EXHIBIT D

Vaccine 42 (2024) 2200–2211

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals

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ARTICLE INFO

Keywords:
Vaccine safety surveillance
Pharmacovigilance
Adverse events following immunization
Adverse events of special interest
COVID-19
Observed vs. expected analysis

ABSTRACT

Background: The Global COVID Vaccine Safety (GCoVS) Project, established in 2021 under the multinational Global Vaccine Data Network™ (GVDN®), facilitates comprehensive assessment of vaccine safety. This study aimed to evaluate the risk of adverse events of special interest (AESI) following COVID-19 vaccination from 10 sites across eight countries.

Methods: Using a common protocol, this observational cohort study compared observed with expected rates of 13 selected AESI across neurological, haematological, and cardiac outcomes. Expected rates were obtained by participating sites using pre-COVID-19 vaccination healthcare data stratified by age and sex. Observed rates were reported from the same healthcare datasets since COVID-19 vaccination program rollout. AESI occurring up to 42 days following vaccination with mRNA (BNT162b2 and mRNA-1273) and adenovirus-vector (ChAdOx1)

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https://doi.org/10.1016/j.vaccine.2024.01.100
Received 29 January 2024; Accepted 30 January 2024
Available online 12 February 2024

vaccines were included in the primary analysis. Risks were assessed using observed versus expected (OE) ratios with 95 % confidence intervals. Prioritised potential safety signals were those with lower bound of the 95 % confidence interval (LBCI) greater than 1.5.

Results: Participants included 99,068,901 vaccinated individuals. In total, 183,559,462 doses of BNT162b2, 36,178,442 doses of mRNA-1273, and 23,093,399 doses of ChAdOx1 were administered across participating sites in the study period. Risk periods following homologous vaccination schedules contributed 23,168,335 person-years of follow-up. OE ratios with LBCI > 1.5 were observed for Guillain-Barré syndrome (2.49, 95 % CI: 2.15, 2.87) and cerebral venous sinus thrombosis (3.23, 95 % CI: 2.51, 4.09) following the first dose of ChAdOx1 vaccine. Acute disseminated encephalomyelitis showed an OE ratio of 3.78 (95 % CI: 1.52, 7.78) following the first dose of mRNA-1273 vaccine. The OE ratios for myocarditis and pericarditis following BNT162b2, mRNA-1273, and ChAdOx1 were significantly increased with LBCIs > 1.5.

Conclusion: This multi-country analysis confirmed pre-established safety signals for myocarditis, pericarditis, Guillain-Barré syndrome, and cerebral venous sinus thrombosis. Other potential safety signals that require further investigation were identified.

1. Introduction

Since declaration of the COVID-19 pandemic by the World Health Organization (WHO) on March 11, 2020 [1] more than 13.5 billion doses of COVID-19 vaccines have been administered worldwide [2]. As of November 2023, at least 70.5 % of the world's population had received at least one dose of a COVID-19 vaccine [2]. This unparalleled scenario underscores the pressing need for comprehensive vaccine safety monitoring as very rare adverse events associated with COVID-19 vaccines may only come to light after administration to millions of individuals.

In anticipation of this unprecedented global rollout of COVID-19 vaccines, the Safety Platform for Emergency vACcines (SPEAC) initiative formulated a list of potential COVID-19 vaccine adverse events of special interest (AESI) in 2020 [3]. AESI selection was based on their pre-established associations with immunization, specific vaccine platforms or adjuvants, or viral replication during wild-type disease; theoretical concerns related to immunopathogenesis; or supporting evidence from animal models using candidate vaccine platforms [3].

One flexible approach for assessing AESI is the comparison of observed AESI rates following the introduction of a vaccine program with the expected (or background) rates based on historical periods pre-vaccine roll out [4,5]. Such comparisons can be executed rapidly and can play a key role in early detection of potential vaccine safety signals or when regulatory and public health agencies need rapid assessment of an emerging safety signal [4,6]. Observed versus (vs.) expected (OE) analysis was integral in identifying thrombosis with thrombocytopenia syndrome (TTS) as a safety signal, prompting the suspension of use of the ChAdOx1 (AstraZeneca COVID-19 vaccine) on March 11, 2021, in Denmark and Norway [7,8].

These evaluations are not only valuable early-on in large-scale vaccine deployment, but also as the vaccination program matures, especially if they can be conducted in a multi-country context. We conducted a global cohort study following the Observed vs. Expected Analyses of COVID-19 Adverse Events of Special Interest Study Protocol [9] with data from 10 sites across eight countries participating in the unique Global COVID Vaccine Safety (GCoVS) Project [10] of the Global Vaccine Data Network™ (GVDN®) [11]. The GCoVS Project, initiated in 2021, is a Centers for Disease Control and Prevention (CDC) funded global collaboration of investigators and data sources from multiple nations for the purpose of COVID-19 vaccine safety monitoring.

2. Methods

2.1. Study design

This retrospective observational study was designed to estimate the OE ratios of selected AESIs after COVID-19 vaccination in a multi-country population cohort.

2.2. Data source and study population

The GCoVS Project compiled electronic healthcare data on AESI related to COVID-19 vaccines from participants across multiple sites within the GVDN network, including Argentina, Australia – New South Wales, Australia – Victoria, Canada – British Columbia, Canada – Ontario, Denmark, Finland, France, New Zealand, and Scotland [10]. The healthcare data comprised of either individual- or population-level data, depending on the availability in the study sites (Supplementary Table 1).

Immunization registers containing individual-level vaccination data were utilized by the majority of study sites. These registers covered the same population and geographic region as the data sets used to calculate background rates. We also examined population-level data on vaccination uptake using regularly updated dashboards from the study sites. If the number of individuals vaccinated in specific age and gender groups was available, we converted those numbers into person-years based on the post-vaccination risk period. Unlike the registers with individual-level data, the age and sex strata used in this approach might not have matched the strata used in the background rates calculations.

Participants were individuals vaccinated with COVID-19 vaccines in the populations represented by the sites. To the extent possible, standardized methods were applied across sites. Patient types included hospital inpatients (Australia – New South Wales, France, New Zealand, Scotland), and combinations of inpatient and outpatient emergency department patients (Argentina, Australia – Victoria, Canada, Denmark, Finland). In countries without clearly defined patient types, hospital contact duration was used as a proxy for patient types. As an example, a contact duration of five hours or longer was used as a proxy for in-patients in Denmark. Site-specific characteristics of data sources and data are presented in Supplementary Table 1.

2.3. Study period and follow-up

The study periods varied across countries, commencing on the date of the site-specific COVID-19 vaccination program rollout, and concluding at the end of data availability (Table 1). In general, the study periods spanned from December 2020 until August 2023. The shortest study period observed occurred in Australia – New South Wales, including 11 months from February 2021 to December 2021. Argentina had the longest study period, from December 2020 to August 2023, encompassing a total of 32 months.

The risk intervals used after each dose were 0–7 days, 8–21 days, 22–42 days, and 0–42 days. For each vaccination dose, day 0 was denoted the day of vaccine receipt. For this manuscript, we present results for the risk interval of 0–42 days only. More data are presented on the GVDN dashboard with all latest updates from participating sites [12]. Outcome events that occurred outside the study period were not included. A 365-day washout period for outcome events was used to define incident outcomes. Outcome events were considered incident if

there was no record of the same outcome event during the preceding 365-day washout period. An individual may have contributed several outcome events on the condition they were separated in time by at least the washout period of 365 days.

2.4. Study variables and outcomes

2.4.1. Adverse events of special interest (AESI)

Thirteen conditions representing AESI of specific relevance to the current landscape of real-world vaccine pharmacovigilance were selected from the list compiled by the Brighton Collaboration SPEAC Project [3] and in response to the safety signals of thrombosis with thrombocytopenia syndrome [7,8] (Supplementary Table 2). The conditions chosen matched the AESI for which background rates were recently generated by GVDN sites [13]. AESI were identified using harmonized International Classification of Diseases 10th Revision (ICD-10) codes. Neurological conditions selected included Guillain-Barré syndrome (GBS), transverse myelitis (TM), facial (Bell's) palsy, acute disseminated encephalomyelitis (ADEM), and convulsions (generalized seizures (GS) and febrile seizures (FS)) as potential safety signals have been identified for some of these conditions [14–16]. Hematologic conditions included cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis (SVT) and pulmonary embolism (PE); the unusual site thromboses (CVST and SVT) were selected as markers of potential TTS that could be accurately identified using diagnostic codes [17,18]. Thrombocytopenia and immune thrombocytopenia (ITP) were also included due to their association with TTS and reports of ITP as an independent safety signal [7,19,20]. Myocarditis and pericarditis were included as cardiovascular conditions and the OE ratios were evaluated separately for each condition [21–23].

2.4.2. COVID-19 vaccines

As of November 2023, multiple vaccines against COVID-19 were in use by the GCoVS sites representing multiple platform types such as inactivated, nucleic acid-based (mRNA), protein-based, and non-replicating viral vector platforms (Table 2). For this manuscript, we focused on three vaccines that recorded the highest number of doses administered, Pfizer/BioNTech BNT162b2, Moderna mRNA-1273, and Oxford/Astra Zeneca/Serum Institute of India ChAdOx1 vaccines. The cumulative number of doses of other vaccines administered (n) across study sites were relatively low, with exceptions for the inactivated Sinopharm (n = 134,550) and Sinovac (n = 31,598) vaccines, the protein-based Novavax (n = 66,856) vaccine, and the adenovirus-vector Janssen/Johnson & Johnson (n = 1,137,505) and Gamaleya Research Institute/Sputnik (n = 84,460) vaccines. The total number of doses of each vaccine brand administered are outlined in Table 2. Exposure to COVID-19 vaccine by platform/type, brand, and dose data were available at the individual level to determine the number of observed cases by vaccine type/brand and dose profile and within the 0–42 days post-vaccination risk interval.

Table 2
Total number of vaccinations by brand.

Vaccine platform	Vaccine brand	Total doses
Inactivated	Covilo or SARS-CoV-2 Vaccine (Vero Cell) [Sinopharm (Beijing)]	134,550
	Covaxin [Bharat Biotech]	1,660
	CoronaVac or Sinovac [Sinovac Biotech]	31,598
	Inactivated (Vero cell) [Sinopharm (Wuhan)]	623
Nucleic acid-based	Comirnaty or Riltozinameran or Pfizer/BioNTech COVID-19 Vaccine Bivalent [Pfizer/BioNTech]	3,516,963
	Comirnaty or Tozinameran [Pfizer/BioNTech or Fosun-BioNTech]	183,677,660
	Comirnaty or Tozinameran Paediatric [Pfizer/BioNTech or Fosun-BioNTech]	2,439,086
	Spikevax bivalent Original/Omicron [Moderna]	2,750,476
	Elasomeran or Spikevax or TAK-919 Half Dose [Moderna or Takeda]	400,395
	Elasomeran or Spikevax or TAK-919 [Moderna or Takeda]	36,222,514
Protein-based	MVC-COV1901 [Medigen]	16
	Covovax or Nuvaxoid [Novavax or Serum Institute of India]	66,856
Non-replicating viral vector	Convidecia or Convidence [CanSino]	3,938
	Covishield or Vaxzevria [AstraZeneca or Serum Institute of India]	23,094,620
	Sputnik Light or Gam-COVID-Vac [Gamaleya Research Institute]	26
	Sputnik V [Gamaleya Research Institute]	84,460
	Janssen [Janssen/Johnson & Johnson]	1,137,505

2.5. Statistical analysis

2.5.1. Calculation of observed vs. expected ratios for each site

For each site, we calculated the observed number of events for each AESI in the risk interval after introduction of COVID-19 vaccination. To

Table 1
Population summary by site. (Only Pfizer/BioNTech BNT162b2, Moderna mRNA-1273, and Oxford/Astra Zeneca/Serum Institute of India ChAdOx1 vaccines and doses 1–4 included).

Characteristics		Argentina	Australia: NSW	Australia: Victoria	Canada: BC	Canada: Ontario	Denmark	Finland	France	New Zealand	Scotland
Study period		12/2020-08/2023	02/2021-12/2021	02/2021-06/2023	12/2020-05/2023	12/2020-03/2023	12/2020-02/2023	12/2020-06/2022	01/2021-12/2021	02/2021-09/2022	12/2020-05/2023
Vaccinated population	n	157,883	6,492,805	5,789,070	4,267,644	12,081,337	4,291,034	4,501,659	52,795,394	4,151,269	4,540,806
	Female (%)	78,374 (49.6)	3,289,381 (50.7)	2,925,886 (50.5)	2,183,666 (51.2)	6,192,991 (51.3)	2,179,415 (50.8)	2,324,067 (51.6)	27,216,365 (51.6)	2,100,071 (50.6)	2,346,694 (51.7)
	0-19 (%)	42,281 (26.8)	692,498 (10.7)	921,635 (15.9)	274,813 (6.4)	1,882,574 (15.6)	620,273 (14.5)	549,589 (12.2)	5,585,455 (10.6)	582,662 (14.0)	501,397 (11.0)
	20-39 (%)	58,567 (37.1)	2,125,624 (32.7)	1,858,706 (32.1)	1,386,513 (32.5)	3,421,403 (28.3)	1,100,566 (25.6)	1,159,303 (25.8)	14,517,426 (27.5)	1,321,332 (31.8)	1,218,142 (26.8)
	40-59 (%)	40,484 (25.6)	1,933,770 (29.8)	1,586,558 (27.4)	1,244,817 (29.2)	3,460,295 (28.6)	1,263,265 (29.4)	1,256,439 (27.9)	16,065,061 (30.4)	1,198,750 (28.9)	1,418,313 (31.2)
	60-79 (%)	15,167 (9.6)	1,433,446 (22.1)	1,139,623 (19.7)	1,103,315 (25.9)	2,706,343 (22.4)	1,063,018 (24.8)	1,234,825 (27.4)	12,997,416 (24.6)	865,928 (20.9)	1,142,053 (25.2)
	80+ (%)	1,384 (0.9)	307,467 (4.7)	282,548 (4.9)	258,186 (6.0)	610,722 (5.1)	243,912 (5.7)	301,503 (6.7)	3,630,036 (6.9)	182,597 (4.4)	260,901 (5.7)
BNT162b2	Dose 1		3,896,923 (60.0)	3,393,207 (58.6)	2,959,369 (69.3)	8,473,103 (70.1)	3,425,161 (79.8)	3,586,237 (79.7)	41,450,092 (78.5)	4,036,859 (97.2)	2,087,109 (46.0)
	Dose 2		3,837,153 (59.1)	3,313,758 (57.2)	2,778,036 (65.1)	7,382,893 (61.1)	3,480,685 (81.1)	3,594,661 (79.9)	38,876,671 (73.6)	3,990,353 (96.1)	1,967,726 (43.3)
	Dose 3		751,169 (11.6)	2,900,036 (50.1)	1,295,609 (30.4)	4,377,649 (36.2)	2,811,507 (65.5)	2,167,380 (48.1)	16,121,693 (30.5)	2,730,880 (65.8)	2,557,434 (56.3)
	Dose 4			969,442 (16.7)	259,228 (6.1)	1,469,297 (12.2)	1,609,558 (37.5)		54,905 (0.1)	595,269 (14.3)	358,410 (7.9)
mRNA-1273	Dose 1	2,850 (1.8)	134,960 (2.1)	199,865 (3.5)	940,656 (22.0)	2,100,866 (17.4)	507,031 (11.8)	554,076 (12.3)	5,853,595 (11.1)	3,255 (0.1)	205,528 (4.5)
	Dose 2	13,046 (8.3)	126,291 (1.9)	190,271 (3.3)	1,196,017 (28.0)	3,589,447 (29.7)	578,985 (13.5)	532,153 (11.8)	5,880,520 (11.1)	3,211 (0.1)	183,966 (4.1)
	Dose 3	45,712 (29.0)	117,804 (1.8)	617,724 (10.7)	1,482,817 (34.7)	2,965,640 (24.5)	61,548 (1.4)	812,002 (18.0)	4,676,771 (8.9)	2,184 (0.1)	970,917 (21.4)
	Dose 4			257,557 (4.4)	380,862 (8.9)	723,201 (6.0)	56,850 (1.3)		14,245 (<0.1)	134 (<0.1)	195,885 (4.3)
ChAdOx1	Dose 1	37,721 (23.9)	2,460,922 (37.9)	1,868,764 (32.3)	308,867 (7.2)	856,603 (7.1)	133,181 (3.1)	360,196 (8.0)	4,398,411 (8.3)	17,087 (0.4)	2,139,669 (47.1)
	Dose 2	36,164 (22.9)	2,433,046 (37.5)	1,835,469 (31.7)	132,111 (3.1)	221,118 (1.8)	1,780 (<0.1)	191,120 (4.2)	3,424,058 (6.5)	14,560 (0.4)	2,093,121 (46.1)
	Dose 3	28,255 (17.9)	7,483 (0.1)	57,841 (1)	1,757 (<0.1)		46 (<0.1)	306 (<0.1)	7,368 (<0.1)	2,058 (<0.1)	9,551 (0.2)
	Dose 4			13,693 (0.2)	76 (<0.1)				90 (<0.1)	212 (<0.1)	695 (<0.1)

Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1).

calculate the expected number of cases, we used pre-COVID-19 vaccination background rates data from 2015 to 2019 (2019–2020 for Denmark) collected in the GCoVS Background Rates of AESI Following COVID-19 vaccination study [13]. The observed follow-up period in person-years for a given vaccination profile and post-vaccination period was stratified according to age group and sex. Each of the age-sex stratified person-years were multiplied by the corresponding age-sex stratified background rate. This resulted in the expected number of cases in each stratum, which were then summed to give the total number of expected cases during the observed follow-up period.

The aggregated OE ratios by last dose were calculated by dividing the observed number of cases by the expected number of cases in the post-vaccination period, 95 % confidence intervals (CI) were derived using the exact Poisson distribution. We also calculated OE ratios for homologous schedules for BNT162b2, mRNA-1273, and ChAdOx1 vaccines up to four doses. Both the aggregated OE ratios and those specific to homologous schedules are presented.

We considered an OE ratio a potential safety signal of concern where the lower bound of the 95 % CI (LBCI) was greater than one and reached statistical significance [5]. However, we prioritised potential safety signals of concern for further evaluation where the LBCI was greater than 1.5, due to increased statistical evidence and the higher likelihood of being a true signal, based on expert opinion from the CDC and GVDN collaborators.

2.5.2. Combining results across sites

The results were aggregated across sites by summing the observed number of events for each AESI and the age-sex stratified person-years for a given vaccination profile and post-vaccination period. For each AESI, individual vaccine profiles were reported if the cumulative amount of follow up (in person-years) in the 0–42 days post-vaccination period was 10,000 or greater. The combined numbers of events and the OE ratio was calculated with 95 % CIs derived using the exact Poisson distribution. No event (i.e., zero) observed for a vaccine brand and dose profile was reported separately without CI.

2.5.3. Sensitivity analysis

Firstly, we conducted site-specific sensitivity analyses to further explore potential associations of the most significant safety signals identified in the main analysis. The observed rates reported by sites were considered in the analysis based on the following constraints. For each vaccine brand and dose profile, and post-vaccination period combination, the OE ratios and 95 % CI were suppressed if fewer than five events were observed. Secondly, we conducted supplemental analysis including other vaccines and doses administered across sites. The person-years threshold for reporting was lowered from 10,000 to 1,000 person-years compared to the main aggregated OE ratios analysis, allowing for broader scope of vaccines to be analysed.

2.6. Ethical approval

Approval from the relevant Human Research Ethics Committees was either acquired or an exemption obtained for all participating sites (Supplementary Table 3).

3. Results

The total vaccinated population across all sites comprised 99,068,901 individuals. Most vaccine recipients were in the 20–39 and 40–59-year age groups (Table 1). In total, 183,559,462 doses of BNT162b2, 36,178,442 doses of mRNA-1273, and 23,093,399 doses of ChAdOx1 were administered across all the sites in the study periods. The

Table 3
Aggregated OE Ratios by last dose, neurological conditions, period 0–42 days.

		GBS		TRM		BP		ADEM		FSZ		GSZ	
Dose	Vaccine	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI
1	ChAdOx1	2.49	(2.15,2.87)	1.91	(1.22,2.84)	0.98	(0.88,1.08)	2.23	(1.15,3.90)	0.93	(0.55,1.46)	0.86	(0.83,0.90)
	BNT162b2	0.90	(0.79,1.03)	0.74	(0.53,1.02)	1.05	(1.00,1.11)	1.28	(0.77,2.00)	0.73	(0.53,0.97)	0.92	(0.91,0.94)
	mRNA-1273	0.95	(0.65,1.34)	1.50	(0.77,2.62)	1.25	(1.11,1.39)	3.78	(1.52,7.78)	1.36	(1.02,1.77)	1.15	(1.10,1.20)
2	ChAdOx1	0.73	(0.54,0.96)	0.58	(0.21,1.26)	0.95	(0.85,1.06)	1.63	(0.70,3.21)	0.45	(0.20,0.89)	0.77	(0.74,0.81)
	BNT162b2	0.69	(0.60,0.79)	0.84	(0.62,1.11)	0.93	(0.88,0.97)	0.54	(0.23,1.06)	0.58	(0.42,0.79)	0.81	(0.80,0.83)
	mRNA-1273	0.84	(0.60,1.15)	1.27	(0.69,2.12)	1.02	(0.91,1.13)	1.21	(0.25,3.55)	1.44	(1.04,1.95)	0.97	(0.93,1.01)
3	ChAdOx1	3.99	(0.48,14.41)	0		0.75	(0.20,1.92)	0		2.88	(0.07,16.04	0.71	(0.44,1.10)
	BNT162b2	0.66	(0.54,0.79)	1.02	(0.68,1.46)	0.81	(0.76,0.87)	0.82	(0.30,1.79)	0.97	(0.69,1.33)	0.80	(0.78,0.82)
	mRNA-1273	0.68	(0.45,1.00)	0.92	(0.40,1.81)	0.83	(0.74,0.94)	0.64	(0.02,3.58)	0.58	(0.19,1.36)	0.69	(0.66,0.73)
4	BNT162b2	0.87	(0.56,1.29)	1.05	(0.39,2.29)	1.14	(0.99,1.29)	2.26	(0.06,12.62)	0.99	(0.43,1.94)	1.09	(1.04,1.14)
	mRNA-1273	0.88	(0.32,1.92)	1.25	(0.15,4.50)	1.08	(0.83,1.38)	0		0.85	(0.02,4.75)	1.00	(0.91,1.10)

AESI: GBS= Guillain-Barré syndrome, TRM= Transverse myelitis, BP= Facial (Bell's) palsy, ADEM= Acute disseminated encephalomyelitis, FSZ= Febrile seizures, GSZ= Generalised seizures
Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1)

Thresholds for statistical indications of potential signals:

Red: LBCI* >1.5, statistically significant safety signal

Yellow: LBCI* >1 and ≤1.5, statistically significant

Green: LBCI* ≤1.0, not statistically significant

*LBCI: Lower bound of confidence interval

Conditions applied to the analysis of aggregated OE ratios:

- PYRS ≥10000
- No censoring on observed counts

AESI: GBS = Guillain-Barré syndrome, TRM = Transverse myelitis, BP = Facial (Bell's) palsy, ADEM = Acute disseminated encephalomyelitis, FSZ = Febrile seizures, GSZ = Generalised seizures.
Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1).

Table 4
Aggregated OE Ratios by last dose, haematologic conditions, period 0–42 days.

		THR		ITP		PEM		CVST		SVT	
Dose	Vaccine	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI
1	ChAdOx1	1.07	(1.03,1.12)	1.40	(1.24,1.58)	1.20	(1.16,1.24)	3.23	(2.51,4.09)	1.02	(0.89,1.16)
	BNT162b2	1.11	(1.08,1.14)	1.08	(1.01,1.16)	1.29	(1.26,1.32)	1.49	(1.26,1.75)	1.25	(1.17,1.34)
	mRNA-1273	1.33	(1.25,1.42)	1.13	(0.93,1.37)	1.33	(1.26,1.40)	1.48	(0.92,2.23)	1.23	(1.03,1.47)
2	ChAdOx1	0.96	(0.91,1.01)	1.02	(0.88,1.18)	0.96	(0.92,1.00)	1.15	(0.70,1.77)	0.95	(0.82,1.10)
	BNT162b2	0.92	(0.89,0.94)	0.93	(0.86,1.00)	0.99	(0.97,1.01)	1.25	(1.06,1.46)	1.03	(0.96,1.10)
	mRNA-1273	0.98	(0.92,1.04)	0.80	(0.65,0.97)	1.05	(0.99,1.10)	1.43	(0.95,2.06)	1.17	(1.01,1.36)
3	ChAdOx1	1.95	(1.29,2.84)	3.65	(0.75,10.67)	1.88	(1.32,2.58)	0		3.59	(0.43,12.96)
	BNT162b2	0.78	(0.75,0.81)	0.85	(0.77,0.93)	0.96	(0.93,0.98)	1.14	(0.89,1.44)	0.90	(0.82,0.99)
	mRNA-1273	0.73	(0.67,0.79)	0.72	(0.57,0.91)	0.97	(0.92,1.02)	0.94	(0.49,1.65)	0.94	(0.77,1.13)
4	BNT162b2	1.04	(0.95,1.13)	1.18	(0.99,1.41)	0.99	(0.94,1.04)	0.99	(0.47,1.81)	1.30	(1.06,1.59)
	mRNA-1273	1.08	(0.93,1.24)	0.96	(0.59,1.47)	1.03	(0.93,1.13)	0		1.53	(1.05,2.16)

AESI: THR= Thrombocytopenia, ITP= Idiopathic thrombocytopenia, PEM= Pulmonary embolism, CVST=Cerebral venous sinus thrombosis, SVT= Splanchnic vein thrombosis

Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1)

Thresholds for statistical indications of potential signals:

Red: LBCI* >1.5, statistically significant safety signal

Yellow: LBCI* >1 and ≤1.5, statistically significant

Green: LBCI* ≤1.0, not statistically significant

*LBCI: Lower bound of confidence interval

Conditions applied to the analysis of aggregated OE ratios:

- PYRS ≥10000
- No censoring on observed counts

AESI: THR = Thrombocytopenia, ITP = Idiopathic thrombocytopenia, PEM = Pulmonary embolism, CVST = Cerebral venous sinus thrombosis, SVT = Splanchnic vein thrombosis.
Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1).

highest numbers of doses were administered in France (120,758,419), followed by Canada – Ontario (32,159,817) and Australia – Victoria (15,617,627). In total, 23,168,335 person-years contributed to the OE ratios for the AESI following homologous schedules. The population summary is presented in Table 1, and more detailed information on the other administered vaccines are presented in Supplementary Table 4. In the results sections below, we provide both aggregated OE ratios (Tables 3–5) and detailed OE ratios for homologous schedules (Figs. 1–3), including the number of events and person-years. Overall, 95.8 % and 86.6 % of vaccinations were included in the aggregated and the homologous schedules analysis, respectively (Supplementary Table 5). The primary results from the individual sites as well as additional risk periods and meta-analyses for each AESI are available in the interactive GVDN Observed vs Expected (OE) Dashboard [12].

3.1. Neurological conditions

There was a statistically significant increase in GBS cases within 42 days after a first ChAdOx1 dose (OE ratio = 2.49; 95 % CI: 2.15, 2.87), indicating a prioritised safety signal (Table 3). Seventy-six GBS events were expected, and 190 events were observed (Fig. 1). The OE ratio for ADEM within 42 days after a first mRNA-1273 dose also fulfilled the significance threshold of a prioritised safety signal (3.78; 95 % CI: 1.52, 7.78), with two expected events compared with seven observed events (Fig. 1).

Statistically significant differences were also found for transverse myelitis (OE ratio = 1.91; 95 % CI: 1.22, 2.84) and ADEM (OE ratio = 2.23; 95 % CI: 1.15, 3.90) after a first ChAdOx1 dose. Bell's palsy had an increased OE ratio after a first dose of BNT162b2 (1.05; 95 % CI: 1.00, 1.11) and mRNA-1273 (1.25; 95 % CI: 1.11, 1.39). There were also increased OE ratios for febrile seizures following a first and second dose of mRNA-1273 (1.36, 95 % CI: 1.02, 1.77 and 1.44, 95 % CI: 1.04, 1.95, respectively), and for generalised seizures following a first mRNA-1273 dose (1.15, 95 % CI: 1.10, 1.20) and a fourth BNT162b2 dose (1.09, 95 % CI: 1.04, 1.14). No increased OE ratios were identified following a third dose of any vaccine. The results are concordant with the OE ratios of homologous schedules; however, an increased OE ratio for generalized seizures following a homologous schedule of four doses of mRNA-1273 (1.33; 95 % CI: 1.07, 1.63) was identified (Fig. 1). These outcomes did not meet the threshold for a prioritised safety signal following vaccination.

3.2. Hematologic conditions

The OE ratio of CVST was 3.23 (95 % CI: 2.51–4.09) within 42 days after a first dose of ChAdOx1, fulfilling the threshold of a prioritised safety signal (Table 4). In total, 21 events were expected, while 69 events were observed (Fig. 2).

Increased OE ratios were also identified for thrombocytopenia after a first dose of ChAdOx1 (1.07; 95 % CI: 1.03, 1.12), BNT162b2 (1.11; 95 % CI: 1.08, 1.14), and mRNA-1273 (1.33; 95 % CI 1.25, 1.42), as well as after a third dose of ChAdOx1 (1.95; 95 % CI: 1.29, 2.84). Immune thrombocytopenia also demonstrated increased OE ratios after a first dose of ChAdOx1 (1.40; 95 % CI: 1.24, 1.58) and BNT162b2 (1.08; 95 % CI: 1.01, 1.16). Pulmonary embolism OE ratios were increased following first doses of ChAdOx1 (1.20; 95 % CI: 1.16, 1.24), BNT162b2 (1.29; 95 % CI: 1.26, 1.32), and mRNA-1273 (1.33, 95 % CI: 1.26, 1.40), as well as after a third dose of ChAdOx1 (1.88; 95 % CI: 1.32, 2.58). The OE ratio of CVST was 1.49 (95 % CI: 1.26, 1.75) after a first dose and 1.25 (95 % CI: 1.06, 1.46) after a second dose of BNT162b2. An increased OE ratio for SVT was found after a first dose of BNT162b2 (1.25; 95 % CI: 1.17, 1.34) and mRNA-1273 (1.23; 95 % CI: 1.03, 1.47); a second dose of

Table 5
Aggregated OE Ratios by last dose, cardiovascular conditions, period 0–42 days.

		MYO		PER	
Dose	**Vaccine**	**OE Ratio**	**95%CI**	**OE Ratio**	**95%CI**
1	ChAdOx1	**1.36**	**(1.08,1.68)**	**1.29**	**(1.15,1.44)**
	BNT162b2	**2.78**	**(2.61,2.95)**	**1.54**	**(1.47,1.62)**
	mRNA-1273	**3.48**	**(3.00,4.01)**	**1.74**	**(1.54,1.97)**
2	ChAdOx1	**1.31**	**(1.01,1.68)**	**1.27**	**(1.12,1.43)**
	BNT162b2	**2.86**	**(2.70,3.03)**	**1.38**	**(1.32,1.45)**
	mRNA-1273	**6.10**	**(5.52,6.72)**	**1.67**	**(1.50,1.85)**
3	ChAdOx1	0		**6.91**	**(3.45,12.36)**
	BNT162b2	**2.09**	**(1.88,2.32)**	**1.19**	**(1.10,1.28)**
	mRNA-1273	**2.01**	**(1.60,2.49)**	**1.39**	**(1.20,1.59)**
4	BNT162b2	**2.06**	**(1.47,2.80)**	**1.55**	**(1.30,1.83)**
	mRNA-1273	**2.91**	**(1.45,5.21)**	**2.64**	**(2.05,3.35)**

AESI: MYO= Myocarditis, PER= Pericarditis

Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1)

Thresholds for statistical indications of potential signals:

Red: LBCI* >1.5, statistically significant safety signal

Yellow: LBCI* >1 and ≤1.5, statistically significant

Green: LBCI* ≤1.0, not statistically significant

*LBCI: Lower bound of confidence interval

Conditions applied to the analysis of aggregated OE ratios:

- PYRS ≥10000
- No censoring on observed counts

mRNA-1273 (1.17; 95 % CI: 1.01, 1.36); and a fourth dose of BNT162b2 (1.30, 95 % CI: 1.06, 1.59) and mRNA-1273 (1.53, 95 % CI: 1.05, 2.16). These outcomes did not meet the threshold for a prioritised safety signal following vaccination.

3.3. Cardiovascular conditions

Increased OE ratios fulfilling the threshold of prioritised safety signals for myocarditis were consistently identified following a first, second and third dose of mRNA vaccines (BNT162b2 and mRNA-1273) (Table 4). The highest OE ratio was observed following a first and second dose of mRNA-1273 (3.48; 95 % CI: 3.00, 4.01 and 6.10; 95 % CI: 5.52, 6.72, respectively). The OE ratio following a third dose of mRNA-1273 was 2.01 (95 % CI: 1.60, 2.49). The numbers of events for up to four doses of homologous schedules are shown in Fig. 3. The OE ratios of homologous schedules align with the aggregated OE ratios. The homologous OE for myocarditis following four doses of mRNA-1273 vaccine could not be estimated due to a lack of observed events.

Similarly, the OE ratio for pericarditis fulfilled the threshold of a prioritised safety signal following a first and fourth dose of mRNA-1273, with OE ratios of 1.74 (95 % CI: 1.54, 1.97) and 2.64 (95 % CI: 2.05, 3.35) respectively. An increased ratio of 6.91 (95 % CI: 3.45, 12.36), fulfilling the threshold of a prioritised safety signal, was also observed following a third dose of ChAdOx1. The aggregated OE ratios for pericarditis were increased following all doses of all the three vaccines presented (Table 4). The results are very similar to the ratios of homologous schedules (Fig. 3), except for the OE ratio of 1.23 (95 % CI: 0.45–2.69) after receipt of the fourth mRNA-1273 dose, which did not meet the threshold for a safety signal. The homologous OE ratio following a third dose of ChAdOx1 was not reported as only a small number of third doses of ChAdOx1 were given across study sites (Table1).

3.4. Sensitivity analysis

Secondary analyses were conducted to further explore GBS, ADEM, CVST, myocarditis, and pericarditis at the site-specific level. We report the aggregated OE ratios by last dose and site in the period 0–42 days after vaccination in Supplementary Tables 6–10. It was not possible to report results for all sites and study outcomes due to insufficient person-years or less than five events observed by site privacy criteria. The majority of identified safety signals following specific vaccine brand and dose combinations from the main analysis were, however, confirmed by individual sites where data were available. The supplementary analysis with person-years threshold of 1,000 and including other vaccines and doses administered within the GVDN sites, showed an increased OE ratio for some outcomes, e.g. for generalized seizures following a first dose of Gamaleya Research Institute/Sputnik vaccine (5.50, 95 % CI: 2.74, 9.84) (Supplementary Tables 11–13).

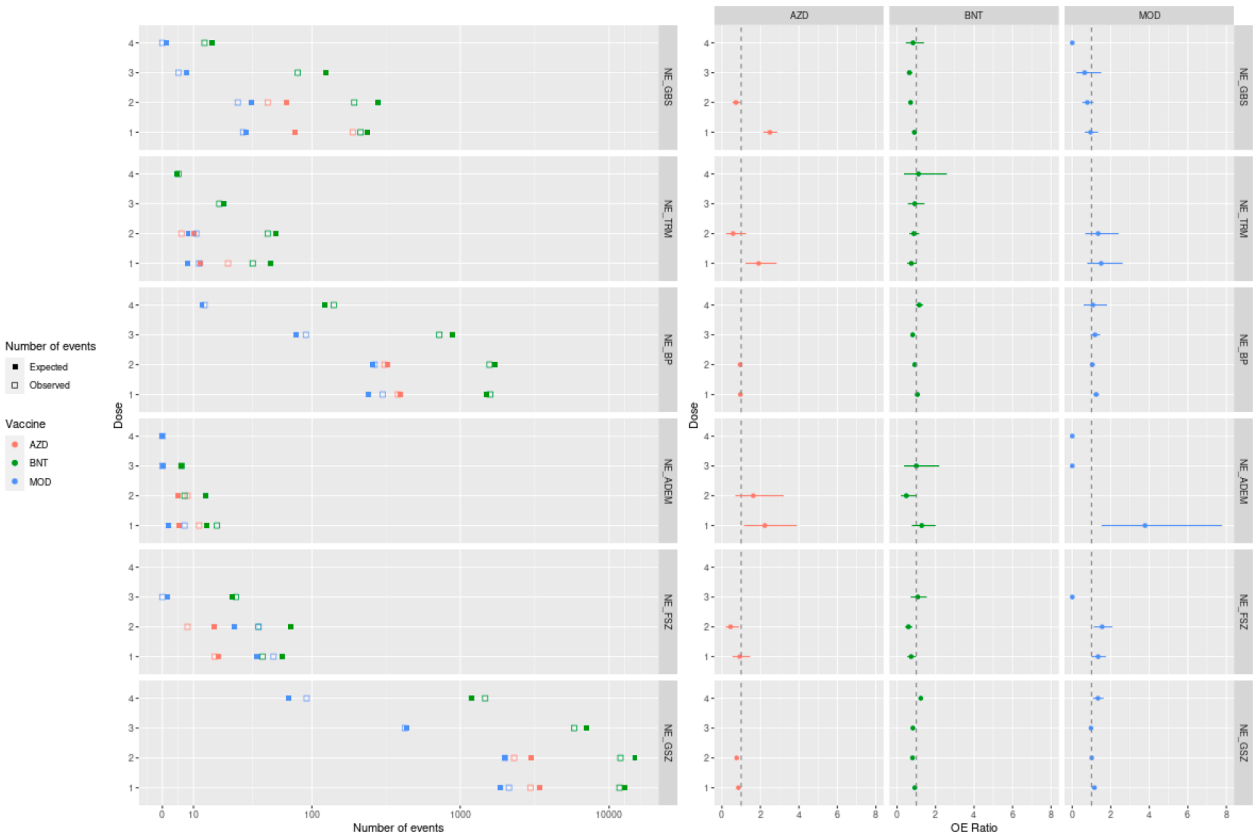

Fig. 1. Number of events and OE ratios (with 95 % confidence interval) for homologous schedules by dose 1–4, neurological conditions. AESI: GBS = Guillain-Barré syndrome, TRM = Transverse myelitis, BP = Facial (Bell's) palsy, ADEM = Acute disseminated encephalomyelitis, FSZ = Febrile seizures, GSZ = Generalised seizures. Vaccines: AZD = Oxford/Astra Zeneca/Serum Institute of India ChAdOx1, BNT = Pfizer/BioNTech (BNT162b2), MOD = Moderna (mRNA-1273).

4. Discussion

This multi-country cohort study was conducted in the unique setting of the GVDN. To date, the number of such large systematically coordinated studies across diverse geographical locations and populations is limited. However, several studies have previously assessed the risks of the identified safety signals following COVID-19 vaccination, primarily in single site settings. We investigated the association between COVID-19 vaccination and 13 AESIs comprising neurological, haematological, and cardiovascular conditions across 10 sites in eight countries including Europe, North America, South America, and Oceania. In this study including more than 99 million people vaccinated against SARS-CoV-2, the risk up to 42 days after vaccination was generally similar to the background risk for the majority of outcomes; however, a few potential safety signals were identified. We observed potential safety signals for GBS and CVST after the first dose of ChAdOx1 based on more than 12 million doses administered.

