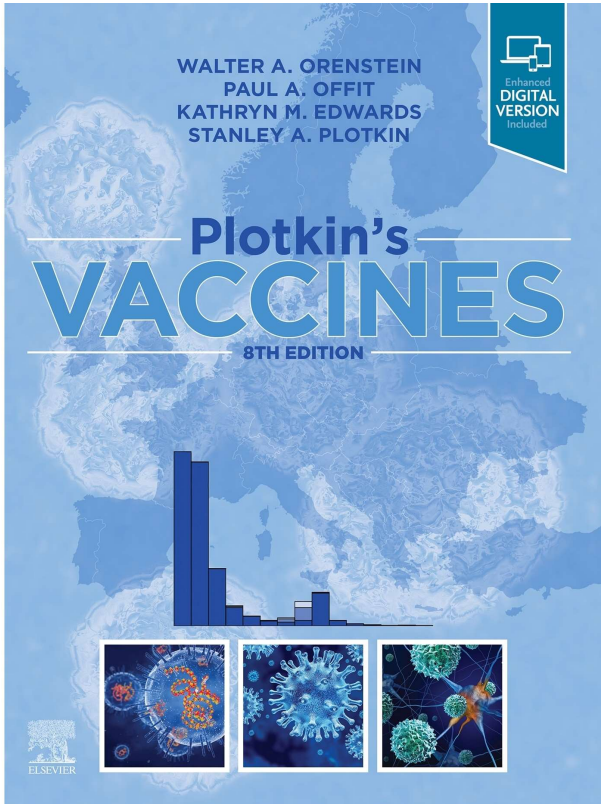
FOURTH QUESTION:
WHAT ARE THE BENEFITS OF THE PRODUCT?

FIFTH QUESTION:

CAN YOU DETERMINE IF THE RISK OUTWEIGHS THE BENEFIT?

SIXTH QUESTION:
CAN YOU TRUST THE PEOPLE RECOMMENDING THE PRODUCT?

SEVENTH QUESTION:
DO YOU HAVE A MORAL OBJECTION TO THE PRODUCT?



Full Deposition: https://thehighwire.com/page/1/?s=stanley+plotkin

EIGHTH QUESTION:

CAN YOUR DOCTOR EXERCISE TRUE INDEPENDENT MEDICAL JUDGEMENT?

FOR EXAMPLE: MEDICAL EXEMPTIONS, LIKE ALL MEDICINE, SHOULD BE BASED ON CLINICAL JUDGMENT

CONCLUSION

WHAT IS
INFORMED CONSENT?

YOU GET INFORMED,
THEN YOU DECIDE WHETHER TO CONSENT

WHY NEED TO MANDATE?

WHEN NOT "SAFE & EFFECTIVE"

WHEN CAN'T PERSUADE ON MERITS

THREE MODEL BILLS TO CONSIDER:

(1) VACCINE CONFIDENCE BILL
(2) NO LIABLITY, NO MANDATE BILL
(3) MEDICAL EXEMPTION BILL

https://icanlegislate.org/model-bills-page/