Overall, studies of the vector-based vaccines such as the ChAdOx1, have observed a higher incidence of GBS after vaccination compared with the background incidence; whereas, most studies of the mRNA vaccines, such as BNT162b2 and mRNA-1273, have not observed increases of GBS [14,15,24–27]. Atzenhoffer et al. [24] reported an elevated OE ratio > 2.0 for adenovirus-vectored COVID-19 vaccines, across countries contributing to VigiBase, an international database of adverse drug events and Patone et al. [27] reported 38 excess cases of GBS per 10 million exposed in the 1–28 days risk period following vaccination with ChAdOx1 in England. The authors did not observe an increased risk in those who received BNT162b2. In contrast, a study by Li et al. [28] showed no increased risk of GBS for ChAdOx1, while only SARS-CoV-2 infection was associated with a higher risk. The discrepancy, compared with the results of Patone et al. [27], could however be explained by a smaller sample size and different outcome measures. Overall, this evidence supports our findings of a GBS safety signal following ChAdOx1 vaccination. Although rare, this association was acknowledged by the WHO, the European Medicines Agency (EMA), and Therapeutic Goods Administration (TGA) of Australia, resulting in GBS being listed as a rare side effect following exposure to ChAdOx1 [15,29,30].

The identified increased risk of CVST following ChAdOx1 vaccination in this study is corroborated by multiple studies. An increased OE ratio was observed in a nationwide cohort study from Denmark and Norway, with increased rates of venous thromboembolic events, including CVST with an excess rate of 2.5 events per 100,000 vaccinations following ChAdOx1 [7]. Based on a variety of methodologies, other studies have also reported increased incidence of CVST after vaccination [31,32]. Ultimately, this rare but concerning safety signal led to the withdrawal of the ChAdOx1 vaccine from COVID-19 vaccine programs or implementation of age-based restrictions in multiple countries [8].

It is crucial to acknowledge the significance threshold of prioritised safety signals applied in this study (LBCI > 1.5). This threshold was selected based on expert opinion within the GVDN and at CDC, to focus on those outcomes most likely to be true signals. Some observed events, although not fulfilling this threshold, may still hold clinical importance and require further investigation. For instance, ITP with an OE ratio > 1.0 and LBCI of 1.2 following vaccination with ChAdOx1 aligns with findings reported in the literature as a potential signal. This concurrence is highlighted in a study conducted in Victoria, Australia, which observed a substantially higher than expected rate of ITP following ChAdOx1 vaccination [33].

Moreover, we observed significantly higher risks of myocarditis following the first, second and third doses of BNT162b2 and mRNA-1273 as well as pericarditis after the first and fourth dose of mRNA-

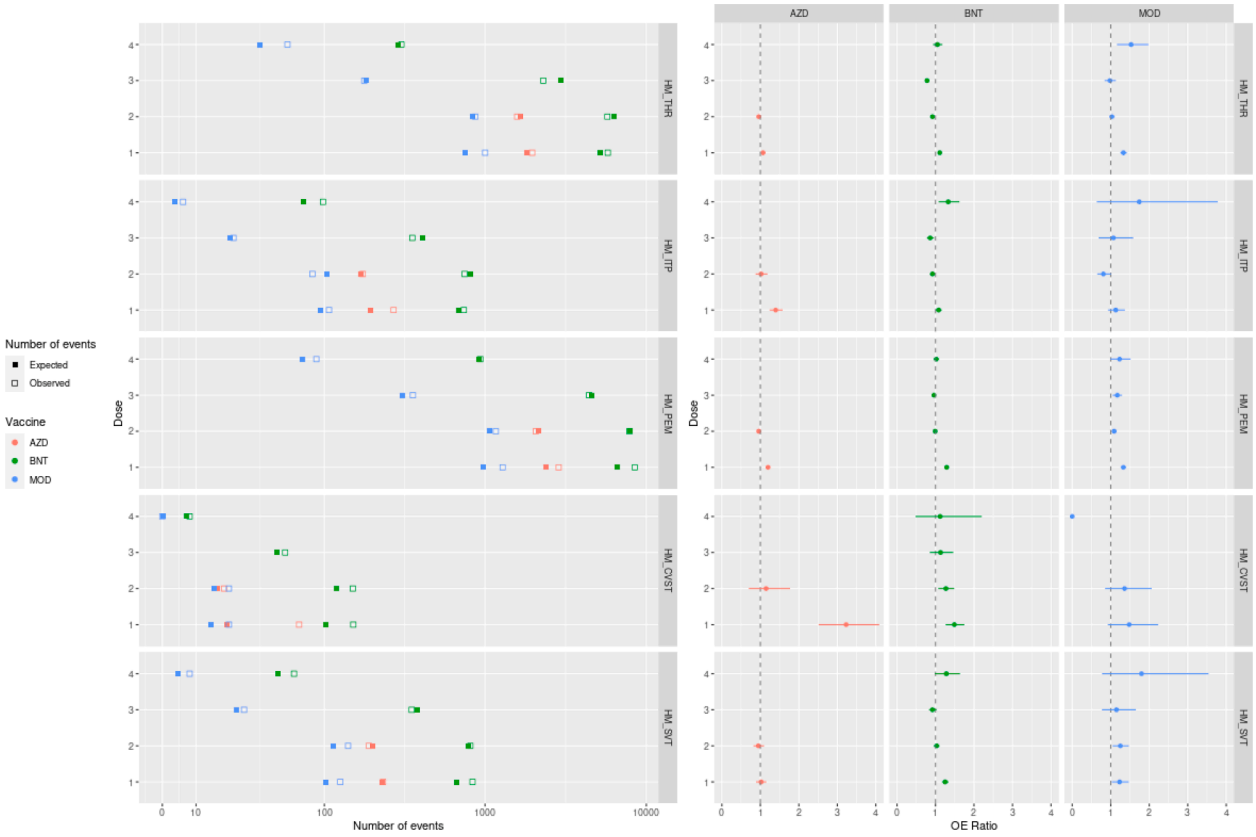

Fig. 2. Number of events and OE ratios (with 95 % confidence interval) for homologous schedules by dose 1–4, hematologic conditions. AESI: THR = Thrombocytopenia, ITP = Idiopathic thrombocytopenia, PEM = Pulmonary embolism, CVST = Cerebral venous sinus thrombosis, SVT = Splanchnic vein thrombosis. Vaccines: AZD = Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1), BNT = Pfizer/BioNTech (BNT162b2), MOD = Moderna (mRNA-1273).

1273, and third dose of ChAdOx1, in the 0–42 days risk period. The elevated rates of pericarditis following ChAdOx1 vaccination identified in this study rely on a limited number of observed counts in the meta-analysis. The wide confidence interval underscores the substantial uncertainty of characterizing pericarditis as a safety signal following ChAdOx1 vaccination. However, our study confirms findings of previously identified rare cases of myocarditis and pericarditis following first and second doses of mRNA vaccines [21–23,34]. A large cohort study of 23.1 million residents across four Nordic countries revealed an increased risk of myocarditis among young males aged 16–24 years, based on 4–7 excess events in 28 days per 100,000 vaccinees after a second dose of BNT162b2, and between 9 and 28 per 100,000 vaccinees after a second dose of mRNA-1273 [22]. Similarly, studies from British Columbia, Canada reported cases of myocarditis to be higher among those receiving a second dose compared with a third dose, and for those who received a second dose of the mRNA-1273 vaccine compared with the BNT162b2 vaccine [35,36]. Patone et al. [37] estimated extra myocarditis events to be between one and 10 per million persons in the month following vaccination, which was substantially lower than the 40 extra events per million persons observed following SARS-CoV-2 infection period. A systematic review by Alami et al. [38] concluded that mRNA vaccinated individuals were twice as likely to develop myocarditis/pericarditis compared with unvaccinated individuals, with a rate ratio of 2.05 (95 % CI 1.49–2.82). Given the evidence, WHO issued updated guidance regarding these safety signals and mRNA COVID-19 vaccination, and EMA provided updates to the Product Information for BNT162b2 and mRNA-1273 vaccines [21,23]. TGA as well as the CDC continue to monitor and review data on myocarditis and pericarditis following COVID-19 vaccination [39,40].

Another potential safety signal was identified for ADEM after the first dose of mRNA-1273 vaccine, with five more observed than expected events based on 1,035,871 person-years and 10.5 million doses administered; however, the number of cases of this rare event were small and the confidence interval wide, so results should be interpreted with caution and confirmed in future studies. Although some case reports have suggested a possible association between COVID-19 vaccination and ADEM, there was no consistent pattern in terms of vaccine or timing following vaccination, and larger epidemiological studies have not confirmed any potential association [41–44]. Moreover, case reports may report on coincidental events and do not establish association nor indicate causality, thus larger observational studies are warranted to further investigate our finding. To address this, a follow-up study is currently being undertaken within the GVDN, focusing on a demographic not included in our analysis. Based on reports of rare ADEM cases to the European Database of Suspected Adverse Drug Reaction, EMA assessed the potential association of ADEM following vaccination with ChAdOx1 [45]. Frontera et al. [46] concluded that chances of having a neurological event following acute SARS-CoV-2 infection were up to 617-fold higher than following COVID vaccination, suggesting that the benefits of vaccination substantially outweigh the risks. A safety signal for generalized seizures was identified following Gamaleya Research Institute/Sputnik vaccination, however the number of vaccinations was relatively low compared with other vaccines in this study. Further studies are warranted to explore this potential safety signal.

Conducting a cohort analysis in the unique multi-country context of the GVDN leverages a vast and diverse data pool. Aggregating data from multiple countries on more than 99 million vaccine recipients has significantly increased the sample size and the statistical power compared with many previous safety studies. This enhances the ability to detect safety signals, especially for extremely rare adverse events, as the larger sample size provides greater precision in estimating observed rates.

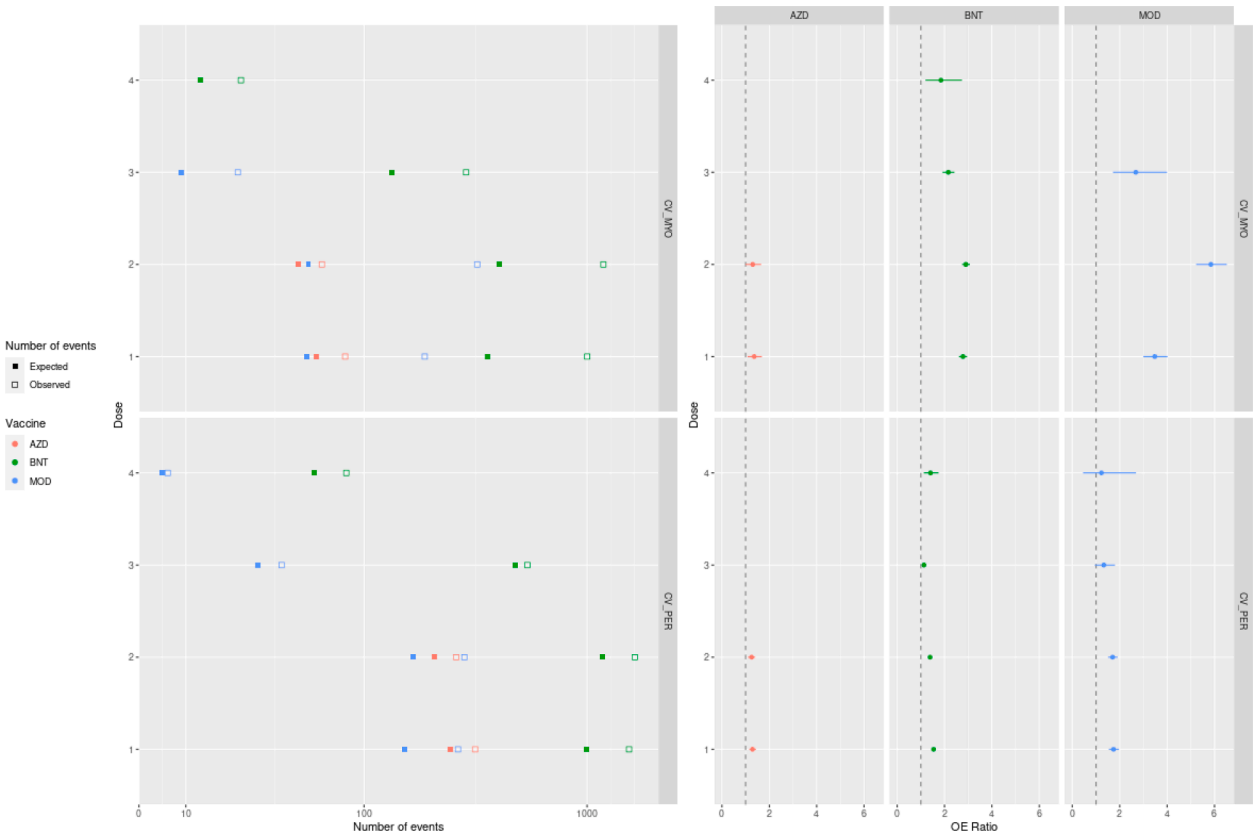

Fig. 3. Number of events and OE ratios (with 95 % confidence interval) for homologous schedules by dose 1–4, cardiovascular conditions. AESI: MYO = Myocarditis, PER = Pericarditis. Vaccines: Vaccines: AZD = Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1), BNT = Pfizer/BioNTech (BNT162b2), MOD = Moderna (mRNA-1273).

Results based on data across Europe, North and South America and Oceania offer stronger external validity, enabling findings to be more generalizable to a broader range of populations and healthcare settings participating in the global COVID-19 vaccination programme. Moreover, multi-country analyses facilitate comparisons between countries with varying vaccination strategies, population demographics, and healthcare systems, yielding insights into how these factors may influence vaccine safety profiles. Data used in our analysis were drawn from multiple databases, including healthcare databases, national immunization registries, and vaccination dashboards, allowing the identification of potential safety signals from various sources.

The results from our study should, however, be interpreted considering multiple limitations. Our analyses inherently involve heterogeneity in data collection, quality, and reporting standards across countries. These differences in healthcare infrastructure and surveillance systems can introduce bias and affect the comparability of results. The participating sites across the eight countries implemented varied vaccination strategies, including vaccine types, dosing schedules, and prioritization of vaccine recipients. Moreover, the multi-country analyses are susceptible to population confounding factors, such as differences in pre-existing health conditions, genetic factors, ethnic profiles, and behavioural patterns, which was not possible to adjust for in our analysis. We consider our approach suitable for application in large datasets representing average populations. However, age- and sex-specific historic background rates that are not adjusted for factors like prior disease may not provide a suitable comparison, for example, in the early stages of a vaccination campaigns where people with co-morbidities were vaccinated prior to other population groups.

Potential underreporting across countries may have led to an underestimation of the significance of potential safety signals. It is important to recognize the potential for false negatives, especially when detecting associations with lower confidence intervals below 1.5 that maintain statistical significance. The safety signals identified in this study should be evaluated in the context of their rarity, severity, and clinical relevance. Moreover, overall risk–benefit evaluations of vaccination should take the risk associated with infection into account, as multiple studies demonstrated higher risk of developing the events under study, such as GBS, myocarditis, or ADEM, following SARS-CoV-2 infection than vaccination. Finally, the use of ICD-10 codes is subject to considerations about specificity and sensitivity, and application may vary by country.

5. Conclusion

Observed vs. expected analyses in a multi-country context of the GVDN and the GCoVS Project offers a larger and more diverse dataset, enhanced generalizability, and improved statistical power over single site or regional studies. It also presents challenges related to data heterogeneity, population confounding factors, and variations in vaccination strategies and reporting systems. The involvement of researchers and data sources from diverse regions of the world promotes inclusivity, reduces potential biases, and fosters collaboration in the pursuit of a shared public health goal. While our study confirmed previously identified rare safety signals following COVID-19 vaccination and contributed evidence on several other important outcomes, further investigation is warranted to confirm associations and assess clinical significance. This could be addressed by conducting association studies specific to individual outcomes by applying methodologies such as the self-controlled case series (SCCS) to validate the associations [6].

Disclaimer

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Funding statement

The GCoVS project is supported by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totalling US $10,108,491 with 100 % per cent funded by CDC/HHS.

The Ontario site contributing to this study was supported by Public Health Ontario and by the ICES, which is funded by an annual grant from the Ontario Ministry of Health. JCK is supported by a Clinician-Scientist Award from the University of Toronto Department of Family and Community Medicine.

CRediT authorship contribution statement

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Jeffrey C. Kwong reports financial support was provided by Centers for Disease Control and Prevention. Naveed Z. Janjua reports financial support was provided by Centers for Disease Control and Prevention. Anders Hviid reports financial support was provided by Global Vaccine Data Network. Helen Petousis-Harris reports financial support was provided by New Zealand Ministry of Health. Steven Black reports a relationship with GSK that includes: consulting or advisory. Jeffrey C. Kwong reports a relationship with Canadian Institutes of Health Research that includes: funding grants. Jeffrey C. Kwong reports a relationship with Public Health Agency of Canada that includes: funding grants. Naveed Z. Janjua reports a relationship with AbbVie Inc that includes: consulting or advisory and speaking and lecture fees. Naveed Z. Janjua reports a relationship with Gilead Sciences Inc that includes: speaking and lecture fees. Anders Hviid reports a relationship with Independent Research Fund Denmark that includes: funding grants. Anders Hviid reports a relationship with Lundbeck Foundation that includes: funding grants. Anders Hviid reports a relationship with Novo Nordisk Foundation that includes: funding grants. Anders Hviid reports a relationship with VAC4EU that includes: consulting or advisory. Finnish Institute for Health and Welfare (THL) conducts Public-Private Partnership with vaccine manufacturers and has received research funding from Sanofi Inc. Petteri Hovi has been an investigator in these studies, but has received no personal remuneration. Helen Petousis-Harris has served on expert advisory boards and had speaking engagements for Pfizer and GSK. She has also received research funding from GSK. She has not received any personal honoraria. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The authors do not have permission to share data.

Acknowledgements

The Observed vs Expected Analyses Of COVID-19 Vaccine Adverse Events of Special Interest Study Protocol was developed by the Observed vs. Expected Work Group led by Anders Hviid[a,b]. Members of the Work Group were Nelson Aguirre Duarte[c], Miia Artama[d], Karin Batty[e], Steven Black[c,f], Hannah Chisholm[c], Hazel Clothier[g,h,i], Fuqiang Cui[j], Lucy Deng[k], Lucy Cullen[l], Heather Gidding[k,m,n], Petteri Hovi[o], Yannan Jiang[c], Janine Paynter[c], Helen Petousis-Harris[c], Anastasia Phillips[k], John Sluyter[c], Thuan Vo[d,o], and Daniel Walsh[c], Eric Weintraub[p].

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2024.01.100.

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EXHIBIT E

Children's Health Defense®

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[redacted] The purpose of this letter is to briefly outline the corruption and fraud committed by the Department of Justice (DOJ) during the Omnibus Autism Proceeding (OAP).[1] Revealing the blatant fraud perpetrated by DOJ attorneys and the same DOJ official[2] who is currently responsible for ensuring the integrity of the past and upcoming presidential elections is key to ending the autism epidemic.

Congress passed the National Childhood Vaccine Injury Act of 1986[3] ("Vaccine Act") with the intent to provide vaccine manufacturers significant protection from liability and compensation to vaccine-injured children, arising from unavoidable adverse effects of vaccines, including brain damage and death. After the Vaccine Act was enacted, the number of recommended childhood vaccines dramatically increased.[4,5] There was a parallel dramatic increase in childhood developmental disabilities, including autism.[6,7,8]

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[3] https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim *See* 42 U.S.C. §§ 300aa-1 to 300aa-34
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The Vaccine Act requires any person alleging injury by a vaccine recommended by the CDC's Advisory Committee on Immunization Practices to first file a petition for compensation under the National Vaccine Injury Compensation Program (NVICP).[9] The Program is an administrative proceeding supervised by the U.S. Court of Federal Claims and is deceptively referred to as "vaccine court."[10] Injured individuals cannot sue directly in state or federal court. "Vaccine court" is not a court of law; it is an invitation for abuse of power.

In 2002, in response to a sudden influx of thousands of cases alleging vaccine-induced autism, the Special Masters in the "vaccine court" formed the Omnibus Autism Proceeding.[11] The purpose of the OAP was to determine "whether the vaccinations…can cause autism and/or similar disorders, and if so in what circumstances; and then, second, apply the conclusions reached in that general inquiry to the individual cases."[12] The outcome of essentially all of the cases in the OAP was determined by six test cases.[13]

By default,[14] my son's case, *Hazlehurst v. HHS*,[15] became the second of the six test cases in the OAP and directly represented nearly 5,000 children[16] with autism in "vaccine court." My son and all but a single child in the OAP were denied compensation.[17] The decision in his case, which was obtained by fraud, was used by the government and the pharmaceutical industry as the centerpiece of their policy argument before the Supreme Court to deny vaccine-injured children access to courts of law.

The decisions in *Hazlehurst v. HHS* [18] and the OAP were at the center of the policy arguments[19] by the government and the vaccine industry before the Supreme Court of the United States in *Bruesewitz v. Wyeth*.[20] In essence, the 2011 *Bruesewitz* decision involved statutory interpretation of one section[21] of the Vaccine Act, which controls whether the U.S. Food and Drug Administration or a jury determines if a vaccine adverse effect is unavoidable. According to the dissenting[22] and concurring[23] opinions in *Bruesewitz*, the decisions in *Hazlehurst* and the OAP

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directly influenced[24] the SCOTUS decision[25] in *Bruesewitz*,[26] which effectively shields the pharmaceutical industry from liability for vaccine injury based upon design defect claims.

In Sept. 2018, Children's Health Defense (CHD),[27] Robert F. Kennedy Jr., Children's Health Defense's chairman on leave, and I submitted a letter[28] to the DOJ's Office of Inspector General as well as the House and Senate Judiciary Committees, outlining the DOJ's fraud upon the court during the OAP. In brief, we alleged[29] that the DOJ attorneys representing HHS in the OAP **intentionally misled both the Special Masters in "vaccine court" and later the Court of Federal Claims and the Court of Appeals for the Federal Circuit as to the opinion of the government's top expert witness, Dr. Andrew Zimmerman,[30] and willfully concealed critical material evidence of how vaccines can cause autism.**

On April 27, 2007, Dr. Zimmerman wrote an expert opinion in the first test case, which stated in part:

> *There is no scientific basis for a connection between measles, mumps and rubella (MMR) vaccine or mercury (Hg) intoxication and autism. Despite well-intentioned and thoughtful hypotheses and widespread beliefs about apparent connections with autism and regression, there is no sound evidence to support a causative relationship with exposure to both, or either, MMR and/or Hg.*[31]

However, on June 15, 2007, before he was to testify in the first OAP test case, Dr. Zimmerman explained to the DOJ attorneys that his expert written opinion in the first test case was *case specific*, and "was not intended to be a blanket statement as to all children and all medical science." Most importantly, **he explained to the DOJ attorneys "that there were exceptions in which vaccinations could cause autism," and how vaccines *did* cause regressive autism in one of his patients (Hannah Poling) and likewise, could cause autism in a subset of children with an underlying mitochondrial disorder.** Dr. Zimmerman referred the DOJ attorneys to a recently published study he co-authored with Dr. Jon Poling in the *Journal of Child Neurology*, now known as "the Poling paper."[32]

The DOJ attorneys responded to Dr. Zimmerman's clarification, modification and alteration of his original opinion by dismissing him as an expert witness by that evening. However, the lead DOJ attorney would go on to intentionally misrepresent[33] Dr. Zimmerman's written case-specific opinion, and without Dr. Zimmerman's caveat, as general causation evidence during the

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[24] https://childrenshealthdefense.org/wp-content/uploads/bruesewitz_vs_wyeth_oral_argument.pdf
[25] https://childrenshealthdefense.org/wp-content/uploads/NEW-everything-combined.pdf
[26] https://supreme.justia.com/cases/federal/us/562/223
[27] https://childrenshealthdefense.org
[28] https://childrenshealthdefense.org/wp-content/uploads/DOJ-Fraud-letter.pdf
[29] https://childrenshealthdefense.org/news/misconduct-mitochondria-and-the-omnibus-autism-proceedings
[30] https://fullmeasure.news/news/cover-story/the-vaccination-debate
[31] https://childrenshealthdefense.org/wp-content/uploads/Affadavit-AZ-090818.pdf
[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2536523
[33] https://childrenshealthdefense.org/wp-content/uploads/Hazlehurst-v.-HHS-p.695-696.pdf

Hazlehurst hearing. The Special Master specifically relied upon the misrepresented interpretation of Dr. Zimmerman's written expert opinion in her decision[34] to deny compensation.

As events unfolded, the DOJ was forced to secretly concede[35] what was to be the fourth test case[36] in the OAP, *Poling v. HHS*.[37] If the DOJ had not conceded *Poling,* Dr. Zimmerman would have testified as a witness in the Poling case, in which event, his full and accurate opinions as to how vaccines cause autism, and how the DOJ intentionally misrepresented his opinions would have been revealed.

In 2008, after the concession in *Poling*[38] was leaked to the media[39] and became international news,[40] DOJ opposed the Poling's Motion for Complete Transparency[41] of the Proceedings and secretly changed the legal basis of compensation in order to cover up DOJ's fraud and deny compensation to the remaining petitioners in the OAP.

During oral arguments[42] before the U.S. Court of Appeals for the Federal Circuit in 2010, the court asked, based on increased knowledge and rapidly developing advances in medicine and science, what level of proof is necessary for petitioners to prove that vaccine injury causes autism, to which Lynne Ricciardella, the DOJ attorney representing HHS, responded by falsely stating:

> *We're not even at the stage where it's medically or scientifically possible. This is not a field of science that is bereft of research. Studies have been done looking at the causal connection between autism and MMR, autism and Thimerosal, and every credible study has shown that there is no causal connection.*

Mrs. Ricciardella knew her statement was a lie, as she had previously opined that vaccine injury caused Hannah Poling's autism when she signed the DOJ rule 4-c report[43] based upon proof of causation[44] by a preponderance of the evidence standard, the expert opinions of Dr. Zimmerman, and "the Poling paper."

The DOJ Office of Professional Responsibility (DOJ OPR) responded to the Sept. 2018 complaint submitted by Mr. Kennedy, CHD and myself with a letter dated June 26, 2019,[45]

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[34] https://childrenshealthdefense.org/wp-content/uploads/Hazlehurst-v.-HHS-p.-9.pdf
[35] https://childrenshealthdefense.org/wp-content/uploads/Poling-Huffington-Post.pdf
[36] https://www.cbsnews.com/news/vaccine-case-an-exception-or-a-precedent
[37] https://www.cbsnews.com/news/family-to-receive-15m-plus-in-first-ever-vaccine-autism-court-award
[38] https://live.childrenshealthdefense.org/chd-tv/videos/cnns-dr-sanjay-gupta-interviews-dr-jon-poling-on-4-4-08
[39] https://childrenshealthdefense.org/wp-content/uploads/Poling-Huffington-Post.pdf
[40] https://live.childrenshealthdefense.org/chd-tv/videos/cdc-director-julie-gerberding-admits-vaccines-can-cause-autism-like-symptom
[41] https://childrenshealthdefense.org/wp-content/uploads/order-deferring-ruling-on-motion.pdf
[42] https://childrenshealthdefense.org/wp-content/uploads/00407haz-full.pdf
[43] https://childrenshealthdefense.org/wp-content/uploads/Poling-Huffington-Post.pdf
[44] https://childrenshealthdefense.org/wp-content/uploads/1-4_6-7_Bruesewitz-vs-wyeth.pdf
[45] https://childrenshealthdefense.org/wp-content/uploads/OPR-441599-v1-Closing_letter_to_Childrens_Health_Defense-1.pdf

absolving the DOJ of any wrongdoing, and closed its inquiry. The cornerstone of the DOJ's fraudulent cover story is as follows:

> *According to Mr. Matanoski, the Department lawyers reviewed the medical records in the Poling case and concluded that Hannah Poling had an encephalopathy, which, in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii),*[46] *was a presumptive MMR vaccine-related injury.*

This statement is a blatant lie. It is contrary to both 42 U.S.C. § 300aa-11(c)(1)(C)(ii)[47] of the Vaccine Act as interpreted by the Supreme Court[48] in *Bruesewitz,* and confidential records[49] that the DOJ opposed the release of.[50]

The DOJ OPR response letter also falsely states:

> *During his OPR interview, Dr. Zimmerman stated that he spoke with CSTL attorney Voris Johnson, not Mr. Matanoski, which is consistent with the other evidence OPR gathered in this matter*.

This statement is yet another lie. The DOJ OPR statement directly contradicts the interview, which was audio recorded.

The DOJ OPR letter[51] is a cover-up of DOJ fraud upon the court and contains multiple false and highly misleading statements of fact and law. The letter was written by the Director & Chief Counsel of the DOJ OPR[52] Corey R. Amundson.[53] In Sept. 2019, Mr. Amundson became Chief of the Public Integrity Section (PIN) within the Criminal Division of the DOJ.[54] The DOJ PIN is the branch of the DOJ that oversees the investigation and prosecution of the highest crimes involving government corruption, including election fraud.

I have subsequently acquired new compelling evidence proving the DOJ fraud was much more sinister and blatant than I had previously realized when Mr. Kennedy, CHD and I submitted our letter requesting an investigation. I respectfully request a meeting with you to discuss the critical evidence I have accumulated, including powerful new evidence acquired as a result of a separate legal action.[55]

Dr. Zimmerman has since testified to the following regarding my son, Yates:

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[46] https://www.law.cornell.edu/uscode/text/42/300aa-11
[47] Ibid.
[48] https://childrenshealthdefense.org/wp-content/uploads/1-4_6-7_Bruesewitz-vs-wyeth.pdf
[49] https://childrenshealthdefense.org/wp-content/uploads/Poling-Huffington-Post.pdf
[50] https://childrenshealthdefense.org/wp-content/uploads/order-deferring-ruling-on-motion.pdf
[51] https://childrenshealthdefense.org/wp-content/uploads/OPR-441599-v1-Closing_letter_to_Childrens_Health_Defense-1.pdf
[52] https://www.justice.gov/opr/role-and-authority
[53] https://www.dni.gov/files/ICIG/Documents/Conference/2023/Bios/Bio%20Corey%20Amundson%20.pdf
[54] https://www.justice.gov/criminal-pin
[55] https://childrenshealthdefense.org/defender/william-yates-hazlehurst-autism-childhood-vaccine-injury-liability

> *In my opinion, and to a reasonable degree of medical certainty, Yates Hazlehurst suffered regressive encephalopathy with features of autism spectrum disorder as a result of a vaccine injury in the same manner as described in the DOJ concession in Poling v. H.H.S.*

I have been an attorney for almost thirty years. I was an Assistant District Attorney General for the State of Tennessee for almost fifteen years. If I did what the United States Department of Justice did, I would be disbarred.

[redacted] **Until this DOJ fraud and corruption is exposed, the autism epidemic will never end.**

Thank you for your consideration.

Sincerely,

Rolf G. S. Hazlehurst
Senior Staff Attorney
Children's Health Defense

cc: [redacted]
cc: [redacted]
cc: [redacted]

EXHIBIT F

SUPREME COURT
OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

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FOOD AND DRUG ADMINISTRATION,)
ET AL.,)
Petitioners,)
v.) No. 23-235
ALLIANCE FOR HIPPOCRATIC MEDICINE,)
ET AL.,)
Respondents.)

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DANCO LABORATORIES, L.L.C.,)
Petitioner,)
v.) No. 23-236
ALLIANCE FOR HIPPOCRATIC MEDICINE,)
ET AL.,)
Respondents.)

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Pages: 1 through 103

Place: Washington, D.C.

Date: March 26, 2024

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IN THE SUPREME COURT OF THE UNITED STATES

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Washington, D.C.

Tuesday, March 26, 2024

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:04 a.m.

APPEARANCES:
GEN. ELIZABETH B. PRELOGAR, Solicitor General,
Department of Justice, Washington, D.C.; on behalf
of the Federal Petitioners.
JESSICA L. ELLSWORTH, ESQUIRE, Washington, D.C.; on
behalf of Petitioner Danco Laboratories, L.L.C.
ERIN M. HAWLEY, ESQUIRE, Washington, D.C.; on behalf
of the Respondents.

C O N T E N T S

P R O C E E D I N G S

(10:04 a.m.)

CHIEF JUSTICE ROBERTS: We will hear argument this morning in Case 23-235, the Food and Drug Administration versus Alliance for Hippocratic Medicine, and the consolidated case.

General Prelogar.

ORAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR
ON BEHALF OF THE FEDERAL PETITIONERS

GENERAL PRELOGAR: Mr. Chief Justice, and may it please the Court:

FDA approved mifepristone based on the agency's scientific judgment that the drug is safe and effective. It's maintained that judgment across five presidential administrations, and millions of Americans have used mifepristone to safely end their pregnancies. Respondents may not agree with that choice, but that doesn't give them Article III standing or a legal basis to upend the regulatory scheme.

At the outset, Respondents lack standing. They now concede they can't rely on a statistical theory of injury like the lower courts did. Instead, they have to identify a

specific doctor who faces imminent harm.

But their theories rest on a long chain of remote contingencies. Only an exceptionally small number of women suffer the kind of serious complications that could trigger any need for emergency treatment. It's speculative that any of those women would seek care from the two specific doctors who asserted conscience injuries. And even if that happened, federal conscience protections would guard against the injury the doctors face.

And there's no basis to conclude that any of that would be traceable to the incremental changes that FDA made in 2016 and 2021 as opposed to the availability of mifepristone in general. Respondents' theories are too attenuated as a matter of law. The Court should say so and put an end to this case.

If the Court reaches the merits, FDA's actions were lawful. The agency relied on dozens of studies involving tens of thousands of women. Respondents don't identify any evidence that the agency overlooked. They just disagree with the agency's analysis of the data before it, but that doesn't provide a license to

authorize judicial second-guessing of the agency's expert judgments.

Finally, on remedy, the relief entered below would severely disrupt the federal system for developing and approving drugs, harming the agency and the pharmaceutical industry. It would also inflict grave harm on women across the nation. Rolling back FDA's changes would unnecessarily restrict access to mifepristone with no safety justification.

Some women could be forced to undergo more invasive surgical abortions. Others might not be able to access the drug at all. And all of this would happen at the request of plaintiffs who have no certain injury of their own. The Court should reject that profoundly inequitable result.

I welcome the Court's questions.

JUSTICE THOMAS: General, if we agree with you on standing, could you give us an example of who would have standing to challenge -- to challenge these FDA actions?

GENERAL PRELOGAR: As a general matter, we've seen lawsuits in the past that are brought by, for example, prescribing physicians

or patients who want greater access to a drug. Sometimes we've seen theories of competitor standing, where a competing drug manufacturer might sue and claim that FDA's approval of a drug creates a competitive harm or in -- or injury in that sense.

You know, Justice Thomas, I think that if the question is whether there would be individuals who generally oppose abortion who would have standing and want to challenge FDA's actions, the answer to that is no, but the reason is because those people aren't regulated in any relevant way under FDA's decisions here.

You know, take these Respondent doctors. They don't prescribe mifepristone. They don't take mifepristone, obviously. FDA is not requiring them to do or refrain from doing anything. They aren't required to treat women who take mifepristone. FDA is not directing the women who take the drug to go seek out care from these specific doctors. And so they stand at a far distance from the upstream regulatory action they're challenging.

And the Court has said in many cases that in a situation like that, when you are not

the direct object of the agency's regulation, it can be substantially more difficult to establish standing.

JUSTICE THOMAS: But isn't that sort of a criticism of some of our associational standing cases and organizational standing cases?

GENERAL PRELOGAR: I don't think it is for a couple of different reasons.

With respect to associational standing, this Court has said time and again that the association needs to identify a specific member who is suffering a concrete harm, a cognizable injury that's non-speculative. And I don't take Respondents now to take issue with that fact. They're agreeing that it would be necessary to come forward and identify a specific doctor.

The problem with their associational standing theories is that they rest on this chain of remote possibilities, so many different steps in the process that would have to occur, each one layering one's speculative remote odds of a chance of injury on top of another to get to the ultimate harm they're claiming on behalf

of these doctors.

CHIEF JUSTICE ROBERTS: Well, you emphasized the remote nature of the injury, the small number of adverse effects, the likelihood that they'll -- the patients will go to the emergency room and so on.

Is there a number at which your argument would -- would change? A significant number of consequences? A higher likelihood of an emergency room visit? Doctors who spend more time in the emergency room? At some point, does this analysis lead to the other result?

GENERAL PRELOGAR: It's hard for me to imagine that it could, and -- and there are a couple of different reasons for that. I take the point that you might pick out different links in the chain and suggest that there are ways to wildly depart from the facts here and suggest maybe, as a statistical matter, one or two of those events could be probabilistically more likely to occur.

But we have an objection here to the underlying theory as a legal matter because it rests on so many different things that would have to happen one on top of another and that

turn on independent decisions made by third parties who are strangers to this litigation, who are not part of the suit.

So we think that brings the case within those like Clapper or Summers, where this Court has recognized that when the theory of injury really turns on so many different intervening events separated by independent decisions, it can mean that there is just an insurmountable hurdle to establishing standing.

JUSTICE ALITO: Could you provide a more specific answer to the first question that Justice Thomas asked you? Is there anybody who could challenge in court the lawfulness of what the FDA did here?

GENERAL PRELOGAR: In this particular case, I think the answer is no.

JUSTICE ALITO: Well, that wasn't my question. Is there anybody who can do that?

Let's -- let's start with the states that intervened below. Will you say in that litigation, fine, you can challenge it, and let's get to the -- to the merits of this issue, the lawfulness of what the FDA did?

GENERAL PRELOGAR: No. We think the

states lack standing. They're asserting indirect injuries that would, if it provided a basis for standing, mean that states could always sue the federal government. And the Court cautioned against that result in United States versus Texas, Footnote 3 of that decision.

JUSTICE ALITO: Okay. How about a -- a doctor who opposes abortion? So she's on duty in an emergency room when a woman comes in with complications from having taken mifepristone, and the doctor is the only one there on duty who can attend to this woman's problem and, as a result, in order to save her life, the doctor has to abort a viable fetus.

Now would that doctor then have standing to seek injunctive relief, or would you say that's too speculative? This was like being struck by lightning and there's no -- it's not sufficiently likely that this is going to happen to this doctor again?

GENERAL PRELOGAR: We would agree that that would represent past harm, so we're not disputing that that kind of conscience violation, providing care in violation of one's

conscience, would be cognizable. But, yes, we think that that situation has never come to pass. Respondents haven't identified any incident in more than 20 years that mifepristone has been available on the market that resembles that kind of hypothetical situation.

And so, yes, our view would be it's unduly speculative. And you have to think about all of the events that would have to transpire to get to that moment in time.

JUSTICE ALITO: Sure. No, I -- I understand the argument.

Now how about a woman who suffers adverse consequences from having taken mifepristone? Would she be able to sue for damages, or you would say that's barred by sovereign immunity?

GENERAL PRELOGAR: I expect that we would have sovereign immunity arguments in that kind of case. I -- I recognize that respect -- with respect to traceability, that's a harder argument for us.

JUSTICE ALITO: Okay. Is there anybody who can sue and get a judicial ruling on whether what FDA did was lawful? And maybe what

they did was perfectly lawful, but shouldn't somebody be able to challenge that in court? Who in your view? Who would have standing to bring that suit?

GENERAL PRELOGAR: I think that with respect to these regulatory changes, it's hard to identify anyone who would have standing to sue, but the Court has said time and again that the fact that no one would have standing doesn't provide a basis to depart from Article III principles.

It said that in Raines, in Richardson, in Valley Forge, and in Clapper, and so I think it's clear that even if there is no alternative person here who could sue, that doesn't mean that the Court should dispense with the indispensable requirements of Article III.

JUSTICE ALITO: Okay. I understand that. And Article III is important.

So your argument is that it doesn't matter if FDA flagrantly violated the law, it didn't do what it should have done, endangered the health of women, it's just too bad, nobody can sue in court?

GENERAL PRELOGAR: Certainly, we think

that this --

JUSTICE ALITO: There's no -- there's no remedy? The American people have no remedy for that?

GENERAL PRELOGAR: Well, I -- I think that it would be wrong to suggest that if FDA had made a mistake and a drug were actually producing safety consequences that there would be nothing to be done. I -- I don't think that these Respondents could invoke Article III jurisdiction to have the Court step in.

But FDA takes very seriously its responsibility to ensure the safety of drugs. It conducts ongoing surveillance and can make adjustments to the regulatory regime if safety situations emerge. The drug sponsors themselves remain responsible at all times. We have a tort system in this country, and that can help ensure that if there are safety problems that come to pass, the sponsors will take action in reaction to that.

So, if the premise here is that unsafe drugs could somehow remain on the market, I think that that's incorrect.

JUSTICE ALITO: I mean, so your

argument here is -- and as I said, I have great respect for Article III. We all do. We have to comply with it.

But your argument here is that even if the FDA acted unlawfully, nobody can challenge that in court? I mean, that's basically the argument you made last week, right, in the Murthy case. We shouldn't get to the question whether the White House and others violated the right to freedom of speech. We should just say, well, these plaintiffs can't bring suit, right?

GENERAL PRELOGAR: We -- we are looking at the specific Respondents in this case and their theories of standing. We don't think they come within a hundred miles of the kind of circumstances this Court has previously identified of non-speculative harm that can create the kind of cognizable injury for forward-looking relief.

JUSTICE JACKSON: General --

JUSTICE SOTOMAYOR: I'm assuming that if there were an -- if this had been unsafe in a grossly visible way, you know, 40 percent more increased hospitalizations, that some doctor who was prescribing it would have challenged the

lack of an in-person --

GENERAL PRELOGAR: Well, no doctor is required, Justice Sotomayor, to dispense other -- in person, so they would have --

JUSTICE SOTOMAYOR: No, but a doctor who wants to, just like a doctor who wants to do abortion, we have said, if there's regulations that stop them from doing it, I guess that doctor could come in and say: This is unsafe, I can't -- by not having people visit me beforehand, we're not warning them, et cetera, et cetera.

GENERAL PRELOGAR: Certainly, I think, if those kinds of -- of distinct safety concerns emerge, there would be steps taken at the agency level. There's nothing like that here. There's no contrary --

JUSTICE SOTOMAYOR: No, I'm -- I'm pondering --

GENERAL PRELOGAR: -- evidence to suggest it.

JUSTICE SOTOMAYOR: -- I'm pondering a hypothetical.

GENERAL PRELOGAR: But I do want to be clear that FDA's regulations here don't require

doctors to -- to not grant an in-person visit if they think that that is the best way to provide a standard of care here. So they are not directly required to dispense mifepristone through any particular arrangement.

JUSTICE SOTOMAYOR: All right.

JUSTICE BARRETT: Counsel, can I ask you a question about the conscience injury. So that's one of the roadblocks you identify in the speculative chain because you say a doctor could invoke federal conscience protections to refuse to complete an abortion that was when the -- the embryo or fetus was still alive.

So I just want to be clear, the federal government's position is that though a doctor would have conscience objections -- I'm thinking about the EMTALA litigation, and the Fifth Circuit criticized the government's inconsistent positions -- but it is your position that such doctors would have recourse to the conscience protections of federal law?

GENERAL PRELOGAR: Yes, absolutely. And let me be clear about this because I think the Fifth Circuit did fundamentally misunderstand our arguments and Respondents have

repeated that misunderstanding here.

The federal government has never taken the position that EMTALA would override an individual doctor's conscience objections. We said exactly the opposite. If you go and look at our Fifth Circuit reply brief in the Texas litigation, we disclaimed that understanding of EMTALA and made clear that we understand the conscience protections to continue to apply and shield a doctor who doesn't want to provide care in violation of those protections.

JUSTICE BARRETT: Would that be true in a healthcare desert as well?

GENERAL PRELOGAR: Yes. So we don't think that EMTALA would override conscience protections for the individual doctor. It, of course, imposes obligations on hospitals, and hospitals have all kinds of plans in place to address these types of contingencies. You know, they have staffing plans. I understand, as a matter of best practices, they often ask for doctors to articulate their conscience objections in advance so they can take account of that in staffing. They have cross-staffing agreements with other hospitals.

And in the government's experience enforcing EMTALA -- this is almost four decades of experience -- we are not aware of any situation where there has been that kind of direct conflict between EMTALA and conscience protections.

JUSTICE BARRETT: Okay. Just one last question. This is about the association's standing, so its own standing in its own right I'm talking about, not its standing that based -- is based on injury to one of its members.

So the injuries that the association is arguing sound in the Havens Realty associational standing, and they're the kinds of allegations we see by immigration advocacy groups, diversion of resources, increased expenses that result from the complications of having to address and explain the new changes.

And I'm not talking about the expenses of filing the petition. That's not what I'm talking about. Let's just talk about the diversion of resources.

Can you distinguish that from Havens Realty?

GENERAL PRELOGAR: Yes. So I think

Havens itself was trying to distinguish between two types of potential organizational injuries, and what Havens said is that in that case, the organization had come forward with direct and concrete demonstrable injury to itself.

And there the organization had a contract to provide low-income housing or -- or search to secure it for clients and the racial steering practices directly interfered with that, made it more difficult for the organization to carry out its contractual obligations.

But Havens itself said that it was not blessing a theory of standing that would allow an organization to assert a setback to its abstract social interests. So I think that reflects the Court trying to distinguish between more concrete, direct demonstrable harms on the one hand and that kind of abstract setback on the other hand.

And I recognize -- and you -- your question touches on it, Justice Barrett -- that some lower courts in particular have seemed to red -- read Havens to -- to endorse far broader theories of standing, including in the

immigration context.

The government has been routinely resisting standing because we think that that would essentially mean that any advocacy organization could say it opposes what the federal government is doing and so, therefore, has to devote resources to that opposition.

If that were enough, then every organization would have standing and it would be a vast expansion of ordinary Article III principles. So we would welcome an eventual clarification from this Court on organizational standing, but, here, I think that the organization's assertion of injury falls in the bucket of the abstract setback and doesn't come close to the kind of demonstrable harm that was at issue in Havens.

JUSTICE GORSUCH: General, that's -- I'm sorry.

JUSTICE BARRETT: I'm done.

JUSTICE GORSUCH: Okay. That -- that -- that's a helpful clarification. I -- I'd like a similar clarification -- thank you -- with respect to individuals.

I -- I -- I've heard and listened to

your argument and read the briefs and I think I understand it, but how does it fit in your mind with offended observer standing under the Establishment Clause or some injuries about I access a park and I like to look at it in -- in a certain way and those kinds of injuries that the Court has sometimes recognized and other times cast doubt on?

GENERAL PRELOGAR: So it's true. I think that there are different strands of this Court's precedent, you know, and -- and I would put the Establishment Clause precedent and First Amendment precedent generally in its own bucket because --

JUSTICE GORSUCH: Well --

GENERAL PRELOGAR: -- the Court has sometimes recognized different theories in the First Amendment context.

JUSTICE GORSUCH: -- let -- let me just push back on that a little bit because standing is standing. It's Article III, right --

GENERAL PRELOGAR: Yes.

JUSTICE GORSUCH: -- that we're interpreting here, and so I think it's got to --

we've got to find some way to stitch it all together, and I'm looking for guidance from you.

GENERAL PRELOGAR: So I -- I -- I think the way to approach this is to -- if you're going to recognize some kind of offense or distress type of injury, that -- to recognize that there has --

JUSTICE GORSUCH: Should we?

GENERAL PRELOGAR: Well --

JUSTICE GORSUCH: I guess as a preliminary.

GENERAL PRELOGAR: No. I mean, I --

JUSTICE GORSUCH: No?

GENERAL PRELOGAR: -- I represent the government, so I think that that kind of theory of injury would likely go far, far too much in the direction of allowing Article III courts to -- to weigh in based on generalized grievances.

But I guess what I would say to distinguish the cases where this Court has sometimes found that type of injury cognizable, generally, it's in a situation where there is a kind of direct governmental action producing that type of injury.

And, here, our argument is that the

FDA's actions in approving mifepristone specifically in 2016 and 2021 and -- if you're looking at that, which was an incremental change, is so far upstream of the downstream assertion of harm or distress that the Respondents are asserting that there is just as a matter of law an attenuated link here that cannot suffice for Article III jurisdiction.

JUSTICE GORSUCH: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas, anything further?

Justice Alito?

JUSTICE ALITO: You say that the -- the Fifth Circuit didn't give any reason to think that the three changes made in 2016 would be more dangerous in combination than they were individually. But isn't that -- isn't that obvious, that three things that may be innocuous or not excessively dangerous, if engaged in by themselves, may become very dangerous when they're all done together? And why shouldn't the FDA have addressed that?

GENERAL PRELOGAR: I think the only way that that would be true would be if the

three changes are interconnected and mutually reinforcing, guarding against the same kind of safety risk. So I agree that if there were a reason to think that the -- the reason why mifepristone is safe up to 10 weeks' gestation is because it's being prescribed by doctors instead of nurse practitioners, for example, then those changes would be interconnected because one change would effectively be the safety net for another.

But there was nothing like that in this record. The studies that FDA examined instead demonstrated that these changes -- and it was an exhaustive examination -- were safe not because there were other different safeguards in place to guard against risks but, rather, because, if you go up to 10 weeks of gestation, there is no observable increase in serious adverse events, no matter who's prescribing.

So, in the absence of that kind of correlative effect of the changes, I don't think you can fault the agency for not giving even more explicit attention to this issue. And it did. It cited multiple studies that combined

multiple changes precisely because the standard of care had evolved over the 15 years mifepristone had been approved, and many of the changes were already being deployed together safely.

JUSTICE ALITO: Shouldn't the FDA have at least considered the application of 18 U.S.C. 1461?

GENERAL PRELOGAR: So I think that the Comstock provisions don't fall within FDA's lane. FDA, under the FDCA, can only maintain restrictions under the REMS program if it's necessary to ensure safe use. In 2021, what FDA determined is you don't need in-person dispensing for safe use, so the FDCA did not independently require that REMS restriction, and, in fact, it couldn't be imposed once FDA had made that determination.

Now that doesn't affect other sources of law. FDA was not affirmatively approving mailing in violation of Comstock, even if you interpreted it that way. We don't think it means what Respondents suggest it means. But, at the very least, I don't think that it was FDA's responsibility to consider that, nor could

it have permissibly considered that under the statute.

JUSTICE ALITO: Well, it didn't say any of that. It didn't say anything about it. And this is a prominent provision. It's not some obscure subsection of a complicated obscure law. They -- they knew about it. Everybody in this field knew about it.

Shouldn't they have at least addressed it? You have answers to the arguments that are made on the other side. Shouldn't the FDA have at least said we've considered those and provide some kind of an explanation?

GENERAL PRELOGAR: Let me give two responses. One is that I don't think it would have even been permissible for FDA to consider maintaining this restriction because of Comstock. If you look at the relevant statutory section here -- it's 355-1(g)(4). This is reproduced at page 6a of the appendix to our brief. It's very clear that the only thing FDA can take into account for restrictions are safety and efficacy concerns in deciding whether to maintain a REMS program.

But the other thing I would say,

Justice Alito, is that the agency did have a memorandum on Comstock. It's at JA 535. That was the advice that FDA received from OLC conveying the interpretation of Comstock.

JUSTICE ALITO: It got the advice from OLC, but it didn't refer to that, did it?

GENERAL PRELOGAR: In the 2021 decision, no. But the REMS was then modified in 2023, and this was part of the administrative record for that.

JUSTICE ALITO: Okay. One -- one last question. The plaintiffs say that the studies that the FDA relied on for the 2021 amendments say that mail-order mifepristone suggests more frequent trips to the emergency room.

Now this is what I see as the FDA's response to that. "Although the literature suggests there may be more frequent emergency room care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other serious adverse events related to mifepristone use."

Does that really count as a reasoned explanation to the suggestion that the data

shows there are going to be more emergency room visits? This is -- the -- the increase in emergency room visits is just of no consequence? It doesn't even merit some -- some comment?

GENERAL PRELOGAR: That is a reasoned explanation. What FDA was observing in that passage is that although it acknowledged the fact that some of the studies reported additional emergency room visits, that didn't equate to additional serious adverse events.

And, in fact, one of the studies, half of the women who went to the emergency room didn't get any treatment at all. Many women might go because they're experiencing heavy bleeding, which mimics a miscarriage, and they might just need to know whether or not they're having a complication. But, in that kind of circumstance, the woman is not having a -- a -- a serious adverse event from mifepristone, and so it doesn't call into question the safety determinations regarding the drug.

And, you know, at the end of the day, FDA carefully parsed those studies. It made specific determinations about the results to be gleaned with respect to safety and efficacy. It

fully explained its decision-making, and I think it falls well within the zone of reasonableness under arbitrary and capricious review.

JUSTICE ALITO: All right. Thank you.

CHIEF JUSTICE ROBERTS: Justice Sotomayor?

JUSTICE SOTOMAYOR: On that last question, because that did trouble me, but the reality is, even if there is some increase in emergency room visits, the question of when that rises to a sufficient safety risk is up to the FDA, correct?

GENERAL PRELOGAR: That's right. And, you know, FDA acknowledged it, so it's not like it overlooked this aspect of the studies.

I also want to emphasize, Justice Sotomayor, that the studies were far from the only evidence FDA consulted. At the time it acted in 2021, it had real-world experience during the COVID-19 pandemic, a period of time when the in-person dispensing requirement was not enforced, and FDA started by looking at, as a comparative analysis, the two periods of time when you had in-person dispensing and when you didn't and saw that there was no relevant

increase in serious adverse events or a difference between those two time frames. So that further supported the safety conclusion.

JUSTICE SOTOMAYOR: The problem with all drugs is there are complications in virtually all of them.

GENERAL PRELOGAR: Yes, virtually all.

JUSTICE SOTOMAYOR: And at what level the cost/benefit analysis tells you to stop prescribing something is a very difficult question, isn't it?

GENERAL PRELOGAR: And that's a question that Congress has entrusted to FDA.

JUSTICE SOTOMAYOR: But putting that aside, here, whatever the statistical increase was, FDA determined under the REMS standard that it wasn't sufficient to create a risk that counterbalanced the need for access, correct?

GENERAL PRELOGAR: Correct, because FDA is instructed to take into account burdens on the healthcare delivery system as well, and it looked at a variety of sources of data to conclude that, on balance, the burdens were -- suggested that it was not necessary to keep this restriction in place to ensure safe use.

JUSTICE SOTOMAYOR: Thank you.
CHIEF JUSTICE ROBERTS: Justice Kagan?
JUSTICE KAGAN: General, if I could take you back to the discussion that you were having with Justice Barrett about the conscience objection and just ask you -- I'm sure that you've read the declarations carefully, and I'm sure Ms. Hawley will have things to say about this too. But, as you read those declarations, what is the conscience objection? What -- what are the doctors objecting to exactly?
GENERAL PRELOGAR: I think the declarations are specific on this point. There are only seven doctors who regularly practice and submitted evidence, and the declarations are relatively short. This is at JA 150 to 200. I encourage reading them because there are only two doctors out of the seven who even provide any information about their specific conscience objections.
JUSTICE KAGAN: Those two are who?
GENERAL PRELOGAR: Those are Dr. Skop and Dr. Francis. The relevant language for Dr. --
JUSTICE KAGAN: The other five don't

refer to conscience objections?

GENERAL PRELOGAR: They don't refer to their own conscience objections or provide any specific detail about exactly what care would violate their conscience. Dr. Francis is at JA 155. Dr. Skop is at JA 167. Both describe the injury in the same terms. They object to ending the life of a human being in the womb and fear that they might have to complete an abortion for a woman who has an ongoing pregnancy.

JUSTICE KAGAN: So, as you understand those declarations, they do not object to providing whatever care is necessary to a person who may have complications from taking mifepristone? In other words, for example, suppose somebody has bled significantly, needs a transfusion, or, you know, any of a number of other things that might happen. As you understand the declarations, there's not an objection to that?

GENERAL PRELOGAR: I think that the fairest reading of the declarations is they are not objecting to that. Now I acknowledge that Respondents, in their red brief, have suggested there's a broader conscience injury in play here

and that there might be other doctors who have a broader concern about providing any care.

Even if that broader conscience injury had been in this declaration, we think still, as a matter of law, they could not demonstrate that they have a non-speculative injury, in part because of all of the upstream things that would have to happen in terms of a woman having the serious event, going to these specific doctors, but also the fact the federal conscience protections are specifically designed to deal with this issue, and they would cover the range of conscience objections that exist in this context.

JUSTICE KAGAN: Right, there are obviously conscience objections of all kinds. I was just asking --

GENERAL PRELOGAR: Yes.

JUSTICE KAGAN: -- about the particular declarations of these particular members of the organizations.

GENERAL PRELOGAR: Yes. And I think, on these declarations, they have not asserted a broader injury. But, even if they could conceivably come forward with other doctors or

try to adjust their declarations in some way, still that would not suffice.

JUSTICE KAGAN: Okay. Can I just ask a quick question about the merits? You -- you open your brief with a -- a somewhat arresting statement, but it starts with, "To the government's knowledge," and this was written a few months ago, and since then, I'm sure that you've had lots of time to think about this case and to get all background information on it.

So I'll just read you this sentence and ask you whether it's still true to the government's knowledge. "To the government's knowledge, this case marks the first time" -- and I'm going to say is it -- is it the first time, is it the only time -- "any court has restricted access to an FDA-approved drug by second-guessing FDA's expert judgment about the conditions required to assure that drug's safe use." Is it still the only time?

GENERAL PRELOGAR: That is still to our knowledge the only time a court has done that. We have seen a disturbing trend of courts sometimes also overriding FDA's judgment to try to grant greater access to drugs when that

overrides FDA's expert judgment about what's necessary to ensure safe use.

And no matter which direction you come at it from, we, on behalf of FDA, think that courts have no business making those judgments in the absence of the kind of arbitrary and capricious error that would satisfy the APA.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Gorsuch?

Justice Kavanaugh?

JUSTICE KAVANAUGH: Just to confirm on the standing issue, under federal law, no doctors can be forced against their consciences to perform or assist in an abortion, correct?

GENERAL PRELOGAR: Yes. We think that federal conscience protections provide broad coverage here. Just to be super precise, there are some triggering requirements of receiving federal funding and so forth. We've cited the relevant provisions at page 5 of our reply brief.

The Church Amendments have the most comprehensive protection here, and we think that those amendments guard against the kind of

injury that Respondents are asserting. There are also state law protections that often apply in this context.

JUSTICE KAVANAUGH: Thank you.

CHIEF JUSTICE ROBERTS: Justice Barrett?

JUSTICE BARRETT: Would that be true even if the declarations were interpreted as Respondents do to say that they regard any participation, even transfusions or D&Cs after the abortion is otherwise complete because tissue needs to be removed?

GENERAL PRELOGAR: Yes, I think that would be true. So the most relevant Church Amendment provision is 42 U.S.C. 300a-7(d), and its language says that a doctor shall not be required to perform or -- or assist in any part of the healthcare program that would violate the doctor's religious or moral beliefs. So it's tied to the nature of the doctor's beliefs rather than particular procedures.

JUSTICE BARRETT: And one other question, and this goes to the merits.

As I understand it, the serious adverse consequences that have to be reported or

that FDA considers risks are death and transfusion but not, say -- I mean, it -- it seems to me, and I think the data bears this out, that the elimination of the in-person dispensing requirement or, you know, the in-person visit at the outset would lead to mistakes in gestational aging, which could increase the need for a D&C or the amount of bleeding, et cetera.

But that does not count, correct, as an adverse event?

GENERAL PRELOGAR: So I want to be careful because there's a list of serious adverse events and I'm not sure that I have all of them down to be able to recite them to you, although they're in the record, but I do think the premise of the question is wrong. This idea that the change to in-person dispensing would necessarily increase the risk of those events, that was not reflected in the data that FDA consulted, and I would point you to JA 383 to 384 in particular --

JUSTICE BARRETT: Okay.

GENERAL PRELOGAR: -- where FDA -- FDA explained that even in person you're not

necessarily getting an ultrasound. That's never been required. And so the relevant question might be is your -- your provider going to ask you a series of screening questions, like when was your last menstrual period, in person or via telemedicine, and there's no evident reason why that difference would actually lead to different safety outcomes.

JUSTICE BARRETT: So there was not even a -- I thought that there was a small percentage increase in the tracking. I'm wrong about that? Which I may well be.

GENERAL PRELOGAR: So --

JUSTICE BARRETT: You know the JA way better than I do, though.

GENERAL PRELOGAR: Yeah. So I think that with respect to the ER visits, there was some evidence that there were increased ER visits, although, as I explained to Justice Alito, that wasn't actually correlated with an increase in serious adverse events.

You know, I don't want to represent all of the different findings of the different studies because they varied a little bit, but FDA's ultimate conclusion was that mifepristone

could safely be dispensed without in-person visits. It had voluminous evidence, I think, to support that conclusion in 2021. And there's been no contrary evidence that's been introduced.

JUSTICE BARRETT: So there was no requirement of either an ultrasound or detecting a fetal heartbeat or anything like that even before the doctor could just go based on the woman's recounting when her last menstrual period was?

GENERAL PRELOGAR: That's right. And that dates all the way back to the initial approval of this drug in 2000. It has never been a required condition of use to have an ultrasound. FDA has always left that up to medical judgment.

Now it is, of course, necessary for providers to be able to diagnose ectopic pregnancy and to date gestational age. That remains true under the REMS now. Prescribers still have to have that capability, and they have to deploy whatever mechanisms they believe would accurately allow them to identify contraindications for use of mifepristone.

But it's wrong to suggest that if the Court reverses 2021 changes, then every woman's going to get an ultrasound. That's never been the state of play in how this drug has been administered.

JUSTICE BARRETT: How, even under the pre-2021 REMS, was it possible to detect an ectopic pregnancy without an ultrasound unless the woman was presenting with pain?

GENERAL PRELOGAR: So there's a set of screening questions that are often deployed. You can ask things like, do you have unilateral pelvic pain? Did you become pregnant while you had an IUD in or after a tubal ligation? Are you experiencing unusual bleeding? You could ask whether the woman has had a prior ectopic pregnancy.

And if the woman has those kinds of risk factors, then imaging may be necessary, but that remains true under the 2021 REMS as well. The prescriber has to be confident that it has excluded those kinds of conditions before prescribing this drug.

And the standard of care around the world, most medication abortion occurs without

an ultrasound.

JUSTICE BARRETT: Thanks.

CHIEF JUSTICE ROBERTS: Justice Jackson?

JUSTICE JACKSON: Good morning, General.

So I'm worried that there is a significant mismatch in this case between the claimed injury and the remedy that's being sought and that that might or should matter for standing purposes. I don't know that our doctrines sort of capture this, but I guess I see it that the injuries that the Respondents allege, as you've articulated them, are a conscience injury, that they are being forced to participate in a medical procedure that they object to.

And so the obvious common-sense remedy would be to provide them with an exemption, that they don't have to participate in this procedure. And you say, and you've said here several times, that federal law already gives them that.

So I guess then what they're asking for in this lawsuit is -- is more than that.

They're saying, because we object to having to be forced to participate in this procedure, we're seeking an order preventing anyone from having access to these drugs at all.

And I guess I'm just trying to understand how they could possibly be entitled to that given the injury that they have alleged.

GENERAL PRELOGAR: I agree, Justice Jackson, and I do think it's relevant to standing. There's a profound mismatch here between the claimed injury and the remedy they were seeking.

And, you know, you can almost think of this as a type of zone of interest kind of analysis. You know, if the doctors have a conscience injury, there's a specific statute designed to deal with it, to specifically tailor-made guard against the risk of that injury occurring.

And, instead, they're reaching out and seeking to invoke rights under a different statute, the FDCA, that doesn't regulate them at all, that doesn't make them do or not do anything, and the -- the relief that they're seeking would dramatically alter the approved

conditions of use for mifepristone and affect women all around the nation simply because of this conscience injury that's already directly addressed by other --

JUSTICE JACKSON: Right. And if it wasn't --

GENERAL PRELOGAR: -- protections under federal law.

JUSTICE JACKSON: -- if it wasn't addressed, then we would see this lawsuit and the remedy would be to exempt them, right?

GENERAL PRELOGAR: Yes. I mean, I think that --

JUSTICE JACKSON: Yeah.

GENERAL PRELOGAR: -- one of the hard things about trying to tailor relief here is that they're asserting such a diffuse theory of injury that it's almost as though the only option was to grant a nationwide remedy of the kind the lower courts issued, and that runs counter to ordinary Article III principles of party-specific relief.

But I just think it shows that there's something wrong with the theory of injury in the first place because it's so attenuated and

because they claim they would need so much relief all over the country.

JUSTICE JACKSON: Let me ask you another question. In addition to the challenges that we have here, the Respondents below challenged the FDA's initial decision to approve mifepristone in -- in the year 2000.

Of course, that occurred a very long time ago. The Fifth Circuit found that that challenge wasn't timely because of the statute of limitations. As you're aware, in the context of another case we heard this term, the Court is currently considering the statute of limitations issue.

So setting aside standing, have you thought about how a ruling from this Court on the statute of limitations in either direction might impact what happens in these kinds of cases with these kinds of challenges?

GENERAL PRELOGAR: Yes. I think that it just reflects the stakes of the Corner Post case and provides a vivid example of the way that it might be possible, if this Court were to approve the request for a broader theory of the statute of limitations in that case, the way it

could open the door to plaintiffs coming in and saying, well, I only became a doctor later, or I only started working in an emergency room later and would try to unsettle longstanding agency actions that maybe occurred decades previously.

I do want to say that I understand the Corner Post petitioner to have suggested maybe there would be equitable defenses that the government could raise in those kinds of cases. We would certainly want to raise that type of defense with respect to the approval of mifepristone, which I think has generated tremendous reliance interests and proven to be safe and effective over decades of use.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Ms. Ellsworth.

ORAL ARGUMENT OF JESSICA L. ELLSWORTH

ON BEHALF OF PETITIONER

DANCO LABORATORIES, L.L.C.

MS. ELLSWORTH: Mr. Chief Justice, and may it please the Court:

In 2016 and 2021, FDA made certain changes to the labeling and use restrictions for

Danco's drug, Mifeprex. The decision below stops Danco from selling Mifeprex in line with that scientific judgment based on a highly attenuated claim that an unknown doctor could be called someday to an unknown emergency room after a series of decisions by third parties. No facts causally link that possible future encounter to a specific change FDA made in 2016 or 2021.

Respondents' view of the Food, Drug, and Cosmetic Act is so inflexible it would upend not just Mifeprex but virtually every drug approval and REMS modification FDA has made for decades.

Reversal is required for two reasons:

First, Article III standing is not an academic exercise in what's conceivable. Respondents lack standing under every prong of the analysis.

Second, on the merits, FDA exhaustively considered the evidence and reasonably explained its conclusions, which is what is required to do.

I welcome the Court's questions.

JUSTICE THOMAS: The government, the

Solicitor General points out, would not be susceptible to a Comstock Act problem. But your -- in your case, you would be.

So how do you respond to an argument that mailing your product and advertising it would violate the Comstock Act?

MS. ELLSWORTH: Justice Thomas, we agree very much with the government that FDA's charge under the Food, Drug, and Cosmetic Act is limited to looking at safety and efficacy considerations. That's true for new drug approvals. It's also true for REMS modifications. FDA routinely approves drugs whose manufacture and distribution is restricted by other laws, like the Controlled Substances Act, environmental laws, customs laws, and so on.

I think this Court should think hard about the mischief it would invite if it allowed agencies to start taking action based on statutory responsibilities that Congress has assigned to other agencies.

On the merits, this issue was not presented below -- excuse me -- was not ruled on below, and in any event, I would also point out

that in 2021, FDA's decision allows use of brick-and-mortar pharmacies, in addition to mail-order pharmacies.

JUSTICE THOMAS: Well, my problem is that you're private. The government -- I understand the government's argument. But you're private, and the statute doesn't have the sort of safe harbor that you're suggesting, and it's fairly broad, and it specifically covers drugs such as yours.

MS. ELLSWORTH: Your Honor, we disagree that that's the correct interpretation of the statute, but we think that in order to address the correct interpretation, there would need to be a situation in which that issue was actually teed up.

This statute has not been enforced for nearly a hundred years, and I -- I don't believe that this case presents an opportunity for this Court to opine on the reach of the statute.

CHIEF JUSTICE ROBERTS: Counsel, I'd like to ask you the same questions I was posing to the Solicitor General. You know, our precedents, Clapper and Susan B. Anthony List, talk about requiring a substantial risk that

harm will recur, and you argue that's not present here.

How are we supposed to find the spot at which the risk becomes substantial?

MS. ELLSWORTH: Your Honor, I think this Court has always thought about these standing inquiries as really a question of degree, and you're trying to evaluate whether something is actual and imminent or whether it's conjectural and hypothetical. And these terms, "substantial risk," "certainly impending," which has been used dating all the way back to 1923, get at where a claim falls in this spectrum.

CHIEF JUSTICE ROBERTS: Right. I mean, we toss around a lot of adjectives, but I'm just trying -- as a practical matter, how do you figure out -- I mean, what percentage of adverse consequences would be enough? What percentage of emergency room visits would be enough?

MS. ELLSWORTH: I think the way Clapper got at that question -- and you can see this in Footnote 5 of the opinion -- is to really think about whether there is an attenuated chain of contingencies that have to

happen.

And in situations where there is this kind of attenuated chain of circumstances involving third-party decisions that have to play out in a particular way -- and, here, that chain is quite long -- that that squarely puts plaintiffs' theory on the side of the conjectural or hypothetical and not the certainly impending injury.

JUSTICE ALITO: How is your company aggrieved by the challenge that is brought in this case? I -- I gather this is -- your version of mifepristone is the only product you are currently marketing, is that right?

MS. ELLSWORTH: That's correct, Justice Alito.

JUSTICE ALITO: And the Fifth Circuit decision does not prohibit you from continuing to produce and -- and sell that product, right?

MS. ELLSWORTH: That is correct.

JUSTICE ALITO: All right. And so I gather your injury is that you think you're going to sell more if the restrictions that previously were in place were lifted?

MS. ELLSWORTH: Yes.

JUSTICE ALITO: So you're going to make more money?

MS. ELLSWORTH: The -- the injury is that we are prevented from selling our product in line with FDA's scientific judgment about the safe and efficacious use of the drug.

JUSTICE ALITO: And you're going to be harmed because you're going to sell more?

MS. ELLSWORTH: I think that certainly a company's ability to market its product is a part of how it considers the regulatory scheme that governs its conduct.

JUSTICE ALITO: During the questioning of the Solicitor General, the statement was made that no court has ever previously second-guessed the FDA's judgment about access to a -- to a drug, right? It's never second-guessed that?

MS. ELLSWORTH: That -- that's correct.

JUSTICE ALITO: Do you think the FDA is infallible?

MS. ELLSWORTH: No, Your Honor, we don't think that at all. And we don't think that question is really teed up in any way in this case.

JUSTICE ALITO: Has the FDA ever approved a drug and then pulled it after experience showed that it had a lot of really serious adverse consequences?

MS. ELLSWORTH: It -- it has certainly done that. And, Your Honor, I think that underscores why the adverse event reporting, the post-market surveillance that FDA does, the ability that these plaintiffs have, even if they don't have standing, certainly, if there are -- if they are seeing patients who are presenting with adverse events, if they are doing studies that show there is some unknown safety component that FDA should acknowledge, they can take significant steps to bring that to the agency's attention, to bring that to Danco's attention.

JUSTICE ALITO: But don't you think the FDA should have continued to require reporting of non-fatal consequences?

MS. ELLSWORTH: Your Honor, the FDA decided not to continue that reporting requirement in 2016 based on more than 15 years of a well-established safety profile when that reporting was required. There is no drug on the market today under any REMS that requires the

kind of reporting that the plaintiffs are saying should be reimposed here.

JUSTICE ALITO: So why would that be a bad thing? Wouldn't your company -- you don't want to sell a product that -- that causes very serious harm to the people who take your product, relying on your tests and the FDA's tests. Wouldn't you want that -- that data?

MS. ELLSWORTH: Your Honor, that -- that data is certainly something that we are looking for all the time. It is part of the reporting obligations for a manufacturer to be aware of any data that's becoming available through any means. We have a 1-800 number on our website. There is a 1-800 number on the labeling.

I think Your Honor's question, though, gets at concern I heard in some of the earlier questioning about who would have standing if these plaintiffs don't have standing. And one of the things I want to note is that drug manufacturers are very frequently subject to tort litigation, product liability suits, failure to warn suits, deceptive advertising suits, when someone is claiming harm from a

pharmaceutical manufacturer's product.

What is so, I think, revolutionary really about the -- the arguments here, both on standing and the merits, are the way that they attempt by individuals who do not use this product, do not prescribe this product, and have a conscience right not to treat anyone who has taken this product, those individuals want to prevent anyone else from using it in line with FDA's considered scientific judgment.

JUSTICE ALITO: Does --

JUSTICE KAGAN: Could you go --

JUSTICE ALITO: -- does your company -- just one more point along the same -- sort of along the same lines. Does your company think that what the FDA has done preempts state laws that prohibit the dispensation of mifepristone within their borders?

MS. ELLSWORTH: We have not taken a position on that issue, and it has not been teed up in this case.

JUSTICE ALITO: Well, what is your -- what is your company's position on it? You haven't even thought about it? One of your competitors made that argument, right?

MS. ELLSWORTH: That's right. There are some lawsuits that have been brought by the generic company that do make that argument. And I think that is for later courts to -- to sort out.

Our position in this case has been that this is about FDA's scientific judgments reached in 2016 and 2021.

JUSTICE ALITO: So you don't want to answer that question?

MS. ELLSWORTH: I don't think we have a position that's -- that's -- on that that I'm prepared to state today.

JUSTICE KAGAN: Could you go back to Justice Alito's questions about adverse event reporting? And you said you were subject, your product, to higher standards, and now we're being brought down to the sort of regular -- could you talk about that a little bit? What are the normal standards for adverse event reporting as you understand them? Why are they there? What instead were you subject to in the past?

MS. ELLSWORTH: May I answer the question?

CHIEF JUSTICE ROBERTS: Go ahead.

MS. ELLSWORTH: Justice Kagan, what changed was not Danco's adverse event reporting responsibility. Danco's adverse event reporting responsibility has been the same throughout this period.

What changed was that from 2000 until 2016, prescribers were obligated to report adverse events to Danco and then Danco then had its separate reporting obligation to FDA.

So what -- in -- in 2016, the REMS for mifepristone were aligned to be more consistent with the reporting requirement that applies to all 20,000-plus FDA-approved drugs. There are only today seven REMS that continue to have even the limited higher adverse event reporting for deaths that apply to -- to mifepristone. So it is only one of seven that have that.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Thomas?

Justice Alito, anything further?

Justice Sotomayor?

Justice Kavanaugh?

Justice Barrett?

Justice Jackson, anything further?

JUSTICE JACKSON: Yeah, I just have one quick question.

So you were asked if the agency is infallible, and I'm -- I guess I'm wondering about the flip side, which is do you think that courts have specialized scientific knowledge with respect to pharmaceuticals, and as a company that has pharmaceuticals, are -- do you have concerns about judges parsing medical and scientific studies?

MS. ELLSWORTH: Yes, Your Honor, I think we have significant concerns about that. And there are two amicus briefs from the pharmaceutical industry that expand on why exactly that's so concerning for pharmaceutical companies who do depend on FDA's gold standard review process to -- to approve their drugs and then to be able to sell their products in line with that considered judgment.

JUSTICE JACKSON: Can you say a little bit about what they say?

MS. ELLSWORTH: I -- I'm -- I'm happy to.

I think the -- the reality is -- and

this Court is a -- this decision below is a good example of it. You have a district court that among other things relied on one study that was an analysis of anonymous blog posts.

You have another set of studies that he relied on that were not in the administrative record and would never be because they post-date the FDA decisions here. They have since been retracted for lack of scientific rigor and for misleading presentations of data.

Those sorts of errors can infect judicial analyses precisely because judges are not -- they are not experts in statistics. They are not experts in -- in the methodology used for scientific studies, for clinical trials.

That is why FDA has many hundreds of pages of analysis in the record of what the scientific data showed, and courts are just not in a position to parse through and second-guess that.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MS. ELLSWORTH: Thank you.

CHIEF JUSTICE ROBERTS: Ms. Hawley?

ORAL ARGUMENT OF ERIN M. HAWLEY
ON BEHALF OF THE RESPONDENTS

MS. HAWLEY: Mr. Chief Justice, and may it please the Court:

FDA approved abortion by mail based on data it admitted was "not adequate." That violates the APA. The lower court's decision merely restored longstanding and crucial protections under which millions of women used abortion drugs.

We've heard a lot this morning about standing. Article III is satisfied here because, one, the FDA relies on OB hospitalists to care for women harmed by abortion drugs. Two, the FDA concedes that between 2.9 and 4.6 percent of women will end up in the emergency room. And, three, the FDA acknowledges that women are even more likely to need surgical intervention and other medical care without an in-person visit.

According to Guttmacher, nearly 650,000 women take mifepristone every single year. It's no surprise that Respondents have experienced an increase in emergency room visits and, indeed, treated women suffering from

abortion drug harms tens of thousands of times -- excuse me, dozens of times, women have suffered tens of thousands of times.

That Respondent doctors will be forced to manage abortion drug harm is not a bug in FDA's system but part of its very design. Ruling against Respondents on standing here would allow federal agencies to conscript non-regulated parties into violating their consciences and suffering other harm without judicial recourse. Article III neither demands nor permits this.

FDA's outsourcing of abortion drug harm to Respondent doctors forces them to choose between helping a woman with a life-threatening condition and violating their conscience. This Hobson's Choice is intolerable.

On the merits, FDA failed to comply with basic APA requirements. In 2021, it eliminated the initial in-person visit based on data it says elsewhere is unreliable. And in 2016, it failed to consider or explain the cumulative effects of its wholesale removal of safeguards. These actions fall far short of what the APA requires. This Court should

affirm.

I welcome the Court's questions.

JUSTICE THOMAS: Counsel, you assert the -- an injury on -- on the part of the Alliance of diverted time and resources.

Isn't that just the cost of litigating, of pursuing this litigation?

MS. HAWLEY: I -- I don't think so, Your Honor, for a couple of reasons.

First, what Respondent doctors have done here is chosen their particular practice, as well as structured that medical practice to bring life into the world.

When they are called from their labor and delivery floor down to the operating room to treat a woman suffering from abortion drug harm, that is diametrically opposed to why they entered the medical profession.

It comes along with emotional harm. Dr. Skop talks about these being heartbreaking situations and some of the most stressful work she's had to deal with, Your Honor.

JUSTICE THOMAS: Well, I -- I understand that, but I'm talking about the injury of having to divert resources to litigate

this.

MS. HAWLEY: Oh, for -- with respect to the organizational standing?

JUSTICE THOMAS: The Alliance.

MS. HAWLEY: Absolutely, Your Honor. So we think Havens Realty is on all fours with this case. The best evidence of that, I believe, is the FDA's reply brief. The government resorts to the underlying briefs in the case to say that there was a contract and an economic harm, but this Court's case specifically said that the fact that the harm -- the nature of the harm was "non-economic" did not prevent the Court from finding an injury.

In Havens, the Court looked to two things, whether -- whether there was an impairment of the organization's mission and, second, whether there was an expenditure of resources. Both things are satisfied here.

If you look at how our organizations have been harmed, they've been forced to divert resources from speaking and advocating for their pro-life mission generally to explaining the dangers of the harm from abortion drugs.

One of the primary reasons that that's

required is because, in 2016, FDA took away the requirement that abortion providers report adverse events --

JUSTICE THOMAS: Well --

MS. HAWLEY: -- aside from deaths.

JUSTICE THOMAS: -- but that would be anyone who is aggressive or vigilant about bringing lawsuits. Just simply by using resources to advocate their position in court you say now causes an injury. That seems easily -- easy to manufacture.

MS. HAWLEY: So I don't think that's true in this case, Justice Thomas. I acknowledge that the lower courts have cabined Havens to say where you have sort of prelude to litigation types of activities, in those sorts of cases, those resource justifications don't count.

In this case, if you look at Respondents' declarations, they note that they have performed studies. They've analyzed studies. Several of those are in the record and -- and they're not short.

They comb through Medicaid data, they comb through FAERS data, so they get at the true

nature of adverse events. And all those sorts of things are neither a prelude to litigation, nor would they have occurred but for FDA's unlawful conduct in this case.

JUSTICE SOTOMAYOR: Counsel, in the line you quoted about economic harm, that had to do with the fact that they didn't intend through their testers to rent an apartment, and so there was no economic loss to them or gain to them from renting the apartment.

But what, I think, the SG is pointing to is that they provided services on their own. It wasn't just the member services that they were relying upon. They were providing services to people to help them rent apartments.

And so that's a very important distinction from here. Separate from the individual defendants' claims of -- of standing based on wasted resources, their resources, the organizations are not losing anything.

MS. HAWLEY: So --

JUSTICE SOTOMAYOR: Their job is to do exactly what you're talking about and they're doing it. They're investigating certain problems, but that's not an injury that's

redressable by this -- by vacating this rule.

MS. HAWLEY: So a couple of things, Your Honor. This Court's opinion in Havens did not rely on the economic nature at all. Again, I'd point Your Honor to the line in Havens where the Court says the non-economic nature of respondents' interest in housing. They were speaking broadly. Again, you have to dig to the underlying briefs to find the economic interest that this Court did not rely on.

With respect to our own injury, it's absolutely redressable. For example, if the regulations are put back in place, the protections whereby individual abortion providers need to provide information about adverse events, that would provide our Respondent organizations with more accurate information about the harms from abortion drugs.

JUSTICE JACKSON: Counsel --

CHIEF JUSTICE ROBERTS: Can --

JUSTICE JACKSON: -- can I ask you --

CHIEF JUSTICE ROBERTS: Go ahead.

JUSTICE JACKSON: -- about the remedy and sort of the way that I was talking with the SG. I mean, it makes perfect sense for the

individual doctors to seek an exemption, but as I understand it, they already have that, and so what they're asking for here is that in order to prevent them from possibly ever having to do these kinds of procedures, everyone else should be prevented from getting access to this medication.

So why isn't that plainly overbroad scope of the remedy the end of this case?

MS. HAWLEY: So, with respect to the premise of that question, Justice Jackson, I don't think our doctors necessarily are able to object for two reasons.

One of this -- this is the emergency nature of these procedures. As the FDA acknowledges, many women do go to the emergency room, and if we just think about what that might look like, take Dr. Francis. She's on the labor and delivery floor, supervising --

JUSTICE JACKSON: No, I don't -- I'm sorry. I don't want to hypothesize. Tell me in her declaration where she talks about not being able to object or pose a conscientious objection.

MS. HAWLEY: She talks about, Your

Honor, being an --

JUSTICE JACKSON: I mean, can you point me to any place in the declarations where a declarant states that they attempted to object but were unable to?

MS. HAWLEY: No, Your Honor, for two reasons. One, these are emergency situations. Respondent doctors don't necessarily know until they scrub into that operating room whether this may or may not be abortion drug harm. It could be a miscarriage, it could be an ectopic pregnancy, or it could be an elective abortion, Your Honor.

In addition, the government simply cannot get its story straight on EMTALA. If you look at the district court brief in that case, we just heard that the Church Amendment applies, and while we would love for this Court to adopt that position, they told the district court the very opposite.

JUSTICE JACKSON: All right. Let me ask you this. If we were to find that there are conscientious objections that, say, hospitals take them into account and these doctors do have a way to not do these kinds of procedures,

should we end this case on that basis?

MS. HAWLEY: No, Your Honor. We would welcome that holding, but it's not broad enough to remedy our doctors' harm.

JUSTICE JACKSON: Why?

MS. HAWLEY: Because these are emergency situations, they -- they can't waste precious moments scrubbing in, scrubbing out --

JUSTICE JACKSON: No, no, no. I'm saying -- I'm saying, assuming we have a world in which they can actually lodge the objections that you say that they have, my question is, isn't that enough to remedy their issue? Do we have to also entertain your argument that no one else in the world can have this drug or no one else in America should have this drug in order to protect your clients?

MS. HAWLEY: So, again, Your Honor, it's not possible given the emergency nature of these situations --

JUSTICE GORSUCH: Counsel, let -- let me interrupt there. I'm sorry.

I think Justice Jackson's saying let's spot you all that, okay, with respect to your -- your clients. Normally, in Article III

traditional equitable remedies, we issue and we say over and over again provide a remedy sufficient to address the plaintiff's asserted injuries and go no further.

We have before us a handful of individuals who have asserted a conscience objection. Normally, we would allow equitable relief to address them. Recently, I think what Justice Jackson's alluding to, we've had one might call it a rash of universal injunctions or vacaturs. And this case seems like a prime example of turning what could be a small lawsuit into a nationwide legislative assembly on -- on -- on an FDA rule or any other federal government action. Thoughts?

MS. HAWLEY: Yes, Your Honor. Again, I have to say that I think it's impracticable to -- to raise a conscience objection. But, even spotting that, I think the -- the district court remedy here was perfectly appropriate under Section 705.

Section 705 grants the reviewing courts the authority to issue all necessary and appropriate relief. And as the government acknowledged in oral argument in Corner Post,

when the parties before the court are non-regulated parties, the only avenue in which they can possibly get relief -- and, of course, that's sort of the sine qua non of equitable relief, is that the parties before the court get it, and that's for, as in this case, a stay to issue or -- or another case is a vacatur, and that's because, without that sort of relief, the very parties before the court won't get it.

JUSTICE ALITO: I think --

CHIEF JUSTICE ROBERTS: Why can't you --

JUSTICE ALITO: -- something as --

CHIEF JUSTICE ROBERTS: Why can't the court specify that this relief runs to precisely the parties before the court, as opposed to looking to the agency in general and saying, Agency, you can't do this anywhere?

MS. HAWLEY: So I think, Your Honor, that might be impracticable. If we're thinking again about the emergency room situation, would Dr. Francis, again, have to know when she's in the emergency room whether this is a miscarriage, an ectopic pregnancy, or an elective abortion? This is what she does day in

and day out.

And so it seems like to say that -- that these would run to particular plaintiffs would be missing that the FDA regulations would still be in place and permit things like mail-order abortions. They would have removed the reporting requirements.

And if we look at the merits of what FDA did in 2021, FDA relied on two things. They relied first on the FAERS data.

JUSTICE GORSUCH: Counsel -- counsel, before you pivot back to the merits, and I can understand your impulse there, but -- but I went back and looked, and there are exactly zero universal injunctions that were issued during Franklin Delano Roosevelt's 12 years in office, pretty consequential ones.

And over the last four years or so, the number is something like 60 and -- maybe more than that, and they're -- they're a relatively new thing. And you're asking us to extend and -- and pursue this relatively new remedial course which this Court has never adopted itself. Lower courts have kind of run with this. And I -- I just want to give you one

more shot at that.

MS. HAWLEY: Sure, Your Honor. So, again, the APA, of course, encapsulates equitable remedies. And as Pomeroy and others have said from the beginning of the 19th Century, equity requires that the parties before the court get relief.

In this instance, again, as the government pointed out in Corner Post, where you have non-regulated parties, those -- those parties could be farmers, they could be ranchers, they could be the seed farms in Geertson, but their only availability for relief is if the court does something to the FDA order or regulation at issue. Otherwise, those parties are simply out of luck, and that's inconsistent with equity.

JUSTICE KAGAN: May I ask, Ms. Hawley, about your basic theory of standing? And just -- this is a clarification question as much as it's anything.

When you did your 1, 2, 3 in your opening statement, it sounded very probabilistic to me. I mean, I don't remember exactly what the 1, 2, 3 are, but, you know, let's say it's

something along the lines of we represent a lot of doctors, and there are a lot of women out there taking mifepristone, and some fraction of them are going to have adverse events, and some fraction of those are going to come to the emergency room, and -- and so there's some probability or likelihood that one of our doctors who has a conscience objection is going to come face-to-face with one of these women who has an adverse event.

Is that your theory?

MS. HAWLEY: No, Your Honor. What we think really shows that Respondents have standing here is FDA's own acknowledgments. I would point you to JA 384. And in regulating mifepristone, FDA has continually said that emergency room doctors and OB-GYN hospitalists are critical to the safe use of drug.

JUSTICE KAGAN: Well, I think then it is your theory. I mean, you're just saying even FDA admits that there are going to be some adverse events, people are going to show up in emergency rooms, people are going to come face-to-face with one of our doctors who objects to some aspect of the treatment. That's the

theory, yes?

MS. HAWLEY: Well, we certainly think all of that is true, but we don't think it's a problem with probabilistic standing, as was the case under Summers, for three reasons.

First, Summers involved unidentified members. Here, we have seven named plaintiffs. In addition, no one in Summers at least that was still part of the case had --

JUSTICE KAGAN: Yeah. So does your theory really depend on your having at least one person? Because I take Summers to be saying these probability theories, they sound very nice; they have nothing to do with our Article III requirements. You need a person. You need a person to be able to come in and meet the courts' regular standing requirements.

So you agree with that, yes?

MS. HAWLEY: I think that's correct, Your Honor, yes.

JUSTICE KAGAN: Okay. So who's your person? I know you have seven of them.

MS. HAWLEY: Mm-hmm.

JUSTICE KAGAN: But, if you had to pick one and say go read that declaration and

that declaration is going to tell you why -- why, you know, we're entitled to be up here, who's the person?

MS. HAWLEY: So I have to pick two, Your Honor, but Dr. Francis and Dr. Skop.

JUSTICE KAGAN: Okay. And what about those two doctors gives you the kind of imminent injury, let alone the traceability, that we've typically required?

MS. HAWLEY: So, to speak to Dr. Francis, at the beginning, there's been some confusion, I think, about the precise nature of the conscience harm. But, if you look at JA 155, paragraph 15, she talks about her and other AAPLOG members who object not only to taking the life of an unborn child during an elective abortion but also to "completing that process." That echoes the CMDA declaration at 142 and 143. It's also consistent with --

JUSTICE KAGAN: Has she ever been -- because I -- I read that declaration pretty carefully. Has -- what actual emergency treatment has she participated in that she objects to and that -- and that she has stated an objection to?

MS. HAWLEY: So the prior page, Your Honor, JA 154, talks about a D&C which she was required to perform due to a life-threatening emergency.

JUSTICE KAGAN: She herself performed that?

MS. HAWLEY: That is correct, Your Honor.

JUSTICE KAGAN: And did she have an opportunity to object? Did she object?

MS. HAWLEY: No, Your Honor. Again, these are life-threatening situations in which the choice for a doctor is either to scrub out and try to find someone else or to treat the woman who's hemorrhaging on the --

JUSTICE KAGAN: Well, usually --

MS. HAWLEY: -- emergency room table.

JUSTICE KAGAN: -- conscience objections, the way people with conscience objections do this is they make those objections known. And, you know, that may be harder. It may be easier in a particular context, but most hospitals have mechanisms in place, routines in place to ensure that doctors who are allowed to do this, you know, in advance, right, and are

allowed to do it at the moment, they say so.

And when I looked at Dr. Francis's and Dr. Skop's, there's just nothing that you have there that suggests -- you know, this is like there are, you know, other requirements that you need, but at the very least, to be able to say, well, this happened to them in the past, I don't think you have it for either one of those doctors.

MS. HAWLEY: So I think we do, Your Honor. Given the emergency nature, it's simply impracticable to have a objection lodged prior to understanding what's going on in that operating room.

And, again, I'd point Your Honor to the district court Fifth Circuit brief in EMTALA where the government says that neither the church nor any of the other sponsors of those federal conscience protections intended them to apply in emergency situations.

So it's a lot to ask our Respondent doctors to go up to the top floor and litigate this with the general counsel when the federal government's telling them they don't have a conscience protection.

JUSTICE JACKSON: Counsel --

JUSTICE ALITO: Is it true that our standing decisions have not relied on probabilistic determinations like the Department of Commerce case? The Court said there was standing because, if a question about citizenship was included on the -- on the -- the questionnaire, a certain percentage, an unknown percentage of residents would then not fill out the census at all and, therefore, it was probable that there was some risk that New York State would risk losing a representative in the House of Representatives or would risk losing money under some federal program, and you put together this chain of probabilities and that was sufficient to establish standing.

MS. HAWLEY: Absolutely. We agree with that, Justice Alito.

In particular, you can look at the Geertson Seed Farms case, which also involved non-regulated parties, and this Court looked at the distance that bees might fly in order to pollinate seed farms.

So it's certainly true that data is appropriate to consider in determining whether

there's a substantial risk under SBA List. Here, the FDA admits -- this is at 533 -- that between 2.9 and 4.6 percent of women will go to the emergency room. It acknowledges -- this is at 542 -- that up to 7 percent of women will need surgical intervention.

And when the FDA talks about there being no increase in adverse events from the increased gestational age, the only way they can say that is by ignoring surgical interventions, and that's because, at JA 207, the FDA --

JUSTICE SOTOMAYOR: Counsel, what do we do with the fact that these two people that you reply -- rely on, Francis and Skop, that Indiana and Texas have abolished abortions and abolished them by pills or otherwise?

Now we can get into whether other people are illegally breaking the law and supplying it contrary to law, but what does that do to your probability, which is -- it's already infinitesimally small because there are thousands of hospitals in the country, 50 states, I don't know how many territories, thousands and thousands of -- of -- of places where pregnant women go who may be suffering

from miscarriages or otherwise, to know or to even imagine how one doctor is going to ever actually see a patient that it's going to be -- that he or she is going to be forced to intervene on their behalf, but then add to it that this is illegal in these states.

MS. HAWLEY: So I think the best answer, Justice Sotomayor, is that past is prologue. In our declarations, we have three doctors who have treated harms from abortion drugs at least a dozen times.

We have two examples when women went out of state. And if you go out of state, there's a higher likelihood you're not going to have a follow-up visit. What FDA's regime has done is turn ER rooms into those follow-up visits.

We had that happen with both Dr. Jester, where a woman went to New Mexico and returned to Texas, as well as Dr. Johnson, where a woman went to Illinois and returned to Indiana. Indeed, according to Guttmacher, one in five abortions take place out of state in certain states, like New Mexico, like Illinois, the border states in which our doctors reside.

JUSTICE BARRETT: Ms. Hawley, can I take you back to the affidavits and some of Justice Kagan's questions?

You were talking about Dr. Francis. And as I read her allegations or her -- as her affidavit reads, she said that her partner was forced to perform a D&C when there was a living fetus, and she said she performed a D&C on a woman who was suffering serious complications, but the fact that she performed a D&C does not necessarily mean that there was a living embryo or a fetus because you can have a D&C after, you know, a miscarriage.

So, if that's right, I mean, I think the difficulty here is that at least to me, these affidavits do read more like the conscience objection is strictly to actually participating in the abortion to end the life of the embryo or fetus, and I don't read either Skop or Francis to say that they ever participated in that.

So do you want to address that?

MS. HAWLEY: Sure. So, first, Justice Barrett, I think Dr. Francis's, combined with CMDA, can be read for the broader conscience

harm. Again, that's how the district court understood that. I'd point you to pages 7 and 8. That's how both the state panel and the Fifth Circuit understood Respondents' conscience harms to extend beyond simply requiring the ending of an unborn life.

And with respect to even the more narrow conscience harm, to whether a doctor may need to end a life, we think there's still a substantial risk of that occurring. If you look at the numbers of the increase from 7 to 10 weeks in gestational age, that means that 3.1 percent of pregnancies will be ongoing, requiring a D&C. We know at JA -- or, excuse me, ROA 870, that 55 percent of those D&Cs occur in the emergency room.

This is a substantial number of women suffering abortion drug harm. Again, Guttmacher says 650,000 women took the drug in 2023.

JUSTICE BARRETT: But not all of those D&Cs will involve a pregnancy that would otherwise be viable or an embryo or a fetus that would otherwise be living, because you can have complications or excessive bleeding even after the abortion is complete in that respect, but

there's pregnancy tissue remaining?

MS. HAWLEY: So with the 3.1, Your Honor, is ongoing pregnancies.

JUSTICE BARRETT: Is ongoing pregnancies?

MS. HAWLEY: Yes. And FDA says at JA 542 that up to 7 percent will need surgeries to stop either bleeding or ongoing pregnancies or failures.

JUSTICE BARRETT: How many members of your organization -- you have a broad number of, you know, doctors that are in your organization, I gather dentists, some doctors who have retired. How many members of your organization are OB-GYNs who practice in hospitals who might be called into these ERs?

MS. HAWLEY: There are hundreds of them, Your Honor. But I think -- may I finish?

CHIEF JUSTICE ROBERTS: Sure.

MS. HAWLEY: I think, in particular, that the named plaintiffs are OB-GYN hospitalists who spend most of their time on the labor and delivery floors but also are called to the OR to treat these sorts of emergencies.

JUSTICE JACKSON: Ms. Hawley, can you

clarify the broader conscience harm from the narrow one? Because I had understood the conscience harm as Justice Barrett does, but you suggest that there's a broader one. So what -- what is that?

MS. HAWLEY: Yes, Your Honor. I'd point you to pages 7 and 8 of the district court opinion, and the district court understands the conscience harm to be either taking the life of an unborn child, which would sometimes be required, Dr. Francis testifies to a partner who was required to do that because of emergency situations --

JUSTICE JACKSON: That's what I understood the narrow one to be, right? I'm participating in a procedure that is ending the life.

MS. HAWLEY: Yes, I think that's correct.

JUSTICE JACKSON: That's narrow?

MS. HAWLEY: Yes.

JUSTICE JACKSON: Okay. So what's the broader one?

MS. HAWLEY: So the broader one, Your Honor, is being complicit in the process that

unnecessarily leaves -- takes an unborn life, such as performing a D&C and abortion. And it's really not that hard to -- to see.

JUSTICE JACKSON: No, wait, I'm sorry. Complicit like I -- I work in the emergency room and this is going on? I'm handing them a water bottle? I'm -- like, what do you mean complicit in the process?

MS. HAWLEY: So this Court, of course, takes religious beliefs and conscience beliefs --

JUSTICE JACKSON: Yes.

MS. HAWLEY: -- as -- as it finds them.

JUSTICE JACKSON: Yes.

MS. HAWLEY: But what harms our doctors, Your Honor, is being involved in completing in the terms of our declaration an elective abortion, and it's really not that hard to see why that might be a conscience harm if you think about what's involved in a D&C.

JUSTICE KAGAN: But you just said, again, it's being involved in completing an elective abortion, so I took that to be the conscience objection.

I think what Justice Jackson is asking or what I asked before or what Justice Barrett is, is there any broader conscience objection that appears -- I don't -- I'm not sure I care all that much about the district court, but that appears in the declarations?

MS. HAWLEY: Yes, Your Honor. And -- and in this sense, completing an elective abortion means removing an embryo, a fetus, whether or not they're alive, as well as placental tissue. Again, Dr. Francis talks about being required to perform a D&C -- this is at 154 --

JUSTICE KAGAN: So --

MS. HAWLEY: -- and remove placental tissue.

JUSTICE KAGAN: -- whether or not there's any live tissue?

MS. HAWLEY: Yes, Your Honor. And, again, this makes sense --

JUSTICE KAGAN: And -- and -- and where are we looking for that?

MS. HAWLEY: So I would point Your Honor to JA 155, paragraph 15, where, again, she talks about completing an abortion. The CMDA

declaration at pages 142 and 143 also describe this sort of complicity harm from being involved in -- in an elective abortion, Your Honor.

And, again, these doctors performing a D&C must scrape out a woman's uterus of -- of a child, the embryo, the fetus, or placental tissue. And this Court has recognized harms like that in cases like Little Sisters of the Poor as well as Hobby Lobby.

JUSTICE JACKSON: May I --

JUSTICE KAGAN: No, go ahead.

JUSTICE JACKSON: It's -- sorry. It's my understanding that sometimes the completion, it doesn't involve surgical intervention. Do you have a sense of how often? I mean, we -- we may get all the way down the chain to the doctor's there, the person is having an emergency procedure. My understanding is, with some of these chemical abortion scenarios, the completion occurs by prescribing additional medication.

Do you have a sense of how many times the completion is that route and could be done by another physician as opposed to your clients doing a -- a medical procedure?

MS. HAWLEY: So -- so that second dose, Your Honor, of misoprostol has been part of the regimen since 2016, really I think all the way back to 2001, but -- but it's been approved by FDA since 2016. So the best numbers we have from FDA are still consistent with that, and that means that 3.1 percent of pregnancies at 10 weeks will be ongoing.

I -- I'd encourage you to look at -- at JA 405 through 407, and this explains that these risks go up without an in-person visit.

JUSTICE JACKSON: Yeah, no, I guess I'm just trying to get at -- we're still -- I'm still working on how many circumstances or how often it would be that your clients actually have to complete the procedure in the way that you are describing.

MS. HAWLEY: So Dr. Skop talks about doing this at least a dozen times, either a D&C or a suction-aspiration abortion to remove, again, embryos, fetuses, or placental tissue.

In addition, Your Honor, if you think about the numbers, again, it says 3.1 percent at 10 weeks, and this has only gone up. In 2020, FDA told this Court that the in-person visit was

both "necessary and minimally burdensome" and necessary to preserve women's health precisely so these sorts of situations occur less frequently.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas?

JUSTICE THOMAS: Ms. Hawley, the -- I am sure you heard the answers of the Solicitor General and the counsel -- counsel for Danco with respect to the Comstock Act.

I'd like you to comment on their answers.

MS. HAWLEY: Sure, Justice Thomas. We don't think that there's any case of this Court that empowers FDA to ignore other federal law.

With respect to the Comstock Act as relevant here, the Comstock Act says that drugs should not be mailed through the -- either through the mail or through common carriers. So we think that the plain text of that, Your Honor, is pretty clear.

JUSTICE THOMAS: When did you first raise the -- the Comstock Act?

MS. HAWLEY: So I believe the Comstock

Act was first raised at -- at the district court, Your Honor. But we think that exhaustion does not apply for two reasons.

First, it would be plainly futile, as FDA's adoption of the OLC memorandum goes. In addition, this is a whole 'nother kettle of fish. But, if you look at Section 704, adoption or -- excuse me -- exhaustion is only required in two instances, either when required by a statute or when -- by an agency rule when that agency rule is stayed pending litigation.

This is consistent with this Court's case in Darby. The -- the lower courts have taken conflicting opinions. But we think the better reading of Section 704 is that there is no exhaustion required unless either a statute or agency rule stays the proceeding during judicial review.

CHIEF JUSTICE ROBERTS: Justice Alito?

Justice Sotomayor?

Justice Kagan?

JUSTICE KAGAN: May I ask about your view of traceability? And, you know, on -- on -- on one understanding -- and I want you to tell me if you agree with this -- that even

beyond proving whatever injury you're trying to prove, that you have to show that that injury is traceable to the 2016 and 2021 FDA actions --

MS. HAWLEY: Yeah.

JUSTICE KAGAN: -- that you're challenging. And, of course, that means showing that these incidents that you're talking about in the emergency room are caused by whatever incremental increase in risk there is as a result of those 2016 and 2021 actions.

And I guess my first question is, do you agree with that statement of what you need to show? And, if you do, how do you satisfy that? Why do you satisfy that?

MS. HAWLEY: So we believe, Justice Kagan, under the case law that -- that we need to show that -- that each of the 2016 action and the 2021 action increased the risk of harm. And we think the way --

JUSTICE KAGAN: But that -- I guess what I'm saying is that you have to link whatever injury your members have to that increased risk. Do you agree with that?

MS. HAWLEY: We do, and we think we can do that for a couple of reasons. First of

all, traceability, of course, is de facto. We're not in the Palsgraf sort of world of -- of tort causation.

And when you look at the 2021 action, we think traceability is satisfied by FDA's own words. It says at JA 405 that without the in-person visit -- this is the Anger study -- in-person -- without that in-person visit, ER and other medical care is likely to increase, as well as surgical interventions. And these are the very same surgical interventions that harm Respondent clients.

JUSTICE KAGAN: So there -- there might be some dispute between the two of you as to exactly how big the increased risk is, but let's even take your view that there is, you know, some measurable increased risk.

How do you connect that risk to particular actions that your members have -- to particular injuries that your members have undergone or imminently will undergo?

MS. HAWLEY: I --

JUSTICE KAGAN: I mean, it could be --

MS. HAWLEY: I think --

JUSTICE KAGAN: -- you know, the --

the -- the -- the original risk.

MS. HAWLEY: So I think the declarations are actually quite clear on this. If you look at Dr. Francis's declaration, she says that when the in-person visit was enjoined in 2020 by a federal district court that she saw an increase in emergency room visits from abortion drug harm. Dr. Johnson, Dr. Skop say the same thing.

And, again, this is entirely consistent with FDA's own numbers. Again, in 2020, FDA told this Court that the in-person visit was necessary to preserve women's health because an in-person exam -- visit is the best opportunity to examine for things like ectopic pregnancy and accurately assess gestational age.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Gorsuch?

Justice Kavanaugh?

Justice Barrett?

JUSTICE BARRETT: So General Prelogar said that that initial in-person visit had no requirement of an ultrasound or, you know, any effort to detect fetal heartbeat, so it wouldn't

necessarily give an accurate read on gestational age or detect an ectopic pregnancy. So why would that necessarily -- the elimination -- why would the elimination of the visit necessarily increase the risks?

MS. HAWLEY: So I think, Your Honor, FDA's own data shows that those risks did go up. If you look at the Kerestes study, it shows a nearly threefold increase in emergency room visits when you have the in-person visit and when you removed it. There was 5.8 percent with an in-person visit, and it was also -- and about 2.1 without.

JUSTICE BARRETT: Is that because doctors were just kind of voluntarily saying, hey, it would be a good idea to give you an ultrasound or try to detect a fetal heartbeat or what?

MS. HAWLEY: So -- so, when FDA removed the in-person visit, Your Honor, it took away the opportunity to do that. I think ACOG -- I think medical organizations agree that that is best practice, so if a woman comes into a doctor's office, she's likely to get an ultrasound to accurately assess both ectopic

pregnancies, diagnose or assess gestational age.

But -- but what's allowed under FDA's rules currently is to be able to order these online with a couple of screening questions, and I don't think that's nearly as good as an in-person exam.

JUSTICE BARRETT: Let me just pivot to the organizational standing question. So let's say that I'm just going to carve out and put aside the costs of filing a petition or litigation as harms to your organization itself.

MS. HAWLEY: Mm-hmm.

JUSTICE BARRETT: Explain to me what additional costs you might have incurred or how your resources were diverted in a way that would satisfy Havens.

MS. HAWLEY: Absolutely, Your Honor. So putting to one side the citizen petition, the AAPLOG declaration is clear that Respondent organizations conducted studies and analyzed studies. This included going through the Medicaid data. It included going through the FAERS data to the extent it was available.

JUSTICE BARRETT: Is that it?

MS. HAWLEY: Well -- well, those

studies, Your Honor, I would point to you, one of them is at ROA 5 -- excuse me -- ROA 870 and before and after, and those are pretty comprehensive studies, Your Honor.

JUSTICE BARRETT: And are they to the end of the litigation and the citizen petition, or what are they to the end of?

MS. HAWLEY: To accurately assess the harm from abortion drugs, Your Honor. So I think it's absolutely separate from the litigation.

And one thing to note with the citizen petition is that is the only way in which anyone can raise a -- a concern to the FDA. These proceedings go on between Danco and the FDA behind closed doors. This is not a notice-and-comment process. The first time anyone can raise these objections is a citizen petition.

CHIEF JUSTICE ROBERTS: Justice Jackson?

JUSTICE JACKSON: So what deference, if any, do courts owe the opinion of the expert agency concerning the safety and efficacy of drugs?

MS. HAWLEY: So, under this Court's administrative procedure precedents, Your Honor, APA review, of course, is not toothless. Instead, in this case, we're not asking that the Court second-guess the agency determinations at all but, rather, look at what FDA said.

Again, in 2021, when FDA took away the in-person visit, it did so based on FAERS data it says elsewhere cannot be used to calculate the instance of an adverse event, as well as studies that says that JA 407 are "not adequate."

JUSTICE JACKSON: I guess I don't understand how that scope of review is not second-guessing the agency. I mean, they're looking at studies and you're saying that the Court can look at studies, maybe different studies, maybe the same studies, and critique their conclusions about them.

So what -- what deference do we owe them at all with respect to their assessment that these studies establish what it is that they say they do about safety and efficacy?

MS. HAWLEY: I don't think that's an accurate portrayal of the -- the APA claim at

issue here, Your Honor, and the reason being, again, is we're just asking this Court to look at what FDA said. The FDCA says you have to have adequate tests and test results, as well as sufficient information.

JUSTICE JACKSON: I understand. But didn't the lower courts go beyond that? I mean, representations were made here today that the lower courts actually relied on studies that have since been found discredited and removed. So they were obviously looking at not just what the FDA was looking at in order to make their assessment.

So are you asking us to just look at the FDA and not anything else?

MS. HAWLEY: So, yes. That claim is not even before this Court. But, with respect to the two claims that are before the Court, the 2016 and the 2021, we think the FDA's own statements here are arbitrary.

In 2016, what the FDA said was we're going to look at individual studies and then, even though we say they're interrelated at JA 298, we're going to take all of the protections away at once.

That was arbitrary in State Farm. It would be arbitrary here as well.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Rebuttal, General Prelogar.

REBUTTAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR
ON BEHALF OF THE FEDERAL PETITIONERS

GENERAL PRELOGAR: Thank you.

On associational standing, Mr. Chief Justice, you asked where do you cross the line to get to a certainly impending injury.

One thing the Court has looked at is whether that harm has materialized in the past and how often. Now it doesn't always guarantee there will be a future injury, but it can be a source of information.

And, here, what is so telling is that Respondents don't have a specific example of any doctor ever having to violate this care in violation of their conscience. Instead, Respondents have pointed to generalized assertions in the declarations that never come out and specifically say by one of their identified members: Here's the care I provided,

here's how it violated my conscience, and here is why conscience protections were unavailable to me.

The fact that they don't have a doctor who's willing to submit that kind of sworn declaration in court, I think, demonstrates that the past harm hasn't happened, and the reason for that is because it is so speculative and turns on so many links in the chain that would have to occur and at the end would be backstopped by having the federal conscience protections in play.

On organizational standing, my friend has pointed to the fact that they invested time in preparing their citizen petition. She says they voluntarily conducted studies and then generally refers to diversion of resources.

If that is enough, then every organization in this country has standing to challenge any federal policy they dislike. Havens Realty cannot possibly mean that. The Court should say so and clarify it is at the outer bounds and Respondents don't qualify under that standard.

On remedy, Justice Gorsuch, Justice

Jackson, you pointed out the striking anomaly here of the nationwide nature of this remedy. Justice Jackson, you suggested maybe a more tailored remedy to the parties protecting their conscience protections should have been entered.

The problem here is they sued the FDA. FDA has nothing to do with enforcement of the conscience protections. That's all happening far downstream at the hospital level. And the only way to provide a remedy based on this theory of injury, therefore, was to grant this kind of nationwide relief that is so far removed from FDA's regulatory authority that it's ultimately requiring all women everywhere to change the conditions of use of this drug.

And I think it's worth stepping back finally and thinking about the profound mismatch between that theory of injury and the remedy that Respondents obtained. They have said that they fear that there might be some emergency room doctor somewhere, someday, who might be presented with some woman who is suffering an incredibly rare complication and that the doctor might have to provide treatment notwithstanding the conscience protections. We don't think that

harm has materialized.

But what the Court did to guard against that very remote risk is enter sweeping nationwide relief that restricts access to mifepristone for every single woman in this country, and that causes profound harm.

It harms the agency, which had the federal courts come in and displace the agency's scientific judgments. It harms the pharmaceutical industry, which is sounding alarm bells in this case and saying that this would destabilize the system for approving and regulating drugs. And it harms women who need access to medication abortion under the conditions that FDA determined were safe and effective.

The Court should reverse and remand with instructions to dismiss to conclusively end this litigation.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

(Whereupon, at 11:37 a.m., the case was submitted.)

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EXHIBIT G

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

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

v. **No. 4:21-cv-1058-P**

FOOD AND DRUG ADMINISTRATION,

Defendant.

ORDER

This case involves the Freedom of Information Act ("FOIA"). Specifically, at issue is Plaintiff's FOIA request seeking "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System" from the Food and Drug Administration ("FDA"). *See* ECF No. 1. As has become standard, the Parties failed to agree to a mutually acceptable production schedule; instead, they submitted dueling production schedules for this Court's consideration. Accordingly, the Court held a conference with the Parties to determine an appropriate production schedule.[1] *See* ECF Nos. 21, 34.

"Open government is fundamentally an American issue"—it is neither a Republican nor a Democrat issue.[2] As James Madison wrote, "[a] popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or, perhaps, both. Knowledge will forever govern ignorance: And a people who mean to be their own Governors, must arm themselves with the power which

[1]Surprisingly, the FDA did not send an agency representative to the scheduling conference.

[2]151 CONG. REC. S1521 (daily ed. Feb. 16, 2005) (statement of Sen. John Cornyn).

knowledge gives."[3] John F. Kennedy likewise recognized that "a nation that is afraid to let its people judge the truth and falsehood in an open market is a nation that is afraid of its people."[4] And, particularly appropriate in this case, John McCain (correctly) noted that "[e]xcessive administrative secrecy . . . feeds conspiracy theories and reduces the public's confidence in the government."[5]

Echoing these sentiments, "[t]he basic purpose of FOIA is to ensure an informed citizenry, [which is] vital to the functioning of a democratic society." *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1977). "FOIA was [therefore] enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir. 2010) (quoting *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976)). And "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Open Soc'y Just. Initiative v. CIA*, 399 F. Supp. 3d 161, 165 (S.D.N.Y. 2019) (quoting H.R. REP. NO. 93-876, at 6271 (1974)). When needed, a court "may use its equitable powers to require an agency to process documents according to a court-imposed timeline." *Clemente v. FBI*, 71 F. Supp. 3d 262, 269 (D.D.C. 2014).

Here, the Court recognizes the "unduly burdensome" challenges that this FOIA request may present to the FDA. *See generally* ECF Nos. 23, 30, 34. But, as expressed at the scheduling conference, there may not be a "more important issue at the Food and Drug Administration . . . than the pandemic, the Pfizer vaccine, getting every American vaccinated, [and] making sure that the American public is assured that this was not [] rush[ed] on behalf of the United States . . . ." ECF No. 34 at 46.

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[3]Letter from James Madison to W.T. Barry (August 4, 1822), *in* 9 WRITINGS OF JAMES MADISON 103 (S. Hunt ed., 1910).

[4]John F. Kennedy, Remarks on the 20th Anniversary of the Voice of America (Feb. 26, 1962).

[5]*America After 9/11: Freedom Preserved or Freedom Lost?: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 302 (2003).

Accordingly, the Court concludes that this FOIA request is of paramount public importance.

"[S]tale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988). The Court, agreeing with this truism, therefore concludes that the expeditious completion of Plaintiff's request is not only practicable, but necessary. *See Bloomberg, L.P. v. FDA*, 500 F. Supp. 2d 371, 378 (S.D.N.Y. Aug. 15, 2007) ("[I]t is the compelling need for such public understanding that drives the urgency of the request."). To that end, the Court further concludes that the production rate, as detailed below, appropriately balances the need for unprecedented urgency in processing this request with the FDA's concerns regarding the burdens of production. *See Halpern v. FBI*, 181 F.3d 279, 284–85 (2nd Cir. 1991) ("[FOIA] emphasizes a preference for the fullest possible agency disclosure of such information consistent with a responsible balancing of competing concerns . . . .").

Accordingly, having considered the Parties' arguments, filings in support, and the applicable law, the Court **ORDERS** that:

1. The FDA shall produce the "more than 12,000 pages" articulated in its own proposal, *see* ECF No. 29 at 24, **on or before January 31, 2022.**
2. The FDA shall produce the remaining documents at a rate of **55,000** pages every **30 days**, with the first production being due **on or before March 1, 2022**, until production is complete.
3. To the extent the FDA asserts any privilege, exemption, or exclusion as to any responsive record or portion thereof, FDA shall, concurrent with each production required by this Order, produce a redacted version of the record, redacting only those portions as to which privilege, exemption, or exclusion is asserted.

4. The Parties shall submit a Joint Status Report detailing the progress of the rolling production by **April 1, 2022**, and every **90 days** thereafter.[6]

SO ORDERED on this **6th day** of **January, 2022.**

Mark T. Pittman
UNITED STATES DISTRICT JUDGE

[6]Although the Court does not decide whether the FDA correctly denied Plaintiff's request for expedited processing, the issue is *not* moot. Should the Parties seek to file motions for summary judgment, the Court will take up the issue then.

EXHIBIT H

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, Plaintiff, v. CENTERS FOR DISEASE CONTROL AND PREVENTION, *et. al.*, Defendants.	2:23-CV-102-Z

MEMORANDUM ORDER AND OPINION

Before the Court is Plaintiff's Motion for Summary Judgment (ECF No. 8) ("Motion") and Defendants' Cross Motion for Summary Judgment (ECF No. 27) ("Cross Motion"). For the following reasons, the Motion is **GRANTED** and the Cross Motion is **DENIED**.

INTRODUCTION

In response to the COVID-19 pandemic, the United States government spearheaded one of the greatest medical endeavors in history. Within months, Congress allocated billions of dollars to fund, develop, manufacture, and distribute hundreds of millions of doses of COVID-19 vaccines. When the first vaccines became available in December of 2020, Defendants launched a massive safety monitoring program called "V-safe." Because of the rapid and extensive rollout of the vaccine, Defendants used V-safe to quickly collect critical health data for symptoms, adverse events, hospitalization or treatment, and safety issues directly from those who received the vaccines. V-safe collected two types of data from millions of Americans: (1) check-the-box options and (2) free-text responses. Plaintiff seeks production of approximately 7.8 million free-text responses pursuant to the Freedom of Information Act ("FOIA").

BACKGROUND

A. COVID-19 Vaccines and Associated Policies

As COVID-19 spread, the federal government collaborated and cooperated with foreign governments and non-governmental humanitarian organizations,[1] private companies,[2] and media[3] to enable and incentivize widespread vaccination. Operation Warp Speed, the effort to fast-track COVID-19 vaccines to the American people, removed many of the regulatory and market hurdles for manufacturers while also authorizing vaccines for emergency use.[4] Pursuant to Emergency Use Authorization, FDA permitted the use of unapproved medical products — and unapproved uses of approved products — to diagnose, treat, or prevent COVID-19.[5] Beginning in 2020, former Secretary of the U.S. Department of Health and Human Services, Alex Azar II, issued a series of PREP Act Declarations covering COVID-19 tests, drugs, and vaccines.[6] Ultimately, the Declarations provided liability immunity for manufacturers, distributors, states, localities, healthcare professions, and other qualified persons involved in COVID-19 campaigns.[7]

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[1] U.S. Agency for International Development, *Executive Summary: Global Vax: Accelerating COVID-19 Vaccination Efforts Around the World*, Global Vax Initiative for Global COVID-19 Vaccine Access (Sept. 14, 2023) (explaining the $2 billion global vaccination campaign).

[2] For instance, HHS partnered directly with Johnson & Johnson to pump over $1 billion into the rapid development of the Janssen COVID-19 vaccination. Jon Cohen, *The $1 billion bet: Pharma giant and U.S. government team up in all-out coronavirus vaccine push*, American Association for the Advancement of Science, available at https://www.science.org/content/article/1-billion-bet-pharma-giant-and-us-government-team-all-out-coronavirus-vaccine-push (Mar. 31, 2020).

[3] S*ee, e.g.*, *Missouri v. Biden*, 83 F.4th 350, 364 (5th Cir. 2023) (explaining social media censorship in response to White House "pressure," how "platforms continued to amplify or assist . . . a vaccine 'booster' campaign," and how "CDC officials authoritatively told the platforms what was (and was not) misinformation").

[4] U.S. Government Accountability Office, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, GAO-21-319 (Feb. 11, 2021).

[5] U.S. Food and Drug Administration, *Emergency Use Authorization for Vaccines Explained*, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

[6] *See* Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30769 (May 12, 2023) (including the most recent update to the COVID PREP Act Declarations and providing a summary of the prior ten Declarations).

[7] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020).

The government promoted vaccination — directly through mandates or indirectly through policies, privileges, and messaging campaigns. Many employers required vaccination via various workplace rules, regulations, and policies. For instance, the Biden Administration issued Executive Orders 14042 and 14043, which mandated COVID-19 vaccinations for all federal employees and federal contractors.[8] Additionally, the Centers for Medicare & Medicaid Services issued regulations requiring vaccinations for all Medicare or Medicaid facilities and staff.[9] And soon, Fortune 500 companies followed suit.[10] OSHA issued regulations requiring (1) vaccination or (2) mandatory weekly testing for companies with more than 100 employees.[11] The government's mission was stated as: "get more people vaccinated, or prolong this pandemic and its impact on our country."[12] Societal reality hinged on vaccination status — from school attendance to family vacations.[13] By early 2023, more than 5.5 billion people (about 72.3 percent of the *world* population) had received a dose of a COVID-19 vaccine,[14] including more than 270 million

[8] Exec. Order No. 14042, 86 Fed. Reg. 50989 (Sept. 9, 2021), *revoked by* Executive Order No. 14099, 88 Fed. Reg. 30891 (May 15, 2023); Exec. Order No. 14043, 86 Fed. Reg. 50989 (Sept. 9, 2021), *revoked by* Executive Order No. 14099, 88 Fed. Reg. 30891 (May 15, 2023).

[9] *See* Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555, 42 C.F.R. §§ 416, 418, 441, 460, 482–86, 491, 494 (Nov. 5, 2021).

[10] *See, e.g.*, *Sambrano v. United Airlines, Inc.*, 19 F.4th 839, 839 (5th Cir. 2021) (Ho, J., dissenting) ("United Airlines claims that it made the 'business judgment' that every employee must obtain a COVID-19 vaccine . . . ."); *see also* Haley Messenger, *From McDonald's to Goldman Sachs, here are the companies mandating vaccines for all or some employees*, NBC News (Updated Nov. 16, 2021).

[11] *See generally* Occupational Safety and Health Administration, RIN 1218-AD42, Docket No. OSHA-2021-0007, Dept. of Labor (Nov. 5, 2021) (fines set at nearly $14,000 per occurrence).

[12] *See* Statement by President Joe Biden on Vaccination Requirements (Nov. 4, 2021), available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/statement-by-president-joe-biden-on-vaccination-requirements/#:~:text=Vaccination%20is%20the%20single%20best,requirements%20%E2%80%93%20and%20they%20are%20working. (announcing OSHA policy for 100+ employee mandate).

[13] *See* ECF No. 1 at 4; *see, e.g.*, Zack Gould, *States Take Action on Vaccine Mandates in Schools*, Nat'l Academy for State Healthy Pol'y (Nov. 9, 2021) (noting California and Illinois require students be vaccinated against COVID-19 to attend school; Hawaii and the District of Columbia required high school students to be vaccinated against COVID-19 to participate in athletics); OpenTable, *Restaurants in the U.S. That Require COVID-19 Vaccination for Indoor Dining* (Sept. 14, 2021) (listing restaurants available on the reservation platform that require proof of vaccination to dine); Zoe Read & Alan Yu, *Which places will require proof of a COVID-19 vaccine? And should they?*, WHYY (Apr. 5, 2021) (noting that the Miami Heat, New York Knicks, and New York Rangers require proof of vaccination or a negative COVID-19 test before allowing fans to attend games); Michelle Baran, *These Hawai'i, Caribbean, and New York Hotels Now Require Vaccination*, AFAR (Sept. 15, 2021) (hotels in various vacation destinations in the United States require proof of COVID-19 vaccination for guests).

[14] Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES (March 13, 2023).

Americans.[15] Defendants have consistently asserted that "COVID-19 vaccines are safe and effective," "recommends everyone ages 6 months and older get an updated COVID-19 vaccine,"[16] and added the COVID-19 vaccine to standard Child and Adolescent Immunization Schedule.[17]

B. The V-safe Program

Contemporaneous with the rollout, Defendants launched the V-safe program to monitor vaccine safety in real time. V-safe employs a smartphone-based application allowing participants to voluntarily enroll and report their (or a dependent's) health after vaccination. ECF No. 29 at 12–13. V-safe collects basic personal information (*e.g.*, name, mobile number, date of birth, sex, zip code) and the vaccine dose(s) he or she has received. *Id.* at 13. To preserve confidentiality, each participant is assigned a registrant code permitting an analyst to connect the participant's various surveys without compromising his or her identity. The application sends text messages to the participant with individualized links to the web-based health check-in surveys. *Id.* The surveys are administered: (1) daily for seven days; (2) weekly for five weeks; and (3) at three-, six-, and twelve-month intervals. *Id.* This schedule repeats with each subsequent dose or booster. Questions include ten pre-specified CTB answer choices for a "Symptom Check" (*e.g.*, chills, headache, and nausea) and "Health Impact" (related to ability to work, perform normal activities, treatment, or hospitalization). *See* ECF No. 10 at 78. The check-the-box data was released pursuant to separate FOIA litigation. *See Informed Consent Action Network v. Centers for Disease Control and Prevention, et al.*, Civil Action No. 1:22-CV-481-RP, ECF No. 19 (W.D. Tex. Sept. 8, 2022).

[15] As of May 9, 2023, approximately 81.39% of Americans had received at least one dose and 69.47% had completed a primary series. *See* Centers for Disease Control and Prevention, *COVID-19 Vaccinations in the United States*, COVID Data Tracker (Updated May 11, 2023).

[16] *See, e.g.*, CDC: Safety of COVID-19 Vaccines (Updated Nov. 3, 2023), available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

[17] CDC: Child and Adolescent Immunization Schedule by Age, available at https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (recommending "1 or more doses of updated (2023–2024 Formula) [COVID-19] vaccine" at 6 months of age).

Each survey also includes optional free-text fields for "[a]ny other symptoms or health conditions you want to report" and "please describe" regarding healthcare treatment or hospital visits. ECF No. 10 at 78. There are approximately 7.8 million responses, limited to 250 characters in length.[18] These FTRs are the subject of the present litigation. Plaintiff alleges the bifurcated data collection method was designed to restrict reports of adverse events to the free-text entries, suppress the number of reported adverse events, render that data difficult to standardize, and thus curate a misleading health and safety profile of the COVID-19 vaccine — that it is "safe and effective."

Notably, V-safe is not synonymous with other reporting systems maintained by Defendants, including the Vaccine Adverse Event Reporting System ("VAERS"). VAERS detects and characterizes "rare and unexpected conditions," ECF No. 29 at 40, while V-safe captures common — even expected — symptoms in the check-the box responses and "any other" symptoms in the free-text fields. While "VAERS data is processed and made publicly available," none of the V-safe data is included in the VAERS disclosure. *Id.* Additionally, Defendants are in the process of converting all free-text responses to standardized medical code ("MedDRA") and have released some 5 million converted entries. *See* ECF No. 39 at 12. Thus, release of the V-safe free-response data, as requested, is separate from the check-the-box and the standard VAERS disclosures.

[18] Defendants explain that two free-text fields were inadvertently designed to collect up to 4,000 characters per response but were modified in June 2021 to capture only the 250-character max. *See* ECF No. 30 at 11.

C. Plaintiff's FOIA Request

While "Trust the Science" became something of a national slogan, [19] the American public's trust in science and scientists are at an all-time low.[20] It is with this background that Plaintiff aims to further the ideals pledged by the Biden-Harris administration: to "Promote trust, transparency, common purpose, and accountability in our government"[21] by making available for public access — and particularly for independent scientific and medical research — all of the relevant health data collected through the V-safe program. As the check-the-box data has already been released, it is the free-text response data Plaintiff seeks.

Plaintiff "is a nonprofit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in the CDC's v-safe database." ECF No. 1 at 7. The group is comprised of medical professionals including practitioners, researcher, and educators. *Id.* The nonprofit is a registered Texas Domestic Non-Profit Corporation with its sole headquarters and principal place of business in Amarillo, Texas 79101. *Id.* at 6; ECF No. 1-7 at 93. Plaintiff maintains a website — www.drsforchoice.org — intended to facilitate publication of the free-text data in anticipation of production pursuant to the FOIA request or a court order.

On January 3, 2023, Plaintiff submitted a FOIA request with Defendants pursuant to 5 U.S.C. §§ 552(a)(6) and (a)(4). *See* ECF No. 30 at 23–28.[22] Plaintiff's request description was: "All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry.

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[19] The White House: COVID-19, The Biden-Harris plan to beat COVID-19, available at https://www.whitehouse.gov/priorities/covid-19/ ("The Biden-Harris administration will always [l]isten to science."); *see also* Nate Hochman, *Trust the Science?*, National Review (Nov. 29, 2021), available at https://www.nationalreview.com/corner/trust-the-science/.

[20] *See e.g.*, Brian Kennedy & Alec Tyson, *Americans' Trust in Scientists, Positive Views of Science Continue to Decline*, Pew Research Center (Nov. 14, 2023).

[21] The White House: COVID-19, The Biden-Harris plan to beat COVID-19, *supra* note 9.

[22] "Defendants respectfully refer the Court to [the letters] for a true and complete statement of [their] contents." ECF No. 26 at 4. Accordingly, the Court reviews the FOIA correspondences filed in Defendants' appendix at ECF No. 30.

(Note that all records from pre-populated fields, other than registrant code, can be excluded.") *Id.* at 23. Further, Plaintiff acknowledged that redaction may be necessary and therefore requested Defendants "segregate and disclose" the non-exempt portions. *Id.* at 28. Plaintiff also requested expedited processing and waiver of associated fees. *Id.* 25.

The CDC immediately denied expedited processing and waiver of fees and asserted that "unusual circumstances" warranted an extension of time to respond to the request. *Id.* at 30–31. Thereafter, Defendants issued a final determination to withhold all the free-text response entries because many free-text responses included unsolicited personally identifiable information ("PII") — like names, birthdates, and social security numbers — and Defendants' lack of resources to manually review the data to segregate the non-exempt portions. *Id.* at 33–34.

Plaintiff administratively appealed. *Id.* at 36–51 (appeal of final determination), 38–149 (appeal of fee waiver). When Defendants did not resolve the appeals within the time limits prescribed by 5 U.S.C. §§ 552(a)(6)(A)(ii) and (a)(6)(B)(i), the matter because immediately justiciable. On July 3, 2023, Defendants notified Plaintiff that they would cease processing the FOIA final determination appeal because Plaintiff had filed suit in this Court. *Id.* at 55–56 (citing 45 C.F.R. § 5.63). Also on July 3, 2023, Plaintiff received untimely notice that Defendants had administratively closed the fee waiver appeal as moot because costs incurred were de minimis. *Id.* at 153. Apparently, on April 12, 2023, Defendants attempted to email Plaintiff regarding the fee waiver appeal, but when the email was "undeliverable," *see id.* at 157, Defendants did not attempt to notify Plaintiff for nearly three months. In the interim, Plaintiff filed suit.

LEGAL STANDARD

A. Modified Summary Judgment Standard in the FOIA Context

The FOIA framework is as follows: First, a requester files a "request for records" that is "sufficiency specific and made in accordance with published procedures for submitting such requests." *Nat'l Sec. Counselors v. C.I.A.*, 898 F. Supp. 2d 233, 254 (D.D.C. 2012) (quoting 5 U.S.C. § 552(a)(3)(A)). Second, the agency must make "reasonable efforts" to search for responsive records. *Id.* Once identified, the agency "shall make the records promptly available." *Id.* An agency, however, must "withhold production of requested records" or "information [that] is exempt from disclosure," *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir. 2010); *Riley v. Fenty*, 7 A.3d 1014, 1018 (D.C. Cir. 2010); *Hyatt v. U.S. Pat. & Trademark Off.*, No. 18-CV-2800(TSC), 2022 WL 1718983, at *1 (D.D.C. May 27, 2022) (citing 5 U.S.C. § 552(b)) — *e.g.*, "medical files and similar files" that "would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "[T]he agency has the burden to prove de novo that the information [requested] is exempt from disclosure" and must be withheld. *Batton*, 598 F.3d at 175.

An asserted exemption does not end the inquiry. FOIA requires that "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt . . . ." 5 U.S.C. § 552(b). Thus, an agency may be compelled to review, redact, and then produce all but the exempted portions of responsive records, documents, and information. The limiting principle is that an agency need not comply with a request that imposes an "unreasonable burden" on the agency. *Mead Data Ctr., Inc. v. U.S. Dep't of Air Force*, 566 F.2d 242, 260 (D.C. Cir. 1977). If the information cannot be segregated — or cannot be segregated without "unreasonable burden" — the agency bears the burden to explain why beyond

conclusory assertions. *See Church of Scientology of Tex. v. I.R.S.*, 816 F. Supp. 1138, 1162 (W.D. Tex. 1993) (internal marks omitted).

When ruling on FOIA summary judgment motions, federal courts must be mindful of FOIA's purpose: to "pierce the veil of administrative secrecy," "open agency action to the light of public scrutiny," and "promote the disclosure of information, not to inhibit it." *Batton*, 598 F.3d at 175 (quoting *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976)); *Riley*, 7 A.3d at 1018 (internal marks omitted). Accordingly, "the provision of the Act giving citizens the right of access are to be generously construed, while the statutory exemptions from disclosure are to be narrowly construed, with ambiguities resolved in favor of disclosure." *Riley*, 7 A.3d at 1018 (internal marks omitted); *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002) (FOIA reflects "a general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language."). "The district court must analyze all underlying facts and inferences in the light most favorable to the FOIA requester." *Ayuda, Inc. v. Fed. Tr. Comm'n*, 70 F. Supp. 3d 247, 259 (D.D.C. 2014) (internal marks omitted).

Courts generally grant an agency's motion for summary judgment "only if the agency proves that it has fully discharged its FOIA obligations," which may mean "the agency identifies the documents at issue and explains why they fall under exemptions." *Id.* (internal marks omitted); *Cooper Cameron Corp. v. U.S. Dep't of Labor, OSHA*, 280 F.3d 539, 543 (5th Cir. 2002). The agency often makes this explanation in an affidavit "concerning the agency's determination as to technical feasibility" — and courts "accord substantial weight" to such an affidavit. *Ayuda*, 70 F. Supp. 3d at 272; 5 U.S.C. § 552(a)(4)(B). Because the agency bears the burden to establish any applicable exemption, conclusory and generalized assertions that documents are exempt from disclosure are insufficient — even if the FOIA requester has not controverted that assertion. *Id.*

(citing *Cooper Cameron Corp. v. U.S. Dep't of Labor, OSHA*, 280 F.3d 539, 543 (5th Cir. 2002)). Likewise, blanket claims that a mass of documents are exempt from disclosure are impermissible. *Vaughn v. Rosen*. 484 F.2d 820, 825 (D.C. Cir. 1973).

B. Standing to Bring a FOIA Action

"Any person" can make a FOIA request. 5 U.S.C. § 552(a)(3). Subject to exhausting administrative appeal requirements, "[a]nyone whose request for specific information has been denied has standing to bring an action under FOIA." *Nat'l Sec. Counselors v. C.I.A.*, 898 F. Supp. 2d 233, 254 (D.D.C. 2012) (internal marks omitted). "The requester is injured-in-fact for standing purposes because he did not get what the statute entitled him to receive." *Id.*

1. Time Limits for FOIA Requests and Appeals

By default, an agency must determine whether to comply with a FOIA request within twenty working days. 5 U.S.C. § 552(a)(6)(A)(i). The same time frame applies to any appeal. 5 U.S.C. § 552(a)(6)(A)(ii). If certain specified "unusual circumstances" exist, the agency may extend its response by an additional ten working days. 5 U.S.C. §§ 552(a)(6)(B)(i), 552(a)(6)(B)(iii) (defining "unusual circumstances" to include retrieval of records maintained elsewhere, voluminous amounts of separate and distinct records, and the need to consult with another agency). Thus, thirty working days operates as the outer limit unless the agency notifies the requester that "the request cannot be processed within the time limits specified" and provides the requester an opportunity to: (1) "limit the scope of the request"; or (2) arrange "an alternative time frame for processing the request or a modified request." 5 U.S.C. § 552(a)(6)(B)(ii).

2. Expedited Processing of a FOIA Request

Federal agencies generally process FOIA requests on a first-in, first-out basis. *See Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976); *see also* ECF

No. 30 at 53 ("Each appeal is handled on a first-in, first-out basis . . . ."). However, sometimes agencies must expedite processing for certain requests — bringing them to the front of the queue. *See* 5 U.S.C. § 552(a)(6)(E)(i)(I); *Daily Caller v. U.S. Dep't of State*, 152 F. Supp. 3d 1, 8 (D.D.C. 2015); *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:22-CV-0915-P, 2023 WL 3335071, at *1 (N.D. Tex. May 9, 2023). A requester is entitled to expedited processing if it shows a "compelling need." *See* 5 U.S.C. § 552(a)(3)(6)(E)(i)(I). A "compelling need" means: (1) there is "an imminent threat to the life or physical safety of an individual"; or (2) for "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity." *See* 5 U.S.C. § 552(a)(3)(6)(E)(v)(I)–(II). If an agency denies a request for expedited processing under FOIA, the requester may file with the district court and seek immediate judicial review. 5 U.S.C. § 552(a)(6)(E)(iii). District courts have "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld." 5 U.S.C. § 552(a)(4)(B). Determinations by the district court are made de novo. *See Bloomberg, L.P. v. FDA*, 500 F. Supp. 2d 371, 374 (S.D.N.Y. 2007).

3. Fee Waivers for FOIA Requests

Production of requested records may involve costs and fees. *See* 5 U.S.C. § 552(a)(4)(A)(i). However, a FOIA requester is entitled to a fee waiver if: (1) "disclosure of the information is in the public interest," meaning disclosure "is likely to contribute significantly to public understanding of the operations or activities of the government"; and (2) disclosure "is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). Matters related to a fee waiver are decided by the district court *de novo* — considering only the record before the agency. 5 U.S.C. § 552(a)(4)(A)(vii).

APPLICATION

A. Defendants must produce the free-text data subject to redaction of PII as required by FOIA Exemption 6.

The development and distribution of the COVID-19 vaccine was one of the greatest endeavors in recent history. Predictably, the American public now seeks access to COVID-related papers to ensure that relevant government policies were — and still are — supported and justified by the available data. That is precisely what FOIA contemplates and facilitates.

It is also what Defendants expected and envisioned for V-safe — at least initially. V-safe protocol intended that "[a] final data set . . . with deidentified data will be made available for external data requests or through Freedom of Information Act (FOIA) requests." V-Safe Protocol: April 18, 2022, version 5, at 12, available at https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V5-508.pdf (last viewed December 27, 2023); *see also* ECF No. 35 at 18. However, Defendants now argue that because the pandemic lasted longer than expected and "the vaccination program in the United States evolved to include recommendations for booster doses . . . the V-safe application collected considerably more data and was operational for a longer period than initially anticipated." ECF No. 30 at 20–21. The simple reason Defendants denied Plaintiff's production request is the 7.8 million free-text response entries are allegedly too numerous for the agency's limited resources. *See* ECF No. 30 at 33. While the burden to produce the requested free-text responses may be heavy, this Court does not find that it is unreasonable.[23]

[23] In 2024, American citizens may be more interested in COVID data following Dr. Francis Collins's statements on the "public-health mindset," which were printed in several media publications in December 2023. *See, e.g.*, Ed. Bd. *Francis Collins Has Regrets, but Too Few*, WALL ST. J. (Dec. 29, 2023), available at https://www.wsj.com/articles/francis-collins-covid-lockdowns-braver-angels-anthony-fauci-great-barrington-declaration-f08a4fcf; John Fund, *Officials Now Admit the Disaster of Their Covid Policies*, NATIONAL REVIEW (Jan. 4, 2024), available at https://www.nationalreview.com/2024/01/officials-now-admit-the-disaster-of-their-covid-policies/ ("If you're a public-health person and you're trying to make a decision, you have this very narrow view of what the right decision is, and that is something that will save a life. It doesn't matter what else happens. So you attach infinite value to stopping the disease and saving a life. You attach a zero value to whether this actually totally disrupts people's lives, ruins the economy, and has many kids kept out of school in a way that they never quite recovered from. . . . This is a

1. Plaintiff submitted an appropriately narrow FOIA request.

Plaintiff's request seeks:

> "*All data obtained from v-safe users/registrants form the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded.)* Date range: 10/01/2020–12/31/2022."

ECF No. 30 at 33. The request is as narrow as possible without compromising the meaningfulness of the request, excludes the already-released check-the-box data, and acknowledges that redacting exempted material may be necessary. *See id.* at 23, 28. Thus, Defendant's form language inviting Plaintiff to "consider narrowing the scope of your request to limit the number of responsive records" is of no effect. *Id.* at 30.

2. Defendants conducted an adequate search.

An agency must demonstrate "that it has conducted a search reasonably calculated to uncover all relevant documents." *Weisberg v. U.S. Dep't of Justice*, 705 F.2d 1344, 1351 (D.C. Cir. 1983); *see also Batton*, 598 F.3d at 176. The parties do not dispute that Defendants conducted an adequate search, identifying the complete, known sum of all responsive records — the 7.8 million V-safe free-text responses together with their respective registrant codes. *See* ECF Nos. 9 at 27–32, 29 at 19–20, 35 at 2.

3. Exemption 6 applies to any PII present in the responsive records.

Exemption 6 prohibits dissemination of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). The Supreme Court explained the "exemption [was] intended to cover detailed Government records on an individual which can be identified as applying to that individual." *U.S.*

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public-health mindset. And I think a lot of us involved in trying to make those recommendations had that mindset, and that was really unfortunate. It's another mistake we made. Okay.")

Dep't of State v. Washington Post Co., 456 U.S. 595, 601–02 (1982). "If the request includes such personal information," courts must examine "whether release of the information would constitute a clearly unwarranted invasion of that person's privacy." *Sherman v. U.S. Dep't of Army*, 244 F.3d 357, 361 (5th Cir. 2001).

The parties do not dispute that it would be improper for Defendants to produce any PII present in responses or even what may constitute PII.[24] In fact, Plaintiff's request contemplated that records would need to be reviewed and redacted. ECF Nos. 29 at 39 ("While the Free-Text Responses were not specifically drafted to capture [PII], V-safe participants did include PII in these fields when answering the questions"); 35 at 6 ("Plaintiff does not contest that [PII] should be redacted from the data produced."). Any information that affects the likelihood that a specific person be individually identified must be redacted and withheld.

Importantly, a participant's registrant number[25] and generalized demographic information are *not* PII. *See Ayuda*, 70 F. Supp. 3d at 271 (finding disclosure of five-digit zip code did not "actually or potentially affect[] the likelihood that the complainant will be identified"). The type of information that must be reviewed for, redacted, and withheld from production must "actually or potentially affect[] the likelihood that [a V-safe participant] will be identified" individually. *Id.* Thus, unsolicited bits of information — like names, birthdates, social security numbers, employer, and location where he or she received the vaccine if sufficiently specific (i.e., "ABC Pharmacy on Main Street in Amarillo" but not "Wal-Mart Pharmacy") — that may be included in some V-safe responses must be redacted. *See* ECF No. 30 at 11–12 (listing examples of PII found within Free-

[24] While an agency must ordinarily produce a *Vaughn* index for in-camera review, the Court finds such review unnecessary. Because the parties do not dispute the kind of information is subject to exemption and redaction, there is no need for the Court to conduct a "review of the agency's decision." *See Coldiron v. U.S. Dep't of Just.*, 310 F. Supp. 2d 44, 46 (D.D.C. 2004).

[25] The registrant ID numbers have already been released ancillary to the check-the-box data pursuant to separate FOIA litigation. An anonymous registrant ID number, without more, does not identify a particular person. Rather, some types of PII *could* identify a particular person, so that information must be withheld.

Text Responses, organized by registrant codes). Defendants aver that sex and zip code constitute PII, but that is not the case. The pieces of information exempt from disclosure by Exemption 6 must risk identifying a specific person — for instance, a telephone number and first name. Descriptions that do not personally identify a specific person are not exempted by Exemption 6.

4. Production of the redacted free-text data is not unreasonably burdensome.

The primary dispute is whether the review, redaction, and production process amount to an unreasonable burden. More specifically, whether the exempted PII contained within some free-text data is reasonably capable of segregation from the non-exempt remainder. Defendants contend "the non-exempt information within the Free-Text Responses is not *reasonably* segregable, because having to review and redact 7.8 million Free-Text Responses to segregate non-exempt information would impose an unreasonable burden on the agency." ECF No. 29 at 32. Typically, courts discuss "the physical difficulty of segregating exempt information within the relevant records." *Ayuda*, 70 F. Supp. 3d at 276 (citing *Int'l Counsel Bureau v. U.S. Dep't of Def.*, 864 F. Supp. 2d 101, 106–07 (D.D.C. 2012)).

Defendants do not argue that the information is *physically* incapable of segregation. Rather, Defendants claim they do not have the manpower to comply. ECF No. 29 at 39 (The FOIA Office "does not have the resources to process this request in-house."). Specifically, Defendants aver that the entirety of "CDC's FOIA Office comprises *thirteen* FOIA analysts who are responsible for responding to all FOIA requests from receipt to completion of any administrative appeal, as well as assisting with any related litigation." ECF No. 29 at 36 (emphasis added). Plaintiff, on the other hand, contends that programs for automated electronic data review are available and capable of minimizing the burden of manual review and, moreover, the task is not as weighty as Defendants describe. ECF No. 35 at 17.

In support, Defendants marshal CDC FOIA Officer Roger Andoh's declaration, ECF No. 30 at 4–21, wherein he opines that review would take a single analyst 59 years, *accord id.* at 14 *with* ECF No. 29 at 36. While "[a]n agency may establish reasonableness through affidavits" — which FOIA instructs should be given substantial weight — a court may nonetheless reject the affiant's determination if "there were some reason to believe that the documents could be located [and produced] without an unreasonably burdensome search." *Goland v. C.I.A.*, 607 F.2d 339, 353 (D.C. Cir. 1978).

Having reviewed Andoh's declaration, the Court does not find it ultimately persuasive. Instead, this Court finds that production is not unreasonably burdensome for at least four reasons: the requested records are not so voluminous; only a small percent of records will require any redaction; the redaction process is largely straightforward and capable of automated assistance; and blanket exemption claims covering a mass of records are impermissible. For those reasons, Defendants are not absolved of their responsibility to produce the redacted free-text responses.

i. The responsive records are not so voluminous as to present an unreasonable burden.

First, Defendants are correct that the sheer volume of responsive records may support of finding of unreasonable burden, especially when considered with an agency's limited resources. *See, e.g., Ayuda*, 70 F. Supp. 3d 277 (finding manually reviewing twenty million responsive records was unreasonably burdensome). However, Defendants' asserted caselaw is misleading as applied. Defendants cite several cases where courts determined that production and/or post-production review of voluminous records amounted to an unreasonable burden. ECF No. 29 at 33–34; *see Shapiro v. U.S. Soc. Sec. Admin.*, 525 F. Supp. 3d 528, 539–40 (D. Vt. 2021) (finding FOIA request unduly burdensome as it would require line-by-line manual review of more than 1.5 million

pages); *Nat'l Day Laborer Org. Network v. U.S. Immigr. & Customs Enf't*, No. 16-CV-387, 2017 WL 1494513, at *14–15 (S.D.N.Y. Apr. 19, 2017) (finding undue burden where responsive records could number up to 1.3 million pages, with review taking up to an estimated 1,300 weeks). Each of those cases considered the number of pages while this case concerns 250-character fields.

But the Court must compare units of measurement, not merely naked numerals. Courts have considered myriad units of measure in the FOIA context. *See, e.g.*, *Long v. Immigr. & Customs Enf't*, 149 F. Supp. 3d 39, 56 (D.D.C. 2015) (considering "1.8 million songs on an iPod") *Goland*, 607 F.2d at 353 (considering "84,000 cubic feet of documents"). Each of Defendants' asserted cases considered a voluminous number of *pages*. However, Defendants report the free-text entries in terms of *characters*. *See, e.g.*, ECF No. 30 at 11. The free-text entries were limited to 250 characters each.[26] For comparison, X (a/k/a "Twitter") permits most users to tweet up to 280 characters.[27] Thus, the parties functionally dispute Defendants' ability to review and redact 7.8 million *tweets*, not *pages*.

Affording Defendants the greatest mathematical latitude by assuming *each* free-text response utilized the full 250 characters, the 7.8 million free-text responses yield 1.95 billion characters. Considering an average page of text — using 12-point Times New Roman font, single spaced, and one-inch margins — an average page contains approximately 3,000–3,276 characters.[28] The 1.95 billion characters would yield approximately 595,238–650,000 pages.

[26] *But see*, *supra* note 18. Defendants have not explained how many responses — if any — actually exceeded 250 characters.

[27] *See* Nicholas Reimann, FORBES: *Twitter Boosts Character Limit to 4,000 For Twitter Blue Subscribers* (Feb. 9, 2023), available at https://www.forbes.com/sites/nicholasreimann/2023/02/08/twitter-boosts-character-limit-to-4000-for-twitter-blue-subscribers/?sh=4554c86c5ab8 (explaining how "non-subscribers," approximately 99.8% of users, are limited to 280 characters per tweet).

[28] Plaintiff represents 3,276 characters per page. *See* ECF No. 35 at 17. Considering the common metric of 500 words per page double-spaced, or 1,000 single-spaced, and average word length at 6 characters (including a space), the range is appropriate for estimation. *See, e.g.*, Wylie Communications: *What's the best length of a word online?*, available at https://www.wyliecomm.com/2021/11/whats-the-best-length-of-a-word-online/ (reporting average word lengths of various publications as between 4 and 6 characters).

Considering the COVID-19 vaccine was the largest federal project in recent history, that is not surprising. This Court does not find that — at most — 650,000 pages amounts to an unreasonable burden. *See Pub. Health & Med. Pros. for Transparency*, 2023 WL 3335071, at *1 n.1 (leaving unchanged the expected end date for producing all documents despite the actual number of documents being 1.2 million rather than 450,000 as the agency previously estimated). Of course, this is likely an excessive overestimation.

But in the FOIA context, "[t]he district court must analyze all underlying facts and inferences in the light most favorable to the FOIA requester." *Ayuda*, 70 F. Supp. 3d at 259. The comparable responses from V-safe's motivation survey averaged a mere 35 characters. ECF No. 1 at 80.[29] Thus, assuming each free-text response is 35 characters like the motivation survey, the total production could be as little as 273,000,000 characters yielding a mere 83,333–91,000 pages.

FOIA Officer Andoh estimates that manual analysis would "take about 123,564 work hours to complete." ECF No. 30 at 16. At the high end (650,000 pages) that is approximately 11.5 work-minutes to review each page. At the low end (83,333 pages), it would be an hour and a half per page of text.

ii. Only a small percent of the records is likely to contain any PII at all.

Second, Defendants have marshaled evidence that approximately 7% of responses will contain unsolicited PII. *See* ECF No. 30 at 11–12. Accordingly, while screening all 7.8 million responses is necessary, approximately 93% will require no redaction at all.

[29] The Court acknowledges Defendants' opposition to analogizing from the motivation survey, *see* ECF No. 39 at 9, and notes that Defendants failed to contest Plaintiff's allegation that the V-safe free-text fields are likely to be of comparable length. Regardless, the Court uses this metric only for calculating a low-end comparison.

iii. Any necessary redactions are simple and capable of automated assistance.

Third, the required redactions are not complex or nuanced. True, a less voluminous production that requires heavy post-production review and redaction may constitute an unreasonable burden. *See Vietnam Veterans of Am. Conn. Greater Hartford Ch. 120 v. DHS*, 8 F. Supp. 3d 188, 203–04 (D. Conn. 2014) (finding undue burden where 26,000 fifty-page packets required heavy redactions).[30] However, the present case does not entail particularly complex redactions. Rather, the redacted information is part-and-parcel of many automated programs utilized by law firms to screen large quantities of documents during discovery. Defendants may deploy automated review and redaction of the free-text responses, significantly reducing the workload for Defendants' analysts. Indeed, the data is already stored in digital form. *See* ECF No. 29 at 13–14 (explaining how V-safe data is stored and transmitted for review).

For this reason, Congress passed the Electronic Freedom of Information Act ("E-FOIA") Amendments. Pub. L. No. 104–231 § 2(a)(6); *People for the American Way*, 451 F. Supp. 2d 6, 13 (D.D.C. 2006). E-FOIA instructs agencies to "use new technology to enhance public access to agency records and information." *People for the American Way*, 451 F. Supp. 2d at 14 (quoting E-FOIA § 2(a)(6)). New technology provides alternative search methodologies that substantially reduce the burden imposed on an agency compared to historic manual review. *See Freedom Watch, Inc. v. Nat'l Sec. Agency*, 783 F.3d 1340, 1345 (D.C. Cir. 2015) ("[N]ot only does FOIA expressly permit automated searches," but "search" in the context of 5 U.S.C. § 552 "means to review, manually or by *automated means*."); *cf. Pub. Citizen, Inc. v. Dep't of Educ.*, 292 F. Supp. 2d 1, 6–7 (D.D.C. 2003) (ordering a search of 25,000 files for irregularly kept data, despite the need for manual review). Insofar as Defendants argue that "manual review" would impose an unreasonable

[30] Notably, *Vietnam Veterans* still concerned some 1.3 million pages (26,000 x 50 = 1,300,000) — approximately double the high-end of the estimated record requested here.

burden, this Court finds that it would — especially employing "automated means." *Freedom Watch*, 783 F.3d at 1345.

Moreover, some 20 years after *Public Citizen, Inc.*, the technology for automated document review has advanced to largely nullify concerns about manual review and even simple search parameters like name, birthdates, social security numbers, phone numbers, and email addresses — the types of PII at issue here. The automated processes acknowledged by both parties, expressly contemplated by FOIA, and mandated by E-FOIA, are capable of substantially reducing the costs and time required to review and redact for exempted PII.

Defendants also aver internal process complicate the matter. First, CDC's FOIA Office comprises only thirteen analysts. ECF No. 30 at 15. Second, Defendants' practice entails "another manual, line-by-line review" by "either a senior FOIA analyst or Team Lead." ECF No. 29 at 35. While neither Plaintiff nor this Court dispute the Defendants' alleged allocation of FOIA staff, "the number of resources an agency dedicates to such requests does not dictate the bounds of an individual's FOIA rights." *Pub. Health & Med. Pros. for Transparency*, 2023 WL 3335071, at *2 (citing *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 621 (D.C. Cir. 1976) (Leventhal, J., concurring). Instead, this Court must ensure that the fullest possible disclosure of the information sought is timely provided — as "stale information is of little value." *Id.* (quoting *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988)).

iv. Blanket exemption claims covering a mass of records are impermissible.

Fourth, Defendants' decision to withhold all free-text responses because some contain PII is tantamount to an impermissible blanket claim. *Vaughn v. Rosen* compels agencies to both segregate and identify the rationale for withholding records that are not segregable and disclosable. *See* 484 F.2d 820; *see also Ray v. Turner*, 587 F.2d 1187 (D.C. Cir. 1978). "[A]n entire document

is not exempt merely because an isolated portion need not be disclosed. Thus, the agency may not sweep a document under a general allegation of exemption, even if that general allegation is correct with regard to part of the information." *Vaughn*, 484 F.2d at 825. "An agency must therefore redact exempt information and produce any relevant non-exempt information." *Coldiron*, 310 F. Supp. 2d at 47 (citing 5 U.S.C. § 552(b)). An agency claiming information is exempt and incapable of reasonable segregation must "describe what proportion of the information is non-exempt and how that material is disbursed throughout the document." *Id.* That particularized description ensures "both litigants and judges will be better position[ed] to test the validity of the agency's claim that the non-exempt material is not segregable." *Id.* (internal marks omitted). To the extent Defendants have particularly described the proportion of affected responses, this Court finds that approximately 7% does not impose an unreasonably burdensome for simple redactions largely capable of automation.

Certainly, blanket claims would be easier for the agency, but convenience is not relevant and segregable portions must be disclosed. *Badhwar v. U.S. Dep't of Air Force*, 622 F. Supp. 1364 (D.D.C. 1985), *order vacated on other grounds*, 829 F.2d 182 (D.C. Cir. 1987). This Court must determine whether segregation is "unreasonable" or merely inconvenient, and then whether the remaining non-exempt portions are intelligible to warrant production of the redacted records. *Simpson v. Vance*, 648 F.2d 10, 17 (D.C. Cir. 1980), *abrogated by U.S. Dep't of State v. Washington Post Co.*, 456 U.S. 595 (1982); *Mead Data Central, Inc. v. U.S. Dep't of Air Force*, 566 F.2d 242, 261 (D.C. Cir. 1977).

Defendants have withheld *all* records because *some* records likely contain *some* exempt material, and segregation would potentially be very inconvenient, considering Defendants' understaffed FOIA office. As addressed, this Court does not find that to be the case. Rather, the

exempt PII is reasonably capable of redaction, leaving the remaining non-exempt portions of the free-text responses capable of production. Additionally, what remains will not only be intelligible, but precisely what Plaintiff seeks — the health and symptom information without PII like emails or social security numbers.

Further, if only 7% of free-text responses contain any PII at all, then the remaining 93% should not be categorically withheld. *Cf. Pub. Citizen v. Dep't of State*, 100 F. Supp. 2d 10, 25 (D.D.C. 2000), *rev'd on other grounds, Pub. Citizen*, 276 F.3d at 644–45 ("[T]he fact that the State Department, of its own accord, re-reviewed its withholdings and released certain additional entries indicates that the agency has been mindful of its obligation to release any segregable information."). Defendants have not evinced similar mindfulness of their obligation.

Therefore, while the burden to review and redact these responses for production may impose a heavy burden on Defendants, this Court does not find that burden to be unreasonable.

5. Even if production entails a *heavy* burden, production is still warranted.

Plaintiff argues that release of the data is essential for myriad reasons. Some groups contend they were injured by the vaccine, and without access to the underlying data they cannot meaningfully seek coverage or treatment. *See* ECF No. 1 at 3. Some parents are hesitant to consent — or even believe they are incapable of consenting — for their minor children to receive the vaccine. *Id.* at 4. Production of the source material is essential for independent researchers to evaluate the vaccines and for medical professionals to provide meaningful treatment to their patients. Some of Plaintiff's members are already engaged in this type of research. ECF No. 30 at 72 ("Many [Freedom Coalition of Doctors for Choice members] share with the public their findings, research, and professional opinions about Covid-19 and related issues.").

Notably, Plaintiff points to several studies published and presented by CDC that rely upon on the V-safe data. *See* ECF No. 35 at 9–13. All but one of those studies considered only the *first seven days* after receiving a vaccine, and the only study that looked beyond the first week considered just *two weeks*. *Id.* at 9 n.2. Defendants do not contest this. *See* ECF No. 39 at 10. Rather, Defendants dismiss the limited scope of the published studies as just "the time period that some scientists have chosen to use in their research studies." *Id.* at 11.

Because Defendants structured V-safe to collect health and symptomatic responses for a full year after a vaccine or booster, reviewing that data is of great importance to the public. If "some scientists" — sponsored or platformed by Defendants — "have chosen to use" only the first week or two of data to report the vaccine is safe and effective, then *other* scientists should be permitted to access the data to "pierce the veil of administrative secrecy," "open agency action to the light of public scrutiny," and "promote the disclosure of information." *Batton*, 598 F.3d at 175 (internal marks omitted); *Riley*, 7 A.3d at 1018 (internal marks omitted). Many of the policies previously addressed were enacted because of guidance from Defendants.[31] With billions of taxpayer dollars expended to develop, distribute, administer, and fund messaging campaigns, Plaintiff assumes a hefty and viable public interest in examining the raw clinical data. Production of the free-text data will permit independent researchers to put the government agencies to their proof by considering *all* of the available data. *See Judicial Watch v. Rossotti*, 326 F.3d 1309, 1314 (D.C. Cir. 2003) (The question is "whether disclosure of the requested documents is likely to contribute to public understanding of the [the government's COVID-19 operations and activities] — a goal that disclosure will promote regardless of what the documents reveal.").

[31] *See generally*, Center for Disease Control and Prevention, *Guidance Documents*, available at https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html (hosting a plethora of guidance documents instructing various entities on best practices to combat the COVID-19 pandemic).

Additionally, Plaintiff marshalled evidence that some vaccine studies may be misleading or based upon cherry-picked data. *See* ECF No. 9 at 17–18. One study reported that 0.8% to 1.1% of users reported needing medical care according to the check-the-box data. *Id.* at 13, 13 n.4. However, when the raw data was released pursuant to separate FOIA litigation, it showed some 7.7% of V-safe users reported needing medical care and an additional 25% missing school or work or unable to perform normal activities. *Id*. Similarly, Plaintiff alleges the check-the-box data captures only the "symptoms CDC says are normal to occur after vaccination and are actually a sign the vaccine is working." ECF No. 30 at 63. Thus, collecting that data and then profiling the vaccine as safe and effective based was a "pointless" exercise. *Id.* Any concerning symptoms would necessarily be restricted to only the free-text responses, to date unexamined by independent researchers not sponsored by Defendants.

Finally, rapid vaccination of a huge percentage of the American population is nothing short of astounding, and the endeavor continues. On November 4, 2021, the White House announced that "70 percent of adult Americans are now fully vaccinated" thanks to the Biden Administration's "policies requiring millions of federal employees and federal contractors to be fully vaccinated."[32] As of May 11, 2023, the CDC reports that more than 81% of Americans have received at least one dose, including nearly 32 million children.[33] Understandably, there is substantial public interest in the data that supported, and continues to support, the government's promotion of the COVID-19 vaccines and boosters.

[32] The White House: *New OSHA and CMS Rules Mean Two-Thirds of All Workers Now Covered by Vaccination Rules* (Nov. 4, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/ (last viewed December 21, 2023). (Press Statements and Releases)

[33] Centers for Disease Control and Prevention: COVID Data Tracker, *COVID-19 Vaccinations in the United States (Data provided by CDC, final update posted May 11, 2023)*, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5 (last viewed December 21, 2023).

It bears repeating that "[a]ny person" can make a FOIA request. 5 U.S.C. § 552(a)(3). "[A]s a corollary of these democratic principles," "the specific motives of the party making the FOIA request are irrelevant." *Cooper Cameron Corp.*, 280 F.3d at 547 (internal marks omitted). "[T]he rights of the requester are no different from those that might be asserted by any other third party, such as a neighbor or prospective employer." *Id.* (internal marks omitted). Justice Ginsberg noted this "main rule serves as a check against selection among requesters, by agencies and reviewing courts, according to idiosyncratic estimations of the request's or requester's worthiness." *United States Dep't of Def. v. Fed. Lab. Rel. Auth.*, 510 U.S. 487, 508 (1994) (Ginsburg, J., concurring). Accordingly, the foregoing analysis does not — and need not — vindicate or credential Plaintiff's request. *See Cooper Cameron Corp.*, 280 F.3d at 548 ("[A]lthough we suspect that Cooper seeks the deponent's statements to impeach testimony in the tort suit, our suspicion counts neither in favor of nor against Cooper's FOIA request."). Rather, the motives addressed herein guide this Court in finding that an arguably *heavy* burden is not synonymous with an *unreasonable* burden when viewed in light of the activities and operations of the government in response to COVID-19.

B. Plaintiff is entitled to expedited processing.

Plaintiff contends that Defendants wrongfully denied its request for expedited processing in the letter dated January 4, 2023. *See* ECF No. 30 at 76. This Court agrees.

A requester is entitled to expedited processing if it shows a "compelling need." *See* 5 U.S.C. § 552(a)(3)(6)(E)(i)(I). As relevant here, for "a person primarily engaged in disseminating information," a "compelling need" means "urgency to inform the public concerning actual or alleged Federal Government activity." *See* 5 U.S.C. § 552(a)(3)(6)(E)(v)(I)–(II).

First, Plaintiff is "primarily engaged in disseminating information." 5 U.S.C. § 552(a)(3)(6)(E)(v)(II). The nonprofit entity "was formed and exists for the sole purpose of

obtaining and disseminating to the public the v-safe free-text data." ECF No. 1 at 5, 7. Defendants' argument to the contrary is unavailing. The January 4, 2023, letter denying expedited processing simply states: "You have not demonstrated that you are a person primarily engaged in disseminating information." ECF No. 30 at 76. Plaintiff is not actively disseminating information to the public because Plaintiff is not yet in receipt of the information it seeks to disseminate. Defendant's argument renders the subpart meaningless: a FOIA requester could only be "engaged in disseminating information" when he is actively disseminating information, which presupposes the information is already in his possession. Because the expedited processing analysis precedes production, no requester could qualify unless he is engaged in disseminating *other* information. Nothing in FOIA or the relevant caselaw supports this reading of the statute. Rather, Plaintiff is "engaged in" *obtaining* information, an essential step that necessarily precedes the *dissemination* of same.

Second, Plaintiff has shown an urgent need to inform the public about "actual or alleged Federal Government activity" — namely, related to the health and safety of the COVID-19 vaccines and policies. Plaintiff points to the federal government's policies and messaging campaigns designed to promote public uptake of vaccines and boosters. *See* ECF No. 9 at 7–8. Plaintiff's initial request cites the recent addition of the COVID-19 vaccine to the routine childhood immunization schedule and the Biden administration's messaging specifically aimed at families. ECF No. 30 at 27. As recent as September 12, 2023, the Biden administration continues to "encourage all Americans to stay up-to-date on their [COVID-19] vaccines."[34]

[34] Statement from President Biden on FDA and CDC Action on Updated COVID-19 Vaccines (Sept. 12, 2023), available at https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/12/statement-from-president-biden-on-fda-and-cdc-actions-on-updated-covid-19-vaccines/.

Additionally, as addressed above, Plaintiff presents evidence that calls into question the claim that the vaccines are safe and effective — or at least the scope of research supporting that claim. "The law is clear that FOIA does not provide requesters with a right to demand an all-encompassing fishing expedition," and courts "need not embark on a time-consuming and costly goose chase in pursuit of phantom reports from the agency." *Cause of Action v. Internal Revenue Service*, 253 F. Supp. 3d 149, 160 (D.D.C. 2017). However, Plaintiff's briefing — both in this litigation and what was presented in the FOIA proceedings — sufficiently establishes "alleged" activity by the Federal Government sufficient to satisfy 5 U.S.C. § 552(a)(3)(6)(E)(v)(II).

Because Plaintiff has shown a compelling need, Defendants wrongfully denied its request for expedited processing. *Pub. Health & Med. Pros. for Transparency*, 2023 WL 3335071, at *2.

C. Plaintiff is entitled to a fee waiver.

A FOIA requester is entitled to a fee waiver if: (1) "disclosure of the information is in the public interest," meaning disclosure "is likely to contribute significantly to public understanding of the operations or activities of the government"; and (2) disclosure "is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). Matters related to a fee waiver are decided by the district court de novo — considering only the record before the agency. 5 U.S.C. § 552(a)(4)(A)(vii). That record includes Plaintiff's initial request, ECF No. 30 at 23–28, and Plaintiff's appeal of the fee waiver denial, *id.* at 58–149.

Plaintiff has made the requisite showing. Plaintiff explained that it sought the "primary source documentation" to permit independent research as to "the overall safety and efficacy of the COVID-19 vaccines." *Id.* at 59. Notably, the sample size is massive — representing between 3–4.5% of the vaccinated population — thus permitting particularly accurate research.[35] The V-safe

[35] Andrade, C. *Sample Size and its Importance in Research*, Indian J. Psychol. Med. 2020; 42: 102–03 ("A sample that is larger than necessary will be better representative of the population and will hence provide more accurate

free-text responses will contribute to the public's understanding of the COVID-19 vaccines — specifically as to the assertion by Defendants, the Biden administration, and others that the vaccine is "safe and effective" for everyone over six months of age — by providing access to the direct source material to treating physicians, researchers, parents, recipients, and non-recipients. ECF No. 30 at 60. "[D]isclosure of the information will" permit any interested person to research and report "whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues that impacted its relevant policies or regulatory decisions and recommendations." *Id.* Further, all Americans continue to be the target audience of marketing and messaging campaigns to promote continued vaccination.[36] Additionally, even if the redacted responses are less useful than extrapolated MedDRA data, a position taken by Defendants, *see* ECF No. 30 at 12–13 ("[I]t is this robust extrapolated [MedDRA] data of any adverse events . . . that would inform the public as to government activities."), the public nonetheless has the right to check the math. Finally, the information is not in Plaintiff's commercial interests, as it expects neither to seek nor gain monetarily from the data. ECF No. 9 at 35. Therefore, Plaintiff is entitled to a waiver of all fees for production.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion is **GRANTED** and Defendants' Cross Motion is **DENIED**. Additionally, parties are to comply with the following:

- Defendants are **ORDERED** to produce all free-text responses, together with the registrant number, redacted personal identifying information as described in this Order, **on or before January 15, 2025**;

results."); Faber J, Fonseca L.M. *How Sample Size Influences Research Outcomes*, Dental Press J. Orthod. 2014 July–UG; 19(4): 27–29 (describing appropriate methods for retrospective study of very large samples).

[36] *See, e.g.*, Pfizer, Inc's recent advertisement series entitled "Got Yours?" featuring various performers, including "Mr. Pfizer" himself — i.e., the Kansas City Chief who also appears in State Farm® commercials and Taylor Swift-related celebrity news.

- Defendants must produce batches of the free-text responses on a first-in, first-out basis;
- Defendants are **ORDERED** to comply with the below-listed *minimum* production schedule:
- Defendants can "bank" any processed free-text responses it reviews and redacts in excess of its monthly quota;
- Parties are **ORDERED** to work together in good faith in the production process;
- Concerns regarding production, redaction, or deadlines should be promptly presented to this Court by a joint filing after parties have attempted to resolve the issue;
- On the first of April, July, October, and January, the parties are **ORDERED** to submit a joint status report regarding rate and quality of production, or any other matter that arises.

DUE-BY DATE	TERM MINIMUM	CUMMULATIVE MINIMUM
February 15, 2024	390,000	390,000
March 15, 2024	390,000	780,000
*April 15, 2024	390,000	1,170,000
May 15, 2024	650,000	1,820,000
June 15, 2024	650,000	2,470,000
*July 15, 2024	650,000	3,120,000
August 15, 2024	780,000	3,900,000
September 15, 2024	780,000	4,680,000
*October 15, 2024	780,000	5,460,000
November 15, 2024	780,000	6,240,000
December 15, 2024	780,000	7,020,000
*January 15, 2025	780,000	7,800,000

SO ORDERED.

January 5, 2024.

MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE

EXHIBIT I

Vaccine 40 (2022) 5798–5805

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults

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ARTICLE INFO

Article history:
Received 31 May 2022
Received in revised form 21 July 2022
Accepted 1 August 2022
Available online 31 August 2022

Keywords:
SARS-CoV-2
COVID-19
Vaccines
COVID-19 vaccines
mRNA vaccines
Pfizer-BioNTech COVID-19 vaccine
BNT162b2
Moderna COVID-19 vaccine mRNA-1273
NCT04368728
NCT04470427
Serious adverse events
Adverse events of special interest
Brighton Collaboration
Coalition for Epidemic Preparedness Innovations
Safety Platform for Emergency vACcines

ABSTRACT

Introduction: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI −0.4 to 20.6 and −3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI –23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

1. Introduction

In March 2020, the Brighton Collaboration and the Coalition for Epidemic Preparedness Innovations partnership, Safety Platform for Emergency vACcines (SPEAC), created and subsequently updated a "priority list of potential adverse events of special interest relevant to COVID-19 vaccine trials." [1] The list comprises adverse events of special interest (AESIs) based on the specific vaccine platform, adverse events associated with prior vaccines in general, theoretical associations based on animal models, and COVID-19 specific immunopathogenesis. [1] The Brighton Collaboration is a global authority on the topic of vaccine safety and in May 2020, the World Health Organization's Global Advisory Committee on Vaccine Safety endorsed and recommended the reporting of AESIs based on this priority list. To our knowledge, however, the list has not been applied to serious adverse events in randomized trial data.

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https://doi.org/10.1016/j.vaccine.2022.08.036
0264-410X/

We sought to investigate the association between FDA-authorized mRNA COVID-19 vaccines and serious adverse events identified by the Brighton Collaboration, using data from the phase III randomized, placebo-controlled clinical trials on which authorization was based. We consider these trial data against findings from post-authorization observational safety data. Our study was not designed to evaluate the overall harm-benefit of vaccination programs so far. To put our safety results in context, we conducted a simple comparison of harms with benefits to illustrate the need for formal harm-benefit analyses of the vaccines that are stratified according to risk of serious COVID-19 outcomes. Our analysis is restricted to the randomized trial data, and does not consider data on post-authorization vaccination program impact. It does however show the need for public release of participant level trial datasets.

2. Methods

Pfizer and Moderna each submitted the results of one phase III randomized trial in support of the FDA's emergency use authorization of their vaccines in adults. Two reviewers (PD and RK) searched journal publications and trial data on the FDA's and Health Canada's websites to locate serious adverse event results tables for these trials. The Pfizer and Moderna trials are expected to follow participants for two years. Within weeks of the emergency authorization, however, the sponsors began a process of unblinding all participants who elected to be unblinded. In addition, those who received placebo were offered the vaccine. These self-selection processes may have introduced nonrandom differences between vaccinated and unvaccinated participants, thus rendering the post-authorization data less reliable. Therefore, to preserve randomization, we used the interim datasets that were the basis for emergency authorization in December 2020, approximately 4 months after trials commenced.

The definition of a serious adverse event (SAE) was provided in each trial's study protocol and included in the supplemental material of the trial's publication. [2–4] Pfizer and Moderna used nearly identical definitions, consistent with regulatory expectations. An SAE was defined as an adverse event that results in any of the following conditions: death; life-threatening at the time of the event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly/birth defect; medically important event, based on medical judgment.

In addition to journal publications, we searched the websites of the FDA (for advisory committee meeting materials) and Health Canada (for sections of the dossier submitted by sponsors to the regulator). [5] For the FDA website, we considered presentations by both the FDA and the sponsors. [6] Within each of these sources, we searched for SAE results tables that presented information by specific SAE type; we chose the most recent SAE table corresponding to the FDA's requirement for a safety median follow-up time of at least 2 months after dose 2.

For each trial, we prepared blinded SAE tables (containing SAE types without results data). Using these blinded SAE tables, two clinician reviewers (JF and JE) independently judged whether each SAE type was an AESI. SAE types that matched an AESI term verbatim, or were an alternative diagnostic name for an AESI term, were included as an AESI. For all other SAE types, the reviewers independently judged whether that SAE type was likely to have been caused by a vaccine-induced AESI, based on a judgment considering the disease course, causative mechanism, and likelihood of the AESI to cause the SAE type. Disagreements were resolved through consensus; if consensus could not be reached, a third clinician reviewer (PW) was used to create a majority opinion. For each included SAE, we recorded the corresponding Brighton Collaboration AESI category and organ system. When multiple AESIs could potentially cause the same SAE, the reviewers selected the AESI that they judged to be the most likely cause based on classical clinical presentation of the AESI.

We used an AESI list derived from the work of Brighton Collaboration's Safety Platform for Emergency vACcines (SPEAC) Project. This project created an AESI list which categorizes AESIs into three categories: those included because they are seen with COVID-19, those with a proven or theoretical association with vaccines in general, and those with proven or theoretical associations with specific vaccine platforms. The first version was produced in March 2020 based on experience from China. Following the second update (May 2020), the WHO Global Advisory Committee on Vaccine Safety (GACVS) adopted the list, and Brighton commenced a systematic review process "to ensure an ongoing understanding of the full spectrum of COVID-19 disease and modification of the AESI list accordingly." [7] This resulted in three additional AESIs being added to the list in December 2020. The subsequent (and most recent fourth) update did not result in any additional AESIs being added to the list. [1].

We matched SAEs recorded in the trial against an expanded list of AESIs created by combining Brighton's SPEAC COVID-19 AESI list with a list of 29 clinical diagnoses Brighton identified as "known to have been reported but not in sufficient numbers to merit inclusion on the AESI list." [7] Sensitivity analysis was used to determine whether use of the original versus expanded list altered our results.

Risk ratios and risk differences between vaccine and placebo groups were calculated for the incidence of AESIs and SAEs. We excluded SAEs that were known efficacy outcomes (i.e. COVID-19), consistent with the approach Pfizer (but not Moderna) used in recording SAE data. The Pfizer study trial protocol states that COVID-19 illnesses and their sequelae consistent with the clinical endpoint definition were not to be reported as adverse events, "even though the event may meet the definition of an SAE." [8] For unspecified reasons, Moderna included efficacy outcomes in their SAE tables, effectively reporting an all-cause SAE result. Because we did not have access to individual participant data, to account for the occasional multiple SAEs within single participants, we reduced the effective sample size by multiplying standard errors in the combined SAE analyses by the square root of the ratio of the number of SAEs to the number of patients with an SAE. This adjustment increased standard errors by 10 % (Pfizer) and 18 % (Moderna), thus expanding the interval estimates. We estimated combined risk ratios and risk differences for the two mRNA vaccines by averaging over the risks using logistic regression models which included indicators for trial and treatment group.

We used a simple harm-benefit framework to place our results in context, comparing risks of excess serious AESIs against reductions in COVID-19 hospitalization.

3. Results

Serious adverse event tables were located for each of the vaccine trials submitted for EUA in adults (age 16 + for Pfizer, 18 + for Moderna) in the United States: Pfizer-BioNTech COVID-19 vaccine BNT162b2 (NCT04368728) [2,9,10] and Moderna COVID-19 vaccine mRNA-1273 (NCT04470427). [3,11,12] (Table 1).

3.1. Reporting windows and serious adverse events

Moderna reported SAEs from dose 1 whereas Pfizer limited reporting from dose 1 to 1 month after dose 2. Both studies

Table 1
Data sources for phase III trials.

Trial	Data cutoff date	Journal articles	FDA sources	Health Canada sources
Pfizer trial in ages 16 and above (NCT04368728)	14 Nov 2020 (supported Dec 2020 EUA)	Aggregate data only	**Table 23 in sponsor briefing document**	**Table 55 in sponsor document C4591001 Final Analysis Interim Report Body**
Moderna trial in ages 18 and above (NCT04470427)	25 Nov 2020 (supported Dec 2020 EUA)	Table S11 in publication	Table 27 in sponsor briefing document	**Table 14.3.1.13.3 in sponsor document mRNA-1273-P301 Unblinded Safety Tables Batch 1 (DS2)**

Note: bolded font indicates dataset chosen for analysis; EUA = Emergency Use Authorization.

reported all data at the time of data cutoff (14 Nov 2020 for Pfizer, 25 Nov 2020 for Moderna). 17 SAEs that were efficacy endpoints were removed from the Moderna trial (16 "COVID-19" SAEs and 1 "COVID-19 pneumonia" SAE). One such efficacy endpoint meeting the definition of a SAE was removed from the Pfizer trial ("SARS-CoV-2 test positive" SAE).

The Pfizer trial exhibited a 36 % higher risk of serious adverse events in vaccinated participants in comparison to placebo recipients: 67.5 per 10,000 versus 49.5 per 10,000; risk difference 18.0 per 10,000 vaccinated participants (95 % compatibility[1] interval 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of SAEs in vaccinated individuals compared to those receiving placebo: 136 per 10,000 versus 129 per 10,000; risk difference 7.1 per 10,000 (95 % CI −23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of SAEs in mRNA vaccine recipients than placebo recipients: 98 per 10,000 versus 85 per 10,000; risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39). **(**Table 2**)**.

3.2. Serious adverse events of special interest

Regarding whether each SAE type was included on the SPEAC derived AESI list, agreement between the two independent clinician reviewers was 86 % (281/325); 40 of the 44 disagreements were resolved through consensus, and only four disagreements necessitated a third clinician reviewer. **Supplemental** Table 1 includes a full list of included and excluded SAEs across both trials.

In the Pfizer trial, 52 serious AESI (27.7 per 10,000) were reported in the vaccine group and 33 (17.6 per 10,000) in the placebo group. This difference corresponds to a 57 % higher risk of serious AESI (RR 1.57 95 % CI 0.98 to 2.54) and a risk difference of 10.1 serious AESI per 10,000 vaccinated participants (95 % CI −0.4 to 20.6). In the Moderna trial, 87 serious AESI (57.3 per 10,000) were reported in the vaccine group and 64 (42.2 per 10,000) in the placebo group. This difference corresponds to a 36 % higher risk of serious AESI (RR 1.36 95 % CI 0.93 to 1.99) and a risk difference of 15.1 serious AESI per 10,000 vaccinated participants (95 % CI −3.6 to 33.8). Combining the trials, there was a 43 % higher risk of serious AESI (RR 1.43; 95 % CI 1.07 to 1.92) and a risk difference of 12.5 serious AESI per 10,000 vaccinated participants (95 % CI 2.1 to 22.9). **(**Table 2**)**.

Of the 236 serious AESIs occurring across the Pfizer and Moderna trials, 97 % (230/236) were adverse event types included as AESIs because they are seen with COVID-19. In both Pfizer and Moderna trials, the largest excess risk occurred amongst the Brighton category of coagulation disorders. Cardiac disorders have been of central concern for mRNA vaccines; in the Pfizer trial more cardiovascular AESIs occurred in the vaccine group than in the placebo group, but in the Moderna trial the groups differed by only 1 case. **(**Tables 3 and 4**)**.

[1] A compatibility interval is identical to a confidence interval, but relabeled to emphasize that it is not a Bayesian posterior interval (as is improperly suggested by the "confidence" label).[13,14].

3.3. Sensitivity analysis

As a sensitivity analysis, we restricted the serious AESI analysis to those AESIs listed in SPEAC's COVID-19 AESI list (i.e. separating out Brighton's list of 29 clinical diagnoses "known to have been reported but not in sufficient numbers to merit inclusion on the AESI list.") This reduced the total number of AESIs across the two trials by 48 (35 vaccine group, 13 placebo group). There was still a higher risk of serious AESI when limited to the SPEAC COVID-19 AESI list, but the magnitude of the excess (in both relative and absolute terms) was smaller than when using the larger AESI list. **(Supplemental** Table 2**)**.

3.4. Harm-benefit considerations

In the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). [3] In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants).

4. Comparison with FDA reviews

In their review of SAEs supporting the authorization of the Pfizer and Moderna vaccines, the FDA concluded that SAEs were, for Pfizer, "balanced between treatment groups," [15] and for Moderna, were "without meaningful imbalances between study arms." [16] In contrast to the FDA analysis, we found an excess risk of SAEs in the Pfizer trial. Our analysis of Moderna was compatible with FDA's analysis, finding no meaningful SAE imbalance between groups.

The difference in findings for the Pfizer trial, between our SAE analysis and the FDA's, may in part be explained by the fact that the FDA analyzed the total number of participants experiencing any SAE, whereas our analysis was based on the total number of SAE events. Given that approximately twice as many individuals in the vaccine group than in the placebo group experienced multiple SAEs (there were 24 more events than participants in the vaccine group, compared to 13 in the placebo group), FDA's analysis of only the incidence of participants experiencing any SAE would not reflect the observed excess of multiple SAEs in the vaccine group.

A more important factor, however, may be that FDA's review of non-fatal SAEs used a different analysis population with different follow-up windows. The FDA reported 126 of 21,621 (0.6 %) of vaccinated participants experienced at least one SAE at data cutoff compared to 111 of 21,631 (0.5 %) of placebo participants. In contrast, our analysis found 127 SAEs among 18,801 vaccine recipients versus 93 SAEs among 18,785 placebo recipients. [15] While summary results for the population we analyzed was provided in a table, FDA did not report an analysis of them. The substantially larger denominators in FDA's analysis (5,666 more participants) reflect the fact that their analysis included all individuals receiving at least one dose (minus 196 HIV-positive participants), irrespec-

Table 2
Serious adverse events.

Trial	Total events (events per 10,000 participants)[a] Vaccine	Placebo	Risk difference per 10,000 participants (95 % CI)[e]	Risk ratio (95 % CI)[e]
Serious adverse events				
Pfizer[b]	127 (67.5)	93 (49.5)	18.0 (1.2 to 34.9)	1.36 (1.02 to 1.83)
Moderna[c,d]	206 (135.7)	195 (128.6)	7.1 (−23.2 to 37.4)	1.06 (0.84 to 1.33)
Combined[f]	333 (98.0)	288 (84.8)	13.2 (-3.2 to 29.6)	1.16 (0.97 to 1.39)
Serious adverse events of special interest				
Pfizer	52 (27.7)	33 (17.6)	10.1 (-0.4 to 20.6)	1.57 (0.98 to 2.54)
Moderna	87 (57.3)	64 (42.2)	15.1 (-3.6 to 33.8)	1.36 (0.93 to 1.99)
Combined[f]	139 (40.9)	97 (28.6)	12.5 (2.1 to 22.9)	1.43 (1.07 to 1.92)

[a] Denominators for Pfizer were 18,801 in the vaccine group and 18,785 in the placebo group, and for Moderna were 15,185 in the vaccine group and 15,166 in the placebo group.
[b] Pfizer excluded efficacy outcomes from its SAE table (COVID-19 illnesses and their sequelae meeting the definition of an SAE). However, at least one SAE appears to have been inadvertently included, which we removed from our calculations (“SARS-CoV-2 test positive”: 0 vaccine group; 1 placebo group).
[c] Moderna included efficacy outcomes in its SAE table (COVID-19 illnesses and their sequelae meeting the definition of an SAE). We removed efficacy SAEs outcomes that could be identified: “COVID-19” and “COVID-19 pneumonia.” Lacking access to participant level data, SAEs that were sequelae of serious COVID-19 could not be identified and therefore remain included in this analysis.
[d] “All SAEs” for Moderna was calculated using the “Number of serious AEs” row in Moderna’s submission to FDA.[11].
[e] Standard errors used to estimate 95% CIs were inflated by the factor $\sqrt{}$[#SAE]/[#patients with SAE] to account for multiple SAE within patients.
[f] The combined risk differences and risk ratios were computed from the fitted logistic regression models and so may not exactly equal comparisons computed from the first two columns.

Table 3
Serious AESIs, Pfizer trial.

Brighton category	Vaccine	Placebo	Vaccine events per 10,000	Placebo events per 10,000	Difference in events per 10,000	Risk ratio
Association with immunization in general						
Anaphylaxis	1	1	0.5	0.5	0.0	1.00
Association with specific vaccine platform(s)						
Encephalitis/encephalomyelitis	0	2	0.0	1.1	−1.1	0.00
Seen with COVID-19						
Acute kidney injury	2	0	1.1	0.0	1.1	N/A
Acute liver injury	0	1	0.0	0.5	−0.5	0.00
Acute respiratory distress syndrome	2	1	1.1	0.5	0.5	2.00
Coagulation disorder	16	10	8.5	5.3	3.2	1.60
Myocarditis/pericarditis	2	1	1.1	0.5	0.5	2.00
Other forms of acute cardiac injury	16	12	8.5	6.4	2.1	1.33
Subtotal	39	28	20.7	14.9	5.8	1.39
Brighton list of 29 clinical diagnoses seen with COVID-19						
Abscess	4	1	2.1	0.5	1.6	4.00
Cholecystitis	4	2	2.1	1.1	1.1	2.00
Colitis/Enteritis	1	1	0.5	0.5	0.0	1.00
Diarrhea	1	0	0.5	0.0	0.5	N/A
Hyperglycemia	1	1	0.5	0.5	0.0	1.00
Pancreatitis	1	0	0.5	0.0	0.5	N/A
Psychosis	1	0	0.5	0.0	0.5	N/A
Subtotal	13	5	6.9	2.7	4.3	2.60
Total	**52**	**33**	**27.7**	**17.6**	**10.1**	**1.57**

tive of the duration of post-injection follow-up time. In contrast, our analysis was based on the study population with median follow-up $\geq$ 2 months after dose 2 (minus 120 HIV-positive participants), of which 98.1 % had received both doses. [2,17] The FDA’s analysis of SAEs thus included thousands of additional participants with very little follow-up, of which the large majority had only received 1 dose.

4.1. Comparison with post-authorization studies

Although the randomized trials offer high level evidence for evaluating causal effects, the sparsity of their data necessitates that harm-benefit analyses also consider observational studies. Since their emergency authorization in December 2020, hundreds of millions of doses of Pfizer and Moderna COVID-19 vaccines have been administered and post-authorization observational data offer a complementary opportunity to study AESIs. Post-authorization observational safety studies include cohort studies (which make use of medical claims or electronic health records) and disproportionality analyses (which use spontaneous adverse event reporting systems). In July 2021, the FDA reported detecting four potential adverse events of interest: pulmonary embolism, acute myocardial infarction, immune thrombocytopenia, and disseminated intravascular coagulation following Pfizer’s vaccine based on medical claims data in older Americans. [18] Three of these four serious adverse event types would be categorized as coagulation disorders, which is the Brighton AESI category that exhibited the largest excess risk in the vaccine group in both the Pfizer and Moderna trials. FDA stated it would further investigate the findings but at the time of our writing has not issued an update. Similarly, spontaneous-reporting systems have registered serious adverse reactions including anaphylaxis (all COVID-19 vaccines), thrombocytopenia syndrome among premenopausal females (Janssen vaccine), and myocarditis and pericarditis among younger males (Pfizer and Moderna vaccines). [19,20].

Using data from three postmarketing safety databases for vaccines (VAERS, EudraVigilance, and VigiBase), disproportionality studies have reported excess risks for many of the same SAE types as in

Table 4
Serious AESIs, Moderna trial.

Brighton category	Vaccine	Placebo	Vaccine events per 10,000	Placebo events per 10,000	Difference in events per 10,000	Risk ratio
Association with specific vaccine platform(s)						
Bell's Palsy	1	0	0.7	0.0	0.7	N/A
Encephalitis/encephalomyelitis	1	0	0.7	0.0	0.7	N/A
Seen with COVID-19						
Acute kidney injury	1	3	0.7	2.0	−1.3	0.33
Acute liver injury	1	0	0.7	0.0	0.7	N/A
Acute respiratory distress syndrome	7	4	4.6	2.6	2.0	1.75
Angioedema	0	2	0.0	1.3	−1.3	0.00
Coagulation disorder	20	13	13.2	8.6	4.6	1.54
Generalized Convulsions	2	0	1.3	0.0	1.3	N/A
Myelitis	0	1	0.0	0.7	−0.7	0.00
Myocarditis/pericarditis	4	5	2.6	3.3	−0.7	0.80
Other forms of acute cardiac injury	26	26	17.1	17.1	0.0	1.00
Other rash	1	1	0.7	0.7	0.0	1.00
Rhabdomyolysis	0	1	0.0	0.7	−0.7	0.00
Single Organ Cutaneous Vasculitis	1	0	0.7	0.0	0.7	N/A
Subtotal	65	56	42.8	36.9	5.9	1.16
Brighton list of 29 clinical diagnoses seen with COVID-19						
Abscess	1	0	0.7	0.0	0.7	N/A
Arthritis	3	1	2.0	0.7	1.3	3.00
Cholecystitis	4	0	2.6	0.0	2.6	N/A
Colitis/Enteritis	6	3	4.0	2.0	2.0	2.00
Diarrhea	2	1	1.3	0.7	0.7	2.00
Hyperglycemia	1	0	0.7	0.0	0.7	N/A
Hyponatremia	1	1	0.7	0.7	0.0	1.00
Pancreatitis	2	0	1.3	0.0	1.3	N/A
Pneumothorax	0	1	0.0	0.7	−0.7	0.00
Psychosis	1	1	0.7	0.7	0.0	1.00
Thyroiditis	1	0	0.7	0.0	0.7	N/A
Subtotal	22	8	14.5	5.3	9.2	2.75
Total	**87**	**64**	**57.3**	**42.2**	**15.1**	**1.36**

the present study. [21–23] For example, a study using VAERS and EudraVigilance comparing the disproportionality of adverse event reports between the influenza vaccine versus the mRNA COVID-19 vaccines reported excess risks for the following Brighton AESIs: cardiovascular events, coagulation events, hemorrhages, gastrointestinal events, and thromboses. [22] While CDC published a protocol[24] in early 2021 for using proportional reporting ratios for signal detection in the VAERS database, results from the study have not yet been reported. [25] Among self-controlled case series, one reported a rate ratio of 1.38 (95 % CI 1.12–1.71) for hemorrhagic stroke following Pfizer vaccine, [26] another reported 0.97 (95 % CI 0.81–1.15), [27] while a cohort study[28] reported 0.84 (95 % CI 0.54–1.27).

5. Discussion

Using a prespecified list of AESI identified by the Brighton Collaboration, higher risk of serious AESI was observed in the mRNA COVID-19 vaccine group relative to placebo in both the Pfizer and Moderna adult phase III trials, with 10.1 (Pfizer) and 15.1 (Moderna) additional events for every 10,000 individuals vaccinated. Combined, there was a risk difference of 12.5 serious AESIs per 10,000 individuals vaccinated (95 % CI 2.1 to 22.9). These results raise concerns that mRNA vaccines are associated with more harm than initially estimated at the time of emergency authorization. In addition, our analysis identified a 36 % higher risk of serious adverse events in vaccinated participants in the Pfizer trial: 18.0 additional SAEs per 10,000 vaccinated (95 % CI 1.2 to 34.9). Consistent with the FDA evaluation, our analysis found no clear difference in SAEs between groups in the Moderna trial.

Results between the Pfizer and Moderna trials were similar for the AESI analysis but exhibited substantial variation in the SAE analysis. Caution is needed in interpreting this variation as it may be substantially explained by differences in SAE recording practices in the trials rather than differences in actual vaccine harm profiles. For reasons that are not documented in the trial protocol, Moderna included efficacy outcomes in its SAE tabulations, while Pfizer excluded them. As a result, Moderna's SAE table did not present a traditional SAE analysis but rather an all-cause SAE analysis. The FDA analysis of the Moderna trial presented an all-cause SAE analysis, which estimates total vaccine effects on SAEs, including effects transmitted via effects on COVID-19. It did not however present a traditional SAE analysis with efficacy endpoints removed, which attempts to estimate only the direct effects on SAEs. While our analysis attempted to perform a traditional SAE analysis by excluding efficacy SAEs (serious COVID-19 and its sequelae), our effort was hindered because we did not have access to patient level data. Easily recognizable efficacy SAEs ("COVID-19", "COVID-19 pneumonia," and "SARS-CoV-2 test positive") could be removed, but many participants who experienced a COVID-19 SAE likely experienced multiple other SAEs (e.g. pneumonia, hypoxia, and thrombotic events) which could not be identified and therefore remain included in our analysis. Of 17 total efficacy SAEs (16 "COVID-19" and 1 "COVID-19 pneumonia") removed from our analysis of the Moderna trial, 16 were in the placebo arm. As a consequence, the background SAE risk (risk in absence of COVID-19) would be overestimated by the Moderna placebo group, resulting in underestimation of the actual risk of SAEs and AESIs attributable to the vaccine in the Moderna comparisons as well as in the combined analysis. Access to patient-level data would allow adjustments for this problem.

Rational policy formation should consider potential harms alongside potential benefits. [29] To illustrate this need in the present context, we conducted a simple harm-benefit comparison using the trial data comparing excess risk of serious AESI against reductions in COVID-19 hospitalization. We found excess risk of serious AESIs to exceed the reduction in COVID-19 hospitalizations in both Pfizer and Moderna trials.

This analysis has the limitations inherent in most harm-benefit comparisons. First, benefits and harms are rarely exact equivalents, and there can be great variability in the degree of severity within both benefit and harm endpoints. For example, intubation and short hospital stay are not equivalent but both are counted in "hospitalization"; similarly, serious diarrhea and serious stroke are not equivalent but both are counted in "SAE." Second, individuals value different endpoints differently. Third, without individual participant data, we could only compare the number of individuals hospitalized for COVID-19 against the number of serious AESI events, not the number of participants experiencing any serious AESI. Some individuals experienced multiple SAEs whereas hospitalized COVID-19 participants were likely only hospitalized once, biasing the analysis towards exhibiting net harm. To gauge the extent of this bias, we considered that there were 20 % (Pfizer) and 34 % (Moderna) more SAEs than participants experiencing any SAE. As a rough sensitivity calculation, if we divide the Pfizer excess serious AESI risk of 10.1 by 1.20 it becomes 8.4 compared to a COVID-19 hospitalization risk reduction of 2.3; if we divide the Moderna excess serious AESI risk of 15.1 by 1.34 it becomes 11.3 compared to a COVID-19 hospitalization risk reduction of 6.4.

Harm-benefit ratios will be different for populations at different risk for serious COVID-19 and observation periods that differ from those studied in the trials. Presumably, larger reductions in COVID-19 hospitalizations would have been recorded if trial follow-up were longer, more SARS-CoV-2 was circulating, or if participants had been at higher risk of serious COVID-19 outcomes, shifting harm-benefit ratios toward benefit. Conversely, harm-benefit ratios would presumably shift towards harm for those with lower risk of serious COVID-19 outcomes--such as those with natural immunity, younger age or no comorbidities. Similarly, waning vaccine effectiveness, decreased viral virulence, and increasing degree of immune escape from vaccines might further shift the harm-benefit ratio toward harm. Large, randomized trials in contemporary populations could robustly answer these questions. Absent definitive trials, however, synthesis of multiple lines of evidence will be essential. [30,48,49].

Adverse events detected in the post-marketing period have led to the withdrawal of several vaccines. An example is intussusception following one brand of rotavirus vaccine: around 1 million children were vaccinated before identification of intussusception, which occurred in around 1 per 10,000 vaccinees. [31] Despite the unprecedented scale of COVID-19 vaccine administration, the AESI types identified in our study may still be challenging to detect with observational methods. Most observational analyses are based on comparing the risks of adverse events "observed" against a background (or "expected") risk, which inevitably display great variation, by database, age group, and sex. [32] If the actual risk ratio for the effect was 1.4 (the risk ratio of the combined AESI analysis), it could be quite difficult to unambiguously replicate it with observational data given concerns about systematic as well as random errors. [33–35].

In addition, disproportionality analyses following COVID-19 vaccination also have limitations, particularly with respect to the type of adverse events seen in our study. The majority of SAEs that contributed to our results are relatively common events, such as ischemic stroke, acute coronary syndrome, and brain hemorrhage. This complicates signal detection because clinical suspicion of an adverse vaccine reaction following an event commonly seen in clinical practice will be lower than for SAEs like myocarditis.[50] For this reason, clinical suspicion leading to the filing of an individual case safety report--may be far less common in the post-authorization setting than in the trials. At the same time, heightened awareness about COVID-19 vaccine SAEs can result in under and overreporting. Public health messages assuring vaccine safety may lower clinical suspicion of potential causal relationships, whereas messages about potential harms can conversely stimulate reports that otherwise may not have been made. These factors can lead to bias both directions, further complicating interpretation. In contrast to these problems, in the randomized trials used in this analysis, all SAEs were to be recorded, irrespective of clinical judgment regarding potential causality.

Although our analysis is secondary, reanalyses of clinical trial data have led to the detection of adverse events well after the market entry of major drugs such as rofecoxib and rosiglitazone. [36,37] Our analysis has an advantage over postmarketing observational studies in that the data are from blinded, placebo-controlled randomized trials vetted by the FDA, which were matched against a list of adverse events created before the availability of the clinical-trial results and designed for use in COVID-19 vaccine trials.

Our study has several important limitations. First, Pfizer's trial did not report SAEs occurring past 1 month after dose 2. This reporting threshold may have led to an undercounting of serious AESIs in the Pfizer trial. Second, for both studies, the limited follow up time prevented an analysis of harm-benefit over a longer period. Third, all SAEs in our analysis met the regulatory definition of a serious adverse event, but many adverse event types which a patient may themselves judge as serious may not meet this regulatory threshold. Fourth, decisions about which SAEs to include or exclude as AESIs requires subjective, clinical judgements in the absence of detailed clinical information about the actual SAEs. We encourage third party replication of our study, with access to complete SAE case narratives, to determine the degree to which these decisions affected our findings. For additional sensitivity analyses, such replication studies could also make use of other AESI lists, such as those prepared by FDA, [38–41] CDC, [24], Pfizer, [42], or a *de novo* AESI list derived from a list of COVID-19 complications understood to be induced via SARS-CoV-2's spike protein. [43,44].

A fifth important limitation is our lack of access to individual participant data, which forced us to use a conservative adjustment to the standard errors. The 95 % CIs[13,14] calculated are therefore only approximate because we do not know which patients had multiple events. Finally, as described above, in the Moderna analysis, the SAEs that were sequelae of serious COVID-19 could not be identified and therefore remain included in our calculations. Because the vaccines prevent SAEs from COVID-19 while adding SAE risks of their own, this inclusion makes it impossible to separately estimate SAEs due to the vaccine from SAEs due to COVID-19 in the available Moderna data, as must be done to extrapolate harm-benefit to other populations. These study limitations all stem from the fact that the raw data from COVID-19 vaccine clinical trials are not publicly available. [45,46].

We emphasize that our investigation is preliminary, to point to the need for more involved analysis. The risks of serious AESIs in the trials represent only group averages. SAEs are unlikely to be distributed equally across the demographic subgroups enrolled in the trial, and the risks may be substantially less in some groups compared to others. Thus, knowing the actual demographics of those who experienced an increase in serious AESI in the vaccine group is necessary for a proper harm-benefit analysis. In addition, clinical studies are needed to see if particular SAEs can be linked to particular vaccine ingredients as opposed to unavoidable consequences of exposure to spike protein, as future vaccines could then be modified accordingly or sensitivities can be tested for in advance. In parallel, a systematic review and meta-analysis using individual participant data should be undertaken to address questions of harm-benefit in various demographic subgroups, particularly in those at low risk of serious complications from COVID-19. Finally, there is a pressing need for comparison of SAEs and harm-benefit for different vaccine types; some initial work has already begun in this direction. [47].

Full transparency of the COVID-19 vaccine clinical trial data is needed to properly evaluate these questions. Unfortunately, as we approach 2 years after release of COVID-19 vaccines, participant level data remain inaccessible. [45,46].

Author contributions

All authors had full access to all of the data in the study (available at https://doi.org/10.5281/zenodo.6564402), and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.
Acquisition of data: Doshi.
Analysis and interpretation: All authors.
Statistical analysis: Jones, Greenland.
Drafting of the manuscript: Fraiman, Doshi.
Critical revision of the manuscript for important intellectual content: All authors.

Data availability

All of the data in the study is available at https://doi.org/10.5281/zenodo.6564402

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We thank Jean Rees for help identifying sources of data.

Funding

This study had no funding support.

Ethical review statement

This research was confirmed to be Not Human Subjects Research (NHSR) by University of Maryland, Baltimore (HP-00102561).

Conflicts of interest

JF, JE, MJ, SG, PW, RK: none to declare. PD has received travel funds from the European Respiratory Society (2012) and Uppsala Monitoring Center (2018); grants from the FDA (through University of Maryland M-CERSI; 2020), Laura and John Arnold Foundation (2017-22), American Association of Colleges of Pharmacy (2015), Patient-Centered Outcomes Research Institute (2014-16), Cochrane Methods Innovations Fund (2016-18), and UK National Institute for Health Research (2011-14); was an unpaid IMEDS steering committee member at the Reagan-Udall Foundation for the FDA (2016-2020) and is an editor at The BMJ. The views expressed here are those of the authors and do not necessarily reflect those of their employers.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2022.08.036.

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EXHIBIT J

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 31, 2020 VOL. 383 NO. 27

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

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ABSTRACT

BACKGROUND

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have afflicted tens of millions of people in a worldwide pandemic. Safe and effective vaccines are needed urgently.

METHODS

In an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial, we randomly assigned persons 16 years of age or older in a 1:1 ratio to receive two doses, 21 days apart, of either placebo or the BNT162b2 vaccine candidate (30 μg per dose). BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The primary end points were efficacy of the vaccine against laboratory-confirmed Covid-19 and safety.

RESULTS

A total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo. There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo; BNT162b2 was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6). Similar vaccine efficacy (generally 90 to 100%) was observed across subgroups defined by age, sex, race, ethnicity, baseline body-mass index, and the presence of coexisting conditions. Among 10 cases of severe Covid-19 with onset after the first dose, 9 occurred in placebo recipients and 1 in a BNT162b2 recipient. The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups.

CONCLUSIONS

A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years of age or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

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*A complete list of investigators in the C4591001 Clinical Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

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This article was published on December 10, 2020, and updated on December 16, 2020, at NEJM.org.

N Engl J Med 2020;383:2603-15.
DOI: 10.1056/NEJMoa2034577

A Quick Take is available at NEJM.org

Coronavirus disease 2019 (COVID-19) has affected tens of millions of people globally[1] since it was declared a pandemic by the World Health Organization on March 11, 2020.[2] Older adults, persons with certain coexisting conditions, and front-line workers are at highest risk for Covid-19 and its complications. Recent data show increasing rates of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 in other populations, including younger adults.[3] Safe and effective prophylactic vaccines are urgently needed to contain the pandemic, which has had devastating medical, economic, and social consequences.

We previously reported phase 1 safety and immunogenicity results from clinical trials of the vaccine candidate BNT162b2,[4] a lipid nanoparticle–formulated,[5] nucleoside-modified RNA (modRNA)[6] encoding the SARS-CoV-2 full-length spike, modified by two proline mutations to lock it in the prefusion conformation.[7] Findings from studies conducted in the United States and Germany among healthy men and women showed that two 30-μg doses of BNT162b2 elicited high SARS-CoV-2 neutralizing antibody titers and robust antigen-specific CD8+ and Th1-type CD4+ T-cell responses.[8] The 50% neutralizing geometric mean titers elicited by 30 μg of BNT162b2 in older and younger adults exceeded the geometric mean titer measured in a human convalescent serum panel, despite a lower neutralizing response in older adults than in younger adults. In addition, the reactogenicity profile of BNT162b2 represented mainly short-term local (i.e., injection site) and systemic responses. These findings supported progression of the BNT162b2 vaccine candidate into phase 3.

Here, we report safety and efficacy findings from the phase 2/3 part of a global phase 1/2/3 trial evaluating the safety, immunogenicity, and efficacy of 30 μg of BNT162b2 in preventing Covid-19 in persons 16 years of age or older. This data set and these trial results are the basis for an application for emergency use authorization.[9] Collection of phase 2/3 data on vaccine immunogenicity and the durability of the immune response to immunization is ongoing, and those data are not reported here.

METHODS

TRIAL OBJECTIVES, PARTICIPANTS AND OVERSIGHT

We assessed the safety and efficacy of two 30-μg doses of BNT162b2, administered intramuscularly 21 days apart, as compared with placebo. Adults 16 years of age or older who were healthy or had stable chronic medical conditions, including but not limited to human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C virus infection, were eligible for participation in the trial. Key exclusion criteria included a medical history of Covid-19, treatment with immunosuppressive therapy, or diagnosis with an immunocompromising condition.

Pfizer was responsible for the design and conduct of the trial, data collection, data analysis, data interpretation, and the writing of the manuscript. BioNTech was the sponsor of the trial, manufactured the BNT162b2 clinical trial material, and contributed to the interpretation of the data and the writing of the manuscript. All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol, which is available with the full text of this article at NEJM.org. An independent data and safety monitoring board reviewed efficacy and unblinded safety data.

TRIAL PROCEDURES

With the use of an interactive Web-based system, participants in the trial were randomly assigned in a 1:1 ratio to receive 30 μg of BNT162b2 (0.3 ml volume per dose) or saline placebo. Participants received two injections, 21 days apart, of either BNT162b2 or placebo, delivered in the deltoid muscle. Site staff who were responsible for safety evaluation and were unaware of group assignments observed participants for 30 minutes after vaccination for any acute reactions.

SAFETY

The primary end points of this trial were solicited, specific local or systemic adverse events and use of antipyretic or pain medication within 7 days after the receipt of each dose of vaccine or placebo, as prompted by and recorded in an electronic diary in a subset of participants (the reactogenicity subset), and unsolicited adverse events (those reported by the participants without prompts from the electronic diary) through 1 month after the second dose and unsolicited serious adverse events through 6 months after the second dose. Adverse event data through approximately 14 weeks after the second dose are included in this report. In this report, safety

data are reported for all participants who provided informed consent and received at least one dose of vaccine or placebo. Per protocol, safety results for participants infected with HIV (196 patients) will be analyzed separately and are not included here.

During the phase 2/3 portion of the study, a stopping rule for the theoretical concern of vaccine-enhanced disease was to be triggered if the one-sided probability of observing the same or a more unfavorable adverse severe case split (a split with a greater proportion of severe cases in vaccine recipients) was 5% or less, given the same true incidence for vaccine and placebo recipients. Alert criteria were to be triggered if this probability was less than 11%.

EFFICACY

The first primary end point was the efficacy of BNT162b2 against confirmed Covid-19 with onset at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose; the second primary end point was efficacy in participants with and participants without evidence of prior infection. Confirmed Covid-19 was defined according to the Food and Drug Administration (FDA) criteria as the presence of at least one of the following symptoms: fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting, combined with a respiratory specimen obtained during the symptomatic period or within 4 days before or after it that was positive for SARS-CoV-2 by nucleic acid amplification–based testing, either at the central laboratory or at a local testing facility (using a protocol-defined acceptable test).

Major secondary end points included the efficacy of BNT162b2 against severe Covid-19. Severe Covid-19 is defined by the FDA as confirmed Covid-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death. Details are provided in the protocol.

An explanation of the various denominator values for use in assessing the results of the trial is provided in Table S1 in the Supplementary Appendix, available at NEJM.org. In brief, the safety population includes persons 16 years of age or older; a total of 43,448 participants constituted the population of enrolled persons injected with the vaccine or placebo. The main safety subset as defined by the FDA, with a median of 2 months of follow-up as of October 9, 2020, consisted of 37,706 persons, and the reactogenicity subset consisted of 8183 persons. The modified intention-to-treat (mITT) efficacy population includes all age groups 12 years of age or older (43,355 persons; 100 participants who were 12 to 15 years of age contributed to person-time years but included no cases). The number of persons who could be evaluated for efficacy 7 days after the second dose and who had no evidence of prior infection was 36,523, and the number of persons who could be evaluated 7 days after the second dose with or without evidence of prior infection was 40,137.

STATISTICAL ANALYSIS

The safety analyses included all participants who received at least one dose of BNT162b2 or placebo. The findings are descriptive in nature and not based on formal statistical hypothesis testing. Safety analyses are presented as counts, percentages, and associated Clopper–Pearson 95% confidence intervals for local reactions, systemic events, and any adverse events after vaccination, according to terms in the *Medical Dictionary for Regulatory Activities* (MedDRA), version 23.1, for each vaccine group.

Analysis of the first primary efficacy end point included participants who received the vaccine or placebo as randomly assigned, had no evidence of infection within 7 days after the second dose, and had no major protocol deviations (the population that could be evaluated). Vaccine efficacy was estimated by $100 \times (1 - \mathrm{IRR})$, where IRR is the calculated ratio of confirmed cases of Covid-19 illness per 1000 person-years of follow-up in the active vaccine group to the corresponding illness rate in the placebo group. The 95.0% credible interval for vaccine efficacy and the probability of vaccine efficacy greater than 30% were calculated with the use of a Bayesian beta-binomial model. The final analysis uses a success boundary of 98.6% for probability of vaccine efficacy greater than 30% to compensate for the interim analysis and to control the overall type 1 error rate at 2.5%. Moreover, primary and secondary efficacy end points are evaluated sequentially to control the

familywise type 1 error rate at 2.5%. Descriptive analyses (estimates of vaccine efficacy and 95% confidence intervals) are provided for key subgroups.

RESULTS

PARTICIPANTS

Between July 27, 2020, and November 14, 2020, a total of 44,820 persons were screened, and 43,548 persons 16 years of age or older underwent randomization at 152 sites worldwide (United States, 130 sites; Argentina, 1; Brazil, 2; South Africa, 4; Germany, 6; and Turkey, 9) in the phase 2/3 portion of the trial. A total of 43,448 participants received injections: 21,720 received BNT162b2 and 21,728 received placebo (Fig. 1). At the data cut-off date of October 9, a total of 37,706 participants had a median of at least 2 months of safety data available after the second dose and contributed to the main safety data set. Among these 37,706 participants, 49% were female, 83% were White, 9% were Black or African American, 28% were Hispanic or Latinx, 35% were obese (body mass index [the weight in kilograms divided by the square of the height in meters] of at least 30.0), and 21% had at least one coexisting condition. The median age was 52 years, and 42% of participants were older than 55 years of age (Table 1 and Table S2).

SAFETY

Local Reactogenicity

The reactogenicity subset included 8183 participants. Overall, BNT162b2 recipients reported more local reactions than placebo recipients. Among BNT162b2 recipients, mild-to-moderate pain at the injection site within 7 days after an injection was the most commonly reported local reaction, with less than 1% of participants across all age groups reporting severe pain (Fig. 2). Pain was reported less frequently among participants older than 55 years of age (71% reported pain after the first dose; 66% after the second dose) than among younger participants (83% after the first dose; 78% after the second dose). A noticeably lower percentage of participants reported injection-site redness or swelling. The proportion of participants reporting local reactions did not increase after the second dose (Fig. 2A), and no participant reported a grade 4 local reaction. In general, local reactions were mostly mild-to-moderate in severity and resolved within 1 to 2 days.

Figure 1 (facing page). Enrollment and Randomization.
The diagram represents all enrolled participants through November 14, 2020. The safety subset (those with a median of 2 months of follow-up, in accordance with application requirements for Emergency Use Authorization) is based on an October 9, 2020, data cut-off date. The further procedures that one participant in the placebo group declined after dose 2 (lower right corner of the diagram) were those involving collection of blood and nasal swab samples.

Systemic Reactogenicity

Systemic events were reported more often by younger vaccine recipients (16 to 55 years of age) than by older vaccine recipients (more than 55 years of age) in the reactogenicity subset and more often after dose 2 than dose 1 (Fig. 2B). The most commonly reported systemic events were fatigue and headache (59% and 52%, respectively, after the second dose, among younger vaccine recipients; 51% and 39% among older recipients), although fatigue and headache were also reported by many placebo recipients (23% and 24%, respectively, after the second dose, among younger vaccine recipients; 17% and 14% among older recipients). The frequency of any severe systemic event after the first dose was 0.9% or less. Severe systemic events were reported in less than 2% of vaccine recipients after either dose, except for fatigue (in 3.8%) and headache (in 2.0%) after the second dose.

Fever (temperature, ≥38°C) was reported after the second dose by 16% of younger vaccine recipients and by 11% of older recipients. Only 0.2% of vaccine recipients and 0.1% of placebo recipients reported fever (temperature, 38.9 to 40°C) after the first dose, as compared with 0.8% and 0.1%, respectively, after the second dose. Two participants each in the vaccine and placebo groups reported temperatures above 40.0°C. Younger vaccine recipients were more likely to use antipyretic or pain medication (28% after dose 1; 45% after dose 2) than older vaccine recipients (20% after dose 1; 38% after dose 2), and placebo recipients were less likely (10 to 14%) than vaccine recipients to use the medications,

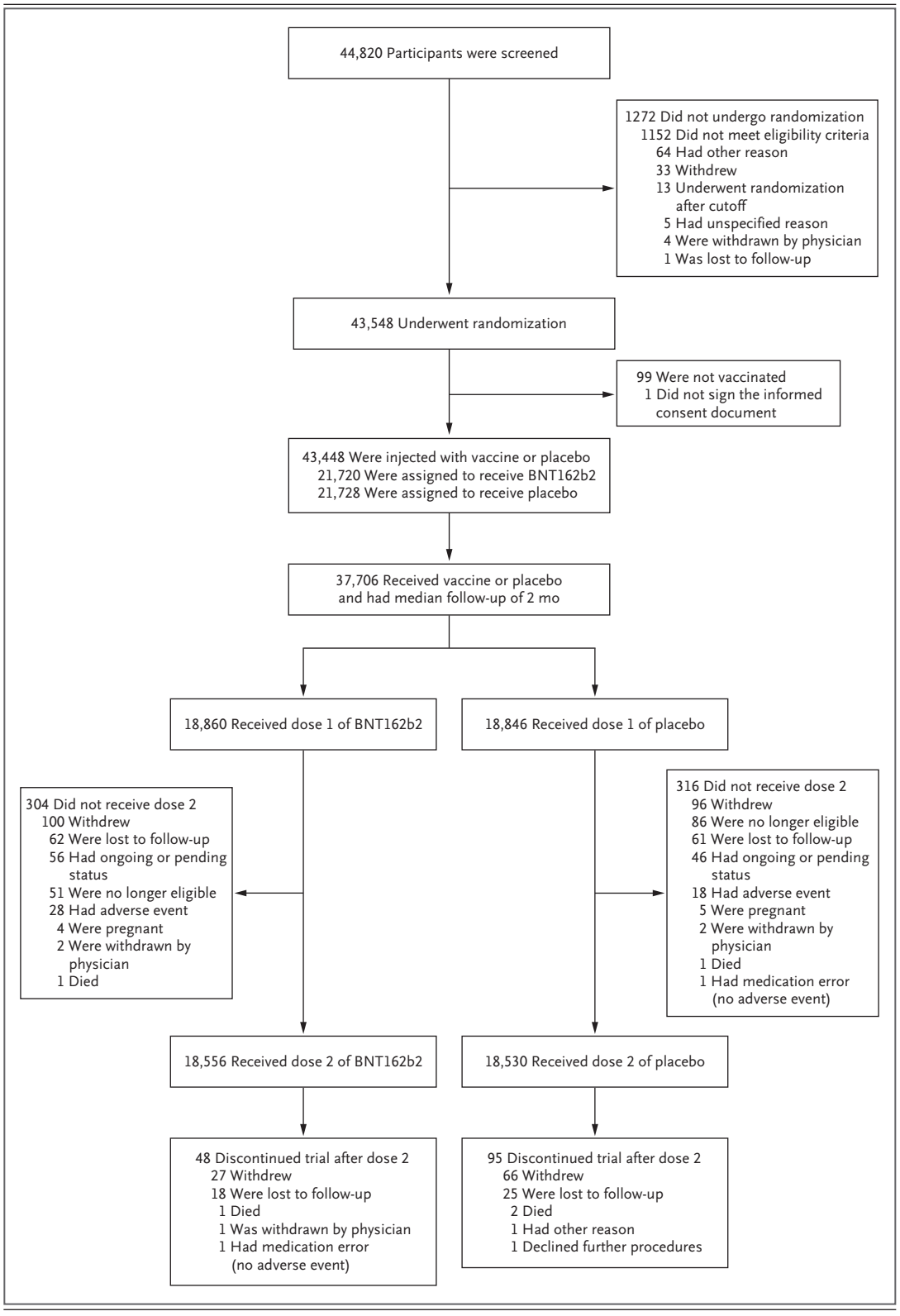


Table 1. Demographic Characteristics of the Participants in the Main Safety Population.*

Characteristic	BNT162b2 (N=18,860)	Placebo (N=18,846)	Total (N=37,706)
Sex — no. (%)			
Male	9,639 (51.1)	9,436 (50.1)	19,075 (50.6)
Female	9,221 (48.9)	9,410 (49.9)	18,631 (49.4)
Race or ethnic group — no. (%)†			
White	15,636 (82.9)	15,630 (82.9)	31,266 (82.9)
Black or African American	1,729 (9.2)	1,763 (9.4)	3,492 (9.3)
Asian	801 (4.2)	807 (4.3)	1,608 (4.3)
Native American or Alaska Native	102 (0.5)	99 (0.5)	201 (0.5)
Native Hawaiian or other Pacific Islander	50 (0.3)	26 (0.1)	76 (0.2)
Multiracial	449 (2.4)	406 (2.2)	855 (2.3)
Not reported	93 (0.5)	115 (0.6)	208 (0.6)
Hispanic or Latinx	5,266 (27.9)	5,277 (28.0)	10,543 (28.0)
Country — no. (%)			
Argentina	2,883 (15.3)	2,881 (15.3)	5,764 (15.3)
Brazil	1,145 (6.1)	1,139 (6.0)	2,284 (6.1)
South Africa	372 (2.0)	372 (2.0)	744 (2.0)
United States	14,460 (76.7)	14,454 (76.7)	28,914 (76.7)
Age group — no. (%)			
16–55 yr	10,889 (57.7)	10,896 (57.8)	21,785 (57.8)
>55 yr	7,971 (42.3)	7,950 (42.2)	15,921 (42.2)
Age at vaccination — yr			
Median	52.0	52.0	52.0
Range	16–89	16–91	16–91
Body-mass index‡			
≥30.0: obese	6,556 (34.8)	6,662 (35.3)	13,218 (35.1)

* Percentages may not total 100 because of rounding.
† Race or ethnic group was reported by the participants.
‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.

regardless of age or dose. Systemic events including fever and chills were observed within the first 1 to 2 days after vaccination and resolved shortly thereafter.

Daily use of the electronic diary ranged from 90 to 93% for each day after the first dose and from 75 to 83% for each day after the second dose. No difference was noted between the BNT162b2 group and the placebo group.

ADVERSE EVENTS

Adverse event analyses are provided for all enrolled 43,252 participants, with variable follow-up time after dose 1 (Table S3). More BNT162b2 recipients than placebo recipients reported any adverse event (27% and 12%, respectively) or a related adverse event (21% and 5%). This distribution largely reflects the inclusion of transient reactogenicity events, which were reported as adverse events more commonly by vaccine recipients than by placebo recipients. Sixty-four vaccine recipients (0.3%) and 6 placebo recipients (<0.1%) reported lymphadenopathy. Few participants in either group had severe adverse events, serious adverse events, or adverse events leading to withdrawal from the trial. Four related serious adverse events were reported among BNT162b2 recipients (shoulder injury related to vaccine administration, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, and right leg

paresthesia). Two BNT162b2 recipients died (one from arteriosclerosis, one from cardiac arrest), as did four placebo recipients (two from unknown causes, one from hemorrhagic stroke, and one from myocardial infarction). No deaths were considered by the investigators to be related to the vaccine or placebo. No Covid-19–associated deaths were observed. No stopping rules were met during the reporting period. Safety monitoring will continue for 2 years after administration of the second dose of vaccine.

EFFICACY

Among 36,523 participants who had no evidence of existing or prior SARS-CoV-2 infection, 8 cases of Covid-19 with onset at least 7 days after the second dose were observed among vaccine recipients and 162 among placebo recipients. This case split corresponds to 95.0% vaccine efficacy (95% confidence interval [CI], 90.3 to 97.6; Table 2). Among participants with and those without evidence of prior SARS CoV-2 infection, 9 cases of Covid-19 at least 7 days after the second dose were observed among vaccine recipients and 169 among placebo recipients, corresponding to 94.6% vaccine efficacy (95% CI, 89.9 to 97.3). Supplemental analyses indicated that vaccine efficacy among subgroups defined by age, sex, race, ethnicity, obesity, and presence of a coexisting condition was generally consistent with that observed in the overall population (Table 3 and Table S4). Vaccine efficacy among participants with hypertension was analyzed separately but was consistent with the other subgroup analyses (vaccine efficacy, 94.6%; 95% CI, 68.7 to 99.9; case split: BNT162b2, 2 cases; placebo, 44 cases). Figure 3 shows cases of Covid-19 or severe Covid-19 with onset at any time after the first dose (mITT population) (additional data on severe Covid-19 are available in Table S5). Between the first dose and the second dose, 39 cases in the BNT162b2 group and 82 cases in the placebo group were observed, resulting in a vaccine efficacy of 52% (95% CI, 29.5 to 68.4) during this interval and indicating early protection by the vaccine, starting as soon as 12 days after the first dose.

DISCUSSION

A two-dose regimen of BNT162b2 (30 μg per dose, given 21 days apart) was found to be safe and 95% effective against Covid-19. The vaccine met both primary efficacy end points, with more than a 99.99% probability of a true vaccine efficacy greater than 30%. These results met our prespecified success criteria, which were to establish a probability above 98.6% of true vaccine efficacy being greater than 30%, and greatly exceeded the minimum FDA criteria for authorization.[9] Although the study was not powered to definitively assess efficacy by subgroup, the point estimates of efficacy for subgroups based on age, sex, race, ethnicity, body-mass index, or the presence of an underlying condition associated with a high risk of Covid-19 complications are also high. For all analyzed subgroups in which more than 10 cases of Covid-19 occurred, the lower limit of the 95% confidence interval for efficacy was more than 30%.

The cumulative incidence of Covid-19 cases over time among placebo and vaccine recipients begins to diverge by 12 days after the first dose, 7 days after the estimated median viral incubation period of 5 days,[10] indicating the early onset of a partially protective effect of immunization. The study was not designed to assess the efficacy of a single-dose regimen. Nevertheless, in the interval between the first and second doses, the observed vaccine efficacy against Covid-19 was 52%, and in the first 7 days after dose 2, it was 91%, reaching full efficacy against disease with onset at least 7 days after dose 2. Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group. This finding is consistent with overall high efficacy against all Covid-19 cases. The severe case split provides preliminary evidence of vaccine-mediated protection against severe disease, alleviating many of the theoretical concerns over vaccine-mediated disease enhancement.[11]

The favorable safety profile observed during phase 1 testing of BNT162b2[4,8] was confirmed in the phase 2/3 portion of the trial. As in phase 1, reactogenicity was generally mild or moderate, and reactions were less common and milder in older adults than in younger adults. Systemic reactogenicity was more common and severe after the second dose than after the first dose, although local reactogenicity was similar after the two doses. Severe fatigue was observed in approximately 4% of BNT162b2 recipients, which is higher than that observed in recipients of some vaccines recommended for older adults.[12] This rate of severe fatigue is also lower than that

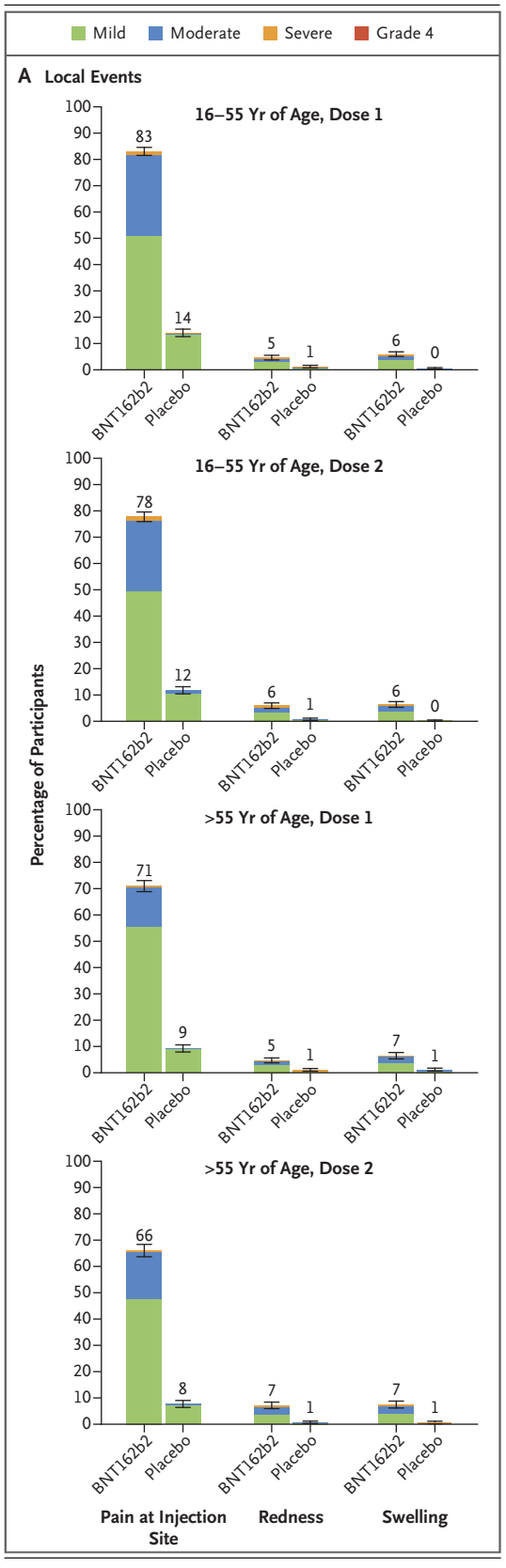


Figure 2. Local and Systemic Reactions Reported within 7 Days after Injection of BNT162b2 or Placebo, According to Age Group.

Data on local and systemic reactions and use of medication were collected with electronic diaries from participants in the reactogenicity subset (8,183 participants) for 7 days after each vaccination. Solicited injection-site (local) reactions are shown in Panel A. Pain at the injection site was assessed according to the following scale: mild, does not interfere with activity; moderate, interferes with activity; severe, prevents daily activity; and grade 4, emergency department visit or hospitalization. Redness and swelling were measured according to the following scale: mild, 2.0 to 5.0 cm in diameter; moderate, >5.0 to 10.0 cm in diameter; severe, >10.0 cm in diameter; and grade 4, necrosis or exfoliative dermatitis (for redness) and necrosis (for swelling). Systemic events and medication use are shown in Panel B. Fever categories are designated in the key; medication use was not graded. Additional scales were as follows: fatigue, headache, chills, new or worsened muscle pain, new or worsened joint pain (mild: does not interfere with activity; moderate: some interference with activity; or severe: prevents daily activity), vomiting (mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; or severe: requires intravenous hydration), and diarrhea (mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; or severe: 6 or more loose stools in 24 hours); grade 4 for all events indicated an emergency department visit or hospitalization. I bars represent 95% confidence intervals, and numbers above the I bars are the percentage of participants who reported the specified reaction.

observed in recipients of another approved viral vaccine for older adults.[13] Overall, reactogenicity events were transient and resolved within a couple of days after onset. Lymphadenopathy, which generally resolved within 10 days, is likely to have resulted from a robust vaccine-elicited immune response. The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively).

This trial and its preliminary report have several limitations. With approximately 19,000 participants per group in the subset of participants with a median follow-up time of 2 months after the second dose, the study has more than 83% probability of detecting at least one adverse event, if the true incidence is 0.01%, but it is not large enough to detect less common adverse events reliably. This report includes 2 months of follow-up after the second dose of vaccine for half the trial participants and up to 14 weeks' maximum follow-up for a smaller subset. Therefore, both

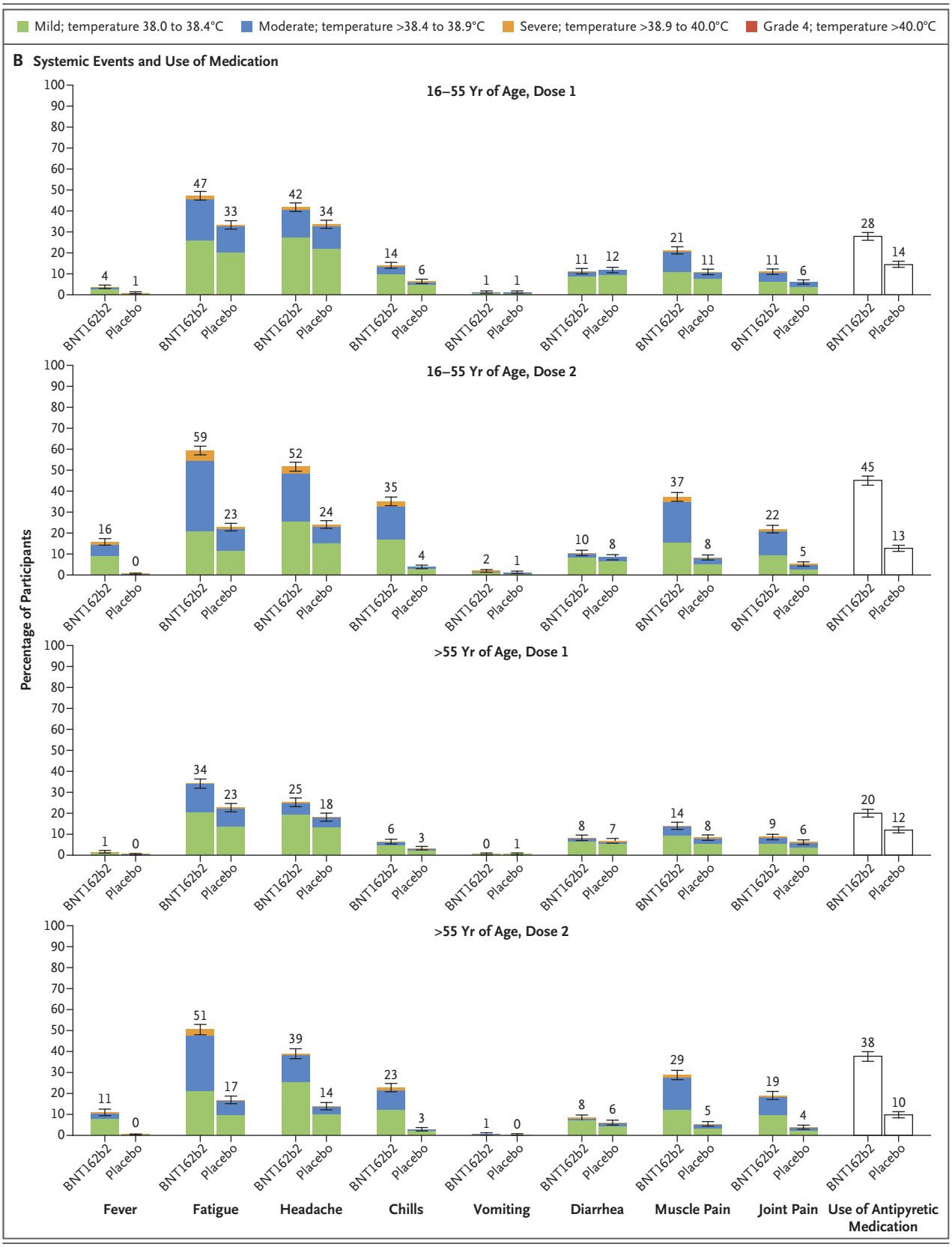


Table 2. Vaccine Efficacy against Covid-19 at Least 7 days after the Second Dose.*

Efficacy End Point	BNT162b2		Placebo		Vaccine Efficacy, % (95% Credible Interval)‡	Posterior Probability (Vaccine Efficacy >30%)§
	No. of Cases	Surveillance Time (n)†	No. of Cases	Surveillance Time (n)†		
		(N=18,198)		(N=18,325)		
Covid-19 occurrence at least 7 days after the second dose in participants without evidence of infection	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.3–97.6)	>0.9999
		(N=19,965)		(N=20,172)		
Covid-19 occurrence at least 7 days after the second dose in participants with and those without evidence of infection	9	2.332 (18,559)	169	2.345 (18,708)	94.6 (89.9–97.3)	>0.9999

* The total population without baseline infection was 36,523; total population including those with and those without prior evidence of infection was 40,137.
† The surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.
‡ The credible interval for vaccine efficacy was calculated with the use of a beta-binomial model with prior beta (0.700102, 1) adjusted for the surveillance time.
§ Posterior probability was calculated with the use of a beta-binomial model with prior beta (0.700102, 1) adjusted for the surveillance time.

the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain to be determined. Although the study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities. Assessment of long-term safety and efficacy for this vaccine will occur, but it cannot be in the context of maintaining a placebo group for the planned follow-up period of 2 years after the second dose. These data do not address whether vaccination prevents asymptomatic infection; a serologic end point that can detect a history of infection regardless of whether symptoms were present (SARS-CoV-2 N-binding antibody) will be reported later. Furthermore, given the high vaccine efficacy and the low number of vaccine breakthrough cases, potential establishment of a correlate of protection has not been feasible at the time of this report.

This report does not address the prevention of Covid-19 in other populations, such as younger adolescents, children, and pregnant women. Safety and immune response data from this trial after immunization of adolescents 12 to 15 years of age will be reported subsequently, and additional studies are planned to evaluate BNT162b2 in pregnant women, children younger than 12 years, and those in special risk groups, such as immunocompromised persons. Although the vaccine can be stored for up to 5 days at standard refrigerator temperatures once ready for use, very cold temperatures are required for shipping and longer storage. The current cold storage requirement may be alleviated by ongoing stability studies and formulation optimization, which may also be described in subsequent reports.

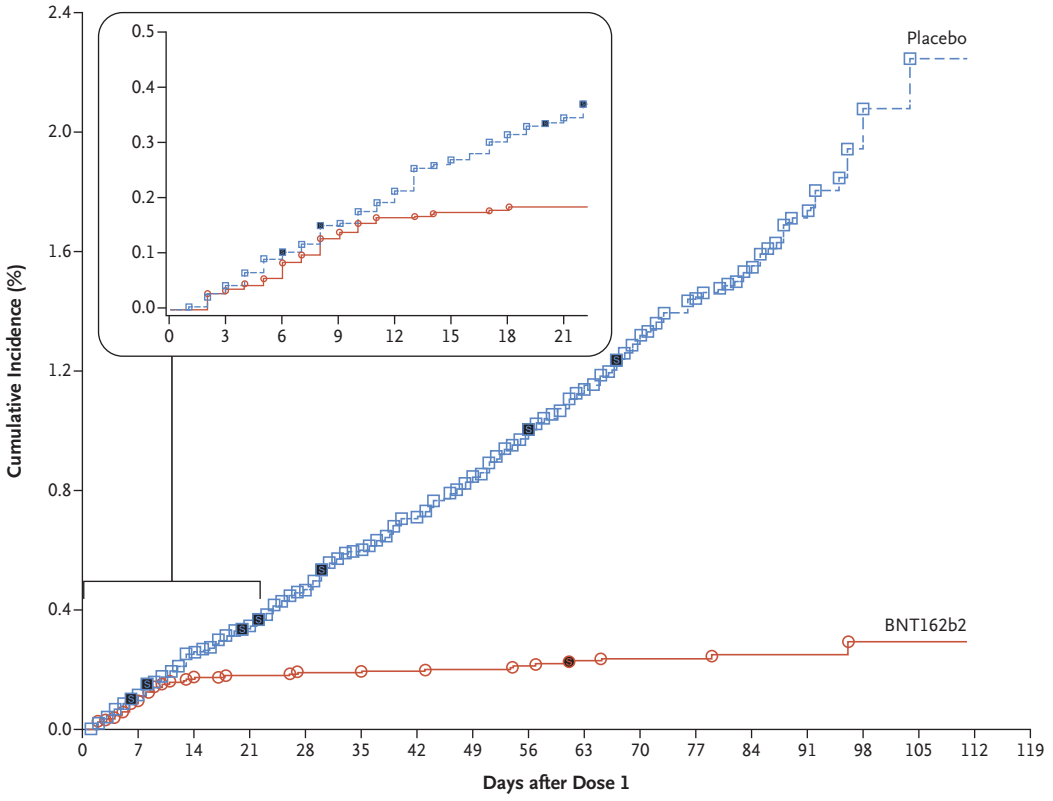
The data presented in this report have significance beyond the performance of this vaccine candidate. The results demonstrate that Covid-19 can be prevented by immunization,

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198)		Placebo (N=18,325)		Vaccine Efficacy, % (95% CI)†
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4–98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6–98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7–99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (–13.1–100.0)
Sex					
Male	3	1.124 (8,875)	81	1.108 (8,762)	96.4 (88.9–99.3)
Female	5	1.090 (8,536)	81	1.114 (8,749)	93.7 (84.7–98.0)
Race or ethnic group‡					
White	7	1.889 (14,504)	146	1.903 (14,670)	95.2 (89.8–98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2–100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6–99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7–98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9–98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3–99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1–99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6–98.2)

* Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.
† The confidence interval (CI) for vaccine efficacy is derived according to the Clopper–Pearson method, adjusted for surveillance time.
‡ Race or ethnic group was reported by the participants. "All others" included the following categories: American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported.

provide proof of concept that RNA-based vaccines are a promising new approach for protecting humans against infectious diseases, and demonstrate the speed with which an RNA-based vaccine can be developed with a sufficient investment of resources. The development of BNT162b2 was initiated on January 10, 2020, when the SARS-CoV-2 genetic sequence was released by the Chinese Center for Disease Control and Prevention and disseminated globally by the GISAID (Global Initiative on Sharing All Influenza Data) initiative. This rigorous demonstration of safety and efficacy less than 11 months later provides a practical demonstration that RNA-based vaccines, which require only viral genetic sequence information to initiate development, are a major new tool to combat pandemics and other infectious disease outbreaks. The continuous phase 1/2/3 trial design may provide a model to reduce the protracted development timelines that have delayed the availability of vaccines against other infectious diseases of medical importance. In the context of the current, still expanding pandemic, the BNT162b2 vaccine, if approved, can contribute, together with other public health measures, to reducing the devastating loss of health,



Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669)		Placebo (N=21,686)		VE (95% CI)
	No. of participants	Surveillance time *person-yr (no. at risk)*	No. of participants	Surveillance time *person-yr (no. at risk)*	*percent*
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

Figure 3. Efficacy of BNT162b2 against Covid-19 after the First Dose.

Shown is the cumulative incidence of Covid-19 after the first dose (modified intention-to-treat population). Each symbol represents Covid-19 cases starting on a given day; filled symbols represent severe Covid-19 cases. Some symbols represent more than one case, owing to overlapping dates. The inset shows the same data on an enlarged y axis, through 21 days. Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from the first dose to the end of the surveillance period. The confidence interval (CI) for vaccine efficacy (VE) is derived according to the Clopper–Pearson method.

life, and economic and social well-being that has resulted from the global spread of Covid-19.

Supported by BioNTech and Pfizer.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

We thank all the participants who volunteered for this study; and the members of the C4591001 data and safety monitoring board for their dedication and their diligent review of the data. We also acknowledge the contributions of the C4591001 Clinical Trial Group (see the Supplementary Appendix); Tricia Newell and Emily Stackpole (ICON, North Wales, PA) for editorial support funded by Pfizer; and the following Pfizer staff: Greg Adams, Negar Aliabadi, Mohanish Anand, Fred Angulo, Ayman Ayoub, Melissa Bishop-Murphy, Mark Boaz, Christopher Bowen, Salim Bouguermouh, Donna Boyce, Sarah Burden, Andrea Cawein, Patrick Caubel, Darren Cowen, Kimberly Ann Cristall, Michael Cruz, Daniel Curcio, Gabriela Dávila, Carmel Devlin, Gokhan Duman, Niesha Foster, Maja Gacic, Luis Jodar, Stephen Kay, William Lam, Esther Ladipo, Joaquina Maria Lazaro, Marie-Pierre Hellio Le Graverand-Gastineau, Jacqueline Lowenberg, Rod MacKenzie, Robert Maroko, Jason McKinley, Tracey Melle-

lieu, Farheen Muzaffar, Brendan O'Neill, Jason Painter, Elizabeth Paulukonis, Allison Pfeffer, Katie Puig, Kimberly Rarrick, Balaji Prabu Raja, Christine Rainey, Kellie Lynn Richardson, Elizabeth Rogers, Melinda Rottas, Charulata Sabharwal, Vilas Satishchandran, Harpreet Seehra, Judy Sewards, Helen Smith, David Swerdlow, Elisa Harkins Tull, Sarah Tweedy, Erica Weaver, John Wegner, Jenah West, Christopher Webber, David C. Whritenour, Fae Wooding, Emily Worobetz, Xia Xu, Nita Zalavadia, Liping Zhang, the Vaccines Clinical Assay Team, the Vaccines Assay Development Team, and all the Pfizer colleagues not named here who contributed to the success of this trial. We also acknowledge the contributions of the following staff at BioNTech: Corinna Rosenbaum, Christian Miculka, Andreas Kuhn, Ferdia Bates, Paul Strecker, Ruben Rizzi, Martin Bexon, Eleni Lagkadinou, and Alexandra Kemmer-Brück; and the following staff at Polymun: Dietmar Katinger and Andreas Wagner.

APPENDIX

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EXHIBIT K

U.S. Department of Justice

Civil Division

Washington, DC 20530

January 10, 2018

PRIVILEGED AND CONFIDENTIAL; FOR INTERNAL GOVERNMENT USE ONLY

MEMORANDUM

TO: Attorneys
Commercial Litigation Branch, Fraud Section

Assistant U.S. Attorneys Handling False Claims Act Cases
Offices of the U.S. Attorneys

FROM: Michael D. Granston MDG
Director
Commercial Litigation Branch, Fraud Section

SUBJECT: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)

Introduction

Over the last several years, the Department has seen record increases in *qui tam* actions filed under the False Claims Act (FCA), 31 U.S.C. § 3729 et seq., with annual totals approaching or exceeding 600 new matters. Although the number of filings has increased substantially over time, the rate of intervention has remained relatively static. Even in non-intervened cases, the government expends significant resources in monitoring these cases and sometimes must produce discovery or otherwise participate. If the cases lack substantial merit, they can generate adverse decisions that affect the government's ability to enforce the FCA. Thus, when evaluating a recommendation to decline intervention in a *qui tam* action, attorneys should also consider whether the government's interests are served, in addition, by seeking dismissal pursuant to 31 U.S.C. § 3730(c)(2)(A).

Historically, the Department has utilized section 3730(c)(2)(A) sparingly, in large part because the statutory text makes clear that relators can proceed with certain *qui tam* actions following the government's declination. Moreover, a decision not to intervene in a particular case may be based on factors other than merit, particularly in light of the government's limited resources.

Accordingly, we have been circumspect with the use of this tool to avoid precluding relators from pursuing potentially worthwhile matters, and to ensure that dismissal is utilized only where truly warranted.

While it is important to be judicious in utilizing section 3730(c)(2)(A), it remains an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent. The Department plays an important gatekeeper role in protecting the False Claims Act, because in *qui tam* cases where we decline to intervene, the relators largely stand in the shoes of the Attorney General. That is why the FCA provides us with the authority to dismiss cases. This memo is intended to provide a general framework for evaluating when to seek dismissal under section 3730(c)(2)(A) and to ensure a consistent approach to this issue across the Department. We reviewed those cases in which the government moved to dismiss relators pursuant to this statutory provision since 1986, when this provision was added to the FCA. As discussed below, we identified approximately seven factors that the government has relied upon in seeking to dismiss a *qui tam* action pursuant to section 3730(c)(2)(A). To ensure consistency across the Department, these factors should serve as a basis for evaluating whether to seek to dismiss future matters, though they are not intended to constitute an exhaustive list, and there may be other reasons for concluding that the government's interests are best served by the dismissal of a *qui tam* action.[1]

Finally, as noted below, when the Department is considering dismissal, relators should be advised of this possibility since it will inform their judgment regarding whether to voluntarily dismiss their actions.

Discussion

The False Claims Act authorizes the Attorney General to dismiss a *qui tam* action over the relator's objection:

> The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the

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[1] In jointly handled and monitored cases, the prior approval of the Assistant Attorney General is required for a motion to dismiss a qui tam action, including under section 3730(c)(2)(A). In delegated cases, the authority for dismissing a *qui tam* complaint will generally be vested in the U.S. Attorney unless dismissal would present a novel issue of law or policy, or for any other reason raises issues that should receive the personal attention of the Assistant Attorney General. *See* Civil Division Directive 1-15, Subpart 1(e). In order to maintain consistency and evaluate the appropriateness of Assistant Attorney General approval, U.S. Attorneys' Offices should provide notice to the assigned Fraud Section attorney at least 10 days prior to filing any motion to dismiss in a delegated matter. In addition, for reporting purposes, the Department will collect information on an annual basis regarding the number of *qui tam* complaints dismissed upon motion by the United States. The Fraud Section will work with the Executive Office of United States Attorneys to formulate a reporting mechanism.

> motion and the court has provided the person with an opportunity for a hearing on the motion.

31 U.S.C. § 3730(c)(2)(A).[2] The FCA does not, however, provide a standard of review for evaluating such a request for dismissal. As a result, courts have developed two differing standards. *Compare United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (holding that the United States must identify a "valid government purpose" that is rationally related to dismissal) *with Swift v. United States,* 318 F.3d 250, 252 (D.C. Cir. 2003) (holding that the United States has an "unfettered right" to dismiss a *qui tam* action).

Moreover, the FCA does not set forth specific grounds for dismissal under section 3730(c)(2)(A). However, below is a non-exhaustive list of factors that the Department can use as a basis for dismissal, along with citations to cases where the government has previously sought dismissal based on these factors.

1. *Curbing Meritless Qui Tams*

The Department should consider moving to dismiss where a *qui tam* complaint is facially lacking in merit—either because relator's legal theory is inherently defective, or the relator's factual allegations are frivolous. Examples of inherent legal defects include *qui tam* actions where the relator failed to allege an actionable obligation to support a reverse false claim violation, *see, e.g.*, *United States ex rel. Hoyte v. American National Red Cross*, 518 F.3d 61 (D.C. Cir. 2008); *United States ex rel. Wright*, No. 5:03-264 (E.D. Tex. Feb. 3, 2005), or to allege a non-federal defendant that is not covered by sovereign immunity. *See, e.g.*, *United States ex rel. Carter v. Board of Governors of the Federal Reserve, et al.*, No. 12-0129-cv-W-HFS (W.D. Mo. May 1, 2013); *United States ex rel. Casey v. Blevins*, No. 4:02-CV-60 (E.D. Ark. July 5, 2002); *Braswell v. Unger*, No. 4:14-cv-02574-JAB (D. Az. August 11, 2015). Factually frivolous cases can take a number of forms. *See, e.g.*, *United States ex rel. Roach v. Obama*, No. 14-0470 (D.D.C. December 18, 2014); *United States ex rel. May v. City of Dallas*, 2014 WL 5454819, at *5 (N.D. Tex. Oct. 27, 2014); *United States ex rel. Berg v. Obama*, 383 F. App'x 7 (D.C. Cir. 2010) (per curiam); *United States ex rel. Lachkovich v. Ashcroft, et al.*, No. 08-cv-00066-WYD-BNB (D. Colo. March 13, 2008).

In certain cases, even if the relator's allegations are not facially deficient, the government may conclude after completing its investigation of the relator's allegations that the case lacks merit. In such a case, the Department should consider dismissing the matter. *See United States ex rel. Nasuti v. Savage Farms, Inc.*, 2014 WL 1327015, at *11 (D. Mass. Mar. 27, 2014), aff'd, 2015

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[2] This is just one of several mechanisms contained in the FCA to ensure that the United States retains substantial control over lawsuits brought on its behalf. *See also* 31 U.S.C. § 3730(c)(1) (providing government with "the primary responsibility for prosecuting the action" when it intervenes); 31 U.S.C. § 3730(c)(2)(B) (allowing government to settle actions over relator's objections); 31 U.S.C. § 3730(c)(2)(C) (providing government with mechanism to restrict relator's participation in the case); 31 U.S.C. § 3730(b)(1) (requiring relator to obtain government consent prior to any dismissal of the action).

WL 9598315 (1st Cir. 2015) (dismissing *qui tam* claims that government concluded were "factually incorrect and without foundation."); *United States ex rel. Dreyfuse v. Farrell, et al.*, 3:16-cv-5273 (S.D. W.Va. March 28, 2017) (granting government's motion to dismiss claims that were submitted to state agency and which did not implicate any federal programs or funds); *United States ex rel. Stierli v. Shasta Services, Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006) (granting government's motion to dismiss because, among other things, there was not any false or fraudulent claim paid or approved by the federal government); *United States v. Fiske*, 968 F. Supp. 1347, 1353 (E.D. Ark. 1997) (holding that relator's allegations, even if true, do not involve the submission of any false or fraudulent claim to the federal government). These cases may be rare, in part, because to maximize its resources the government typically will investigate a *qui tam* action only to the point where it concludes that a declination is warranted. This may not equate to a conclusion that no fraud occurred. If the Department is concerned that a case lacks any merit, but elects to afford the relator an opportunity to further develop the case, the Department attorney may consider advising the relator that dismissal will be considered if the relator is unable to obtain additional support for the relator's claims by a specified date.

2. *Preventing Parasitic or Opportunistic Qui Tam Actions*

The Department should consider moving to dismiss a *qui tam* action that duplicates a pre-existing government investigation and adds no useful information to the investigation. In these cases, the government should consider whether the relator would receive an unwarranted windfall at the expense of the public fisc because Congress intended for the relator share to incentivize and award the provision of meaningful information and assistance instead of merely providing duplicative information already known to the government. *See* 132 Cong. Rec. 29, 322 (1986) (citing S. Rep. No. 99-345, at 28 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5293) (discussing factors relevant to awarding a relator share, including "the significance of the information provided" and whether the government was already aware of the information prior to relator providing it). For example, in *United States ex rel. Amico, et al. v. Citi Group, Inc., et al.*, No. 14-cv-4370 (CS) (S.D.N.Y. August 7, 2015), relators filed a *qui tam* action against Citi Group and its subsidiaries alleging fraud in connection with the marketing and sale of residential mortgage backed securities; however, the Department of Justice had been investigating the same conduct for several years prior to the filing and had engaged in extensive settlement negotiations before relators filed their complaint. The government successfully moved to dismiss the action under section 3730(c)(2)(A) because, among other factors, relators' belated complaint provided no assistance to the government in its pre-existing investigation. *See also United States ex rel. Piacentile v. Amgen Inc.*, No. 04-cv-3983-SJ-RML, 2013 WL 5460640, at *4 (E.D.N.Y. Sept. 30, 2013) (granting government's motion to dismiss *qui tam* complaint filed by serial relator who filed one of ten *qui tams* alleging similar wrongdoing by the same defendant).

3. *Preventing Interference with Agency Policies and Programs*

Dismissal should be considered where an agency has determined that a *qui tam* action threatens to interfere with an agency's policies or the administration of its programs and has recommended dismissal to avoid these effects. For example, in *United States ex rel. Ridenour v. Kaiser-Hill Co., LLC*, 397 F.3d 925 (10th Cir. 2005), relator alleged that a security contractor submitted false claims to the Department of Energy for deficient security services at Rocky Flats, a

radiologically-contaminated nuclear weapons manufacturing facility that was slated to undergo decontamination and closure. The government successfully moved to dismiss the action because, among other things, litigation would delay the clean-up and closure of the facility by diverting agency personnel and resources away from the project. 397 F.3d at 937; *see also United States ex rel. Sequoia Orange Co.*, 151 F.3d at 1146 (concluding that valid government interests supporting dismissal included the Department of Agriculture's desire to "end the divisiveness in the citrus industry" by promulgating new citrus marketing regulations to replace invalidated regulations upon which the relator based its claims); *United States ex rel. Toomer v. TerraPower*, No. 4:16-cv-00226-BLW (D. Idaho) (Under Seal) (seeking dismissal of allegation that defendant's invention constituted government property, based in part on the concern that this allegation would hinder the Energy Department's ability to collaborate with private sector partners). Finally, there may be instances where an action is both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry. *Cf. United States ex rel. Harmon v. Trinity Indus., Inc.*, 872 F.3d 645 (5th Cir. 2017) (reversing $680 million judgment against highway guardrail manufacturer based on alleged manufacturing defects that agency concluded did not affect eligibility of defendant's claims).

4. *Controlling Litigation Brought on Behalf of the United States*

Relatedly, the Department should consider dismissing cases when necessary to protect the Department's litigation prerogatives. For example, in *In Re Natural Gas Royalties Qui Tam Litigation*, MDL Docket No. 1293 (D. Wyo. October 9, 2002), relator filed separate *qui tam* actions in various districts against more than 300 defendants accused of underpaying royalties owed to the United States in connection with natural gas produced from federal lands. After intervening as to a limited number of defendants, the government sought to dismiss certain declined claims to, among other things, avoid interference with the government's ability to litigate the intervened claims. The court agreed, finding that the interest in avoiding interference with ongoing litigation warranted dismissal of the declined claims. *See also Lion Raisins v. Kagawa, et al.*, No. CV-F-02-5665-REC-LJO (E.D. Cal. Nov. 3, 2003) (granting government's motion to dismiss, concluding that government's desire to avoid interference with pending Federal Torts Claims Act action involving the same parties was a valid government purpose that was rationally related to dismissal). In addition, in *United States ex rel. Wright v. Agip Petroleum Co.*, No. 5:03-264 (E.D. Tex. Feb. 3, 2005), the government moved to dismiss, in part, to avoid the risk of unfavorable precedent. *See id.* Finally, in *United States ex rel. Piacentile*, 2013 WL 5460640, the government moved to dismiss a declined claim that was serving as an obstacle to the settlement of the government's intervened claims. *But cf. United States ex rel. Schweizer v. Oce*, 677 F.3d 1228 (D.C. Cir. 2012) (once the government reaches a settlement with defendant of relator's claims, the dismissal of those claims is governed by section 3730(c)(2)(B), requiring a showing that the settlement is fair, adequate, and reasonable, rather than by section 3730(c)(2)(A)).[3]

[3] In each of the foregoing cases, in addition to determining that the dismissed claims were interfering with the government's litigation prerogatives, the government's briefs make clear that the government had determined that the claims lacked substantial merit.

5. *Safeguarding Classified Information and National Security Interests*

In certain cases, particularly those involving intelligence agencies or military procurement contracts, we should seek dismissal to safeguard classified information. For example, in *United States ex rel. Fay v. Northrup Grumman Corp.*, No. 06-cv-00581-EWN-MJW, 2008 WL 877180 (D. Colo. Mar. 27, 2008), the relator alleged that a defense contractor defrauded the United States in connection with work performed on a classified contract. After declining to intervene, the Department moved to dismiss the action under section 3730(c)(2)(A), asserting that continued litigation would pose "an unacceptable risk to national security" due to the potential for disclosure of classified information. Applying the *Sequoia Orange* standard, the Court agreed, concluding that the claims and defenses were inextricably tied to classified information and dismissal was rationally related to the valid government interest of preventing the disclosure of such information. *Id.* at * 6-7. *See also United States ex rel. Matseki v. Raytheon Co.*, 634 F. App'x 192 (9th Cir. 2015) (per curiam) (holding that government interest in avoiding disclosure of classified information was sufficient basis for dismissal); *United States ex rel. Schwartz v. Raytheon Co.*,150 F. App'x 627 (9th Cir. 2005) (holding that "federal interest in protecting military and state secrets" was valid basis for dismissal); *United States ex rel. Ridenour*, 397 F.3d at 936-37 ("The Government demonstrated that classified documents required in the litigation would present a risk of inadvertent disclosure, implicating national security."). Finally, it should be noted that the government need not demonstrate that continued litigation *will* result in the disclosure of classified information. In jurisdictions that apply the "rational basis" basis test, the government has a strong argument that the *risk of disclosure*, alone, justifies dismissal. *See United States ex rel. Ridenour,* 397 F.3d at 937 (finding risk of inadvertent disclosure of classified information, "even if theoretically minimal," sufficed to justify dismissal). (In jurisdictions that apply the "unfettered right" standard, no showing by the government is required.)

6. *Preserving Government Resources*

The Department should also consider dismissal under section 3730(c)(2)(A) when the government's expected costs are likely to exceed any expected gain.[4] *See, e.g.*, *Swift v. United States,* 318 F.3d 250, 251 (D.C. Cir. 2003) (the government moved to dismiss the complaint, arguing that the amount of money involved did not justify the expense of litigation even if the allegations could be proven); *United States ex rel. Nicholson v. Spigelman, et al.*, No. 1:10-cv-03361, 2011 WL 2683161, at *2 (N.D. Ill. July 8, 2011) (explaining that the estimated government losses, even with statutory penalties and damages multiplier, were less than the costs of monitoring the litigation and responding to discovery requests) Examples of potential costs may include, among other things, the need to monitor or participate in ongoing litigation, including responding to discovery requests. *See, e.g.*, *United States ex rel. Sequoia Orange Co.*, 151 F.3d at 1146 (holding that district court "properly noted that the government can legitimately consider the burden imposed on taxpayers by its litigation, and that, even if the relators were to litigate the FCA claims, the government would continue to incur enormous internal staff costs"); *United States ex rel. Levine v. Avnet, Inc.*, No. 2:14-cv-17-WOB-CJS, 2015 WL 42359 (E.D. Ky.

[4] Cost to the government includes the opportunity cost of expending resources on other matters with a higher and/or more certain recovery.

Apr. 1, 2015) (holding that dismissal of *qui tam* complaint "will further [the government's] interest in preserving scare resources" that would otherwise be spent "monitoring [relator's] action"). In some cases, the government may also be liable for the defendant's litigation costs if the defendant prevails in the action. *See, e.g.*, FAR §31.205-47(c).

7. *Addressing Egregious Procedural Errors*

The Department may also seek dismissal of a *qui tam* action pursuant to section 3730(c)(2)(A) based on problems with the relator's action that frustrate the government's efforts to conduct a proper investigation. For example, in *United States ex rel. Surdovel v. Digirad Imaging Solutions*, No. 07–cv-0458, 2013 WL 6178987 (E.D. Pa. Nov. 25, 2013), the relator ignored repeated requests from the Office of the U.S. Attorney to serve the *qui tam* complaint and disclose material facts as required by 31 U.S.C. § 3730(b). The Court granted the government's motion to dismiss the action because the "egregious procedural errors completely frustrated the government's ability to investigate the relator's claims." *Id.* at *4. *But cf. State Farm Fire and Cas. Co. v. United States ex rel. Rigsby*, – U.S. –, 137 S.Ct. 436, 440 (2016) (holding that relators' violation of FCA's seal requirement did not mandate automatic dismissal of relators' complaint).

* * *

Several additional points are in order with respect to the use of the government's dismissal authority under section 3730(c)(2)(A). First, while the Department's position has been that the appropriate standard for dismissal under section 3730(c)(2)(A) is the "unfettered" discretion standard adopted by the D.C. Circuit rather than the "rational basis" test adopted by the 9th and 10th Circuits, we should argue that even the latter standard was intended to be a highly deferential one. Moreover, in those jurisdictions where the standard remains unresolved, in many cases the prudent course may be to identify the government's basis for dismissal and to argue that it satisfies any potential standard for dismissal under section 3730(c)(2)(A).

Second, the factors identified above are not mutually-exclusive, and the Department has often relied on multiple grounds for dismissal (for example, lack of merit and need to safeguard classified information). Nor, as noted above, are the factors identified in this memorandum intended to constitute an exhaustive list—there may be other reasons for concluding that the government's interests are best served by the dismissal of a *qui tam* action.

Third, in some cases there may be alternative grounds for seeking dismissal other than section 3730(c)(2)(A), such as the first to file bar, the public disclosure bar, the tax bar, the bar on *pro se* relators, or Federal Rule of Civil Procedure 9(b). Although the Department has sometimes moved to dismiss on these grounds under section 3730(c)(2)(A), we believe the better approach is to assert these grounds separately since they can provide alternative, independent legal bases for dismissal. It may sometimes be appropriate, however, to move for dismissal under section 3730(c)(2)(A) in the alternative based on one or more for the factors listed above.

Fourth, section 3730(c)(2)(A) does not require the government "to proceed in an all or nothing manner." *See Juliano v. Fed. Asset Disposition Ass'n*, 736 F. Supp. 348, 351–53 (D.D.C.1990) ("The [FCA] nowhere states that federal prosecutors are confined to proceed in an all or nothing manner, being forced to take or leave the qui tam plaintiff's charges wholesale."). In certain situations, it may be appropriate to seek only partial dismissal of some defendants or claims. *See id.* (granting motion for partial dismissal under 3730(c)(2)(A)); *United States ex rel. Grober v. Summit Medical Group, Inc.*, No. 02-177-C (W.D. Ky. July 9, 2004) (same).

Fifth, where a *qui tam* case is a potential candidate for dismissal, Department attorneys should consult closely with the affected agency as to whether dismissal is warranted under any of the factors set forth in this guidance. The agency's recommendation should be obtained in advance of the filing of any request to dismiss. In cases where dismissal under section 3730(c)(2)(A) is opposed by the agency (because, for example, it would require the government to disclose sensitive information or could result in other collateral consequences), there may be alternative ways to address the deficiencies while accommodating the agency's desire to forego seeking dismissal. For example, if the agency views the alleged falsity as immaterial, the United States can provide an agency declaration to that effect. *See Trinity*, 872 F.3d at 664 (holding that district court erred in concluding alleged falsity was material to agency despite agency memorandum stating that there was "an unbroken chain of eligibility for Federal reimbursement" for the allegedly defective product at issue).

Sixth, although a motion to dismiss under section 3730(c)(2)(A) will often be filed at or near the time of declination, there may be cases where dismissal is warranted at a later stage, particularly when there has been a significant intervening change in the law or evidentiary record. However, if one waits until the close of discovery or trial, there is a risk that the court may be less receptive to the request given the expenditure of resources by the court and parties. The court may also be less receptive to a motion filed at a later stage when doing so undercuts a claimed desire to avoid or reduce costs associated with discovery or safeguard information in discovery. Attorneys considering dismissal should therefore allow for sufficient time to consult with the affected agency and, in delegated cases, to provide appropriate notice to the Fraud Section

Finally, attorneys planning to recommend declination or dismissal should, to the extent possible, consider advising relators of perceived deficiencies in their cases as well as the prospect of dismissal so that relators may make an informed decision regarding whether to proceed with the action. In many cases, relators may choose to voluntarily dismiss their actions, particularly if the government has advised the relator that it is considering seeking dismissal under section 3730(c)(2)(A).[5]

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[5] Since January 1, 2012, more than 700 *qui tam* actions have been dismissed by relators after the government elected not to intervene. The frequency with which relators voluntarily dismiss declined *qui tam* actions has significantly reduced the number of cases where the government might otherwise have considered seeking dismissal pursuant to section 3730(c)(2)(A).

EXHIBIT L

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

DEC 19 2019

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Grassley:

This responds to your letter to the Attorney General dated September 4, 2019, regarding the Department of Justice's (Department) recent use of its statutory dismissal authority pursuant to the False Claims Act, 31 U.S.C. 3730(c)(2)(A).

As an initial matter, the Department underscores that it shares your view of the importance of the False Claims Act (the Act) and its *qui tam* provisions in combatting fraud against government agencies and programs. Largely because of your efforts to strengthen and reform the statute in 1986, the Act has become the government's single most important tool in combatting fraud. Since 1986, the Department has recovered over $60 billion under the Act, more than 70 percent of which was recovered in connection with lawsuits filed pursuant to the statute's *qui tam* provisions. The Department appreciates the important contributions made by whistleblowers, as well as your staunch support of the Department's False Claims Act enforcement efforts.

While *qui tam* cases serve an important role in identifying fraud against taxpayer-funded programs, not every *qui tam* case advances this objective. In the limited instances where we have determined that a relator's continued pursuit of a *qui tam* case would undermine the goal of preventing fraud or other important governmental interests, we have sought dismissal. From January 1, 2018 to present, over 1,170 *qui tam* actions have been filed, and yet the Department has filed motions to dismiss only 45 cases pursuant to 31 U.S.C.§ 3730(c)(2)(A) during the same period. These statistics demonstrate that the Department has exercised its dismissal authority judiciously and has allowed the vast majority of *qui tam* cases to proceed.

Enclosed please find a chart identifying 42 of the 45 cases that the government has moved to dismiss over the last 22 months; the other three actions remain under seal and thus are not listed. Although these cases involve unique factual and evidentiary considerations, the information below may provide some helpful context.

- Since January 1, 2018, more than 1,170 *qui tam* actions have been filed. Accordingly, the 45 cases that the United States has moved to dismiss since then account for less than 4 percent of the *qui tam* cases that were filed since January 1, 2018.

- The above referenced 45 cases involve a wide variety of federal agencies, including, but not limited to: the Department of Health and Human Services; the Department of Defense; the Department of Housing and Urban Development; the Department of Education; the Department of Energy; the Department of Commerce; the Department of Transportation; and the Department of the Treasury.

- Courts have rendered decisions in 26 of the 45 cases, granting the Department's motions to dismiss in 25 cases, and denying the Department's motion to dismiss in one case. In the one case where the government's motion was denied, the Department has appealed the decision.

- Ten of the cases the United States moved to dismiss were filed by the same for-profit private investment group that filed *qui tam* complaints throughout seven judicial districts against 38 defendants; the allegations in the 10 complaints were substantially the same (at times copied word-for-word) and all lacked merit.

- Twelve cases were filed by relators who were unrepresented by counsel, notwithstanding that every appellate court that has considered the question has concluded that *pro se* relators may not prosecute *qui tam* actions once the United States has declined to intervene.

- Two cases were filed by a relator who is alleged to have shorted the stock of the defendants named in his complaints.

- In several cases, the relators filed claims that are not legally cognizable under the False Claims Act.

- In ten cases, the affected agency expressed valid concern that the cases could undermine patient care. For that reason and others, the United States sought their dismissal.

- In one case, the Department cited, among other factors, the United States' interest in safeguarding classified information from inadvertent disclosure.

With respect to each *qui tam* action filed, the Department investigates the matter and evaluates the facts, law, and claims asserted before deciding how to proceed. The Department seeks dismissal only when we have determined that the relator's pursuit of the case would adversely affect the government's interests. The fact that we have sought to dismiss fewer than 4% of cases reflects our serious commitment to allow appropriate *qui tam* matters to proceed. Neither the government, the taxpayers, nor future whistleblowers benefit when poorly devised cases proceed. As such, he Department strives to reach a decision that best protects the public interest in each case.

The Department is proud of its record of recoveries under the False Claims Act and greatly appreciates your continued support of the Act to combat fraud against the taxpayers. We hope this information is helpful. Please do not hesitate to contact this office if we may provide further assistance on this or any other matter.

Sincerely,

Stephen E. Boyd
Assistant Attorney General

Enclosure

Qui Tam Actions for Which the United States Filed Motions to Dismiss Pursuant to 31 U.S.C. § 3730(c)(2)(A) After January 1, 2018[i]

	CASE CITATION	STATUS
1	*United States ex rel. Chang, et al. v. Children's Advocacy Ctr. of Delaware*, No. 1:15-cv-00442 (D. Del.)	Motion Granted
2	*United States ex rel. Maldonado v. Ball Homes, LLC, et al.*, No. 5:17-cv-00379 (E.D. Ky.)	Motion Granted
3	*United States ex rel. Stovall v. Webster Univ.*, No. 3:15-cv-03530 (D. S.C.)	Motion Granted
4	*United States ex rel. Kammarayil v. Sterling Operations, Inc., et al.*, No. 1:15-cv-01699 (D.D.C.)	Motion Granted
5	*United States ex rel. Davis, et al. v. Hennepin Cty., et al.*, No. 0:18-cv-01551 (D. Minn.)	Motion Granted
6	*United States ex rel. Schneider v. J.P. Morgan Chase Bank, N.A., et al.*, No. 1:14-cv-01047 (D.D.C.)	Motion Granted
7	*United States ex rel. Sibley v. Delta Reg'l Med. Ctr.*, No. 4:17-cv-00053 (N.D. Miss.)	Motion Granted
8	*United States ex rel. Browne, et al. v. CenseoHealth, LLC*, No. 4:18-cv-00347 (E.D. Tex.)	Motion Granted
9	*United States ex rel. Golden v. Kelley, et al.*, No. 3:18-cv-06051 (W.D. Wash.)	Motion Granted
10	*United States ex rel. De Sessa v. Dallas Cty. Hosp. Dist.*, No. 3:17-cv-01782 (N.D. Tex.)	Motion Granted
11	*United States ex rel. Henneberger v. Ticom Geomatics, Inc.*, No. 1:17-cv-00670 (E.D. Va.)	Motion Granted
12	*United States ex rel. Melhorn v. Hogan, et al.*, No. 3:18-cv-00236 (E.D. Tenn.)	Motion Granted
13	*United States ex rel. Johnson v. Raytheon Co.*, No. 3:17-cv-01098 (N.D. Tex.)	Motion Granted
14	*United States ex rel. Borzilleri, et al. v. AbbVie, Inc., et al.*, No. 1:15-cv-07881 (S.D.N.Y.)	Motion Granted

15	*United States ex rel. Borzilleri v. Bayer, AG, et al.*, No. 1:14-cv-00031 (D. R.I.)	Motion Granted
16	*Kelly v. Carson, et al.*, No. 8:18-cv-00532 (D. Neb.)	Motion Granted
17	*United States ex rel. Little v. Rolls-Royce North America, Inc., et al.*, No. 1:19-cv-0005 (W.D. Tex.)	Motion Granted
18	*United States ex rel. Graves v. ICANN, Inc., et al.*, No. 1:18-cv-05482 (N.D. Ga.)	Motion Granted
19	*United States ex rel. Davidheiser v. Capital Rail Constructors*, No. 1:19-CV-593 (E.D. Va.)	Motion Granted
20	*United States ex rel. Crandell v. Hardy Cty. Rural Dev. Corp.*, No. 2:18-cv-00124 (N.D. W. Va.)	Motion Granted
21	*United States ex rel. Backer v. Cooperative Rabobank, U.A., et al.*, No. 17-cv-02708 (S.D.N.Y.)	Motion Granted
22	*United States ex rel. Campie, et al. v. Gilead Sciences, Inc., et al.*, No. 3:11-cv-00941 (N.D. Cal.)	Motion Granted
23	*United States ex rel. Polansky, et al. v. Exec. Health Res., Inc., et al.*, No. 2:12-cv-04239 (E.D. Pa.)	Motion Granted
24	*United States ex rel. SMSPF, LLC, et al. v. EMD Serono, Inc., et al.*, No. 2:16-cv-05594 (E.D. Pa.)*[ii]	Motion Granted
25	*United States ex rel. Health Choice Group, LLC, et al. v. Bayer Corp., et al.*, No. 5:17-cv-00126 (E.D. Tex.)*	Motion Granted
26	*United States ex rel. Health Choice All., LLC, et al. v. Eli Lilly & Co., et al.*, No. 5:17-cv-00123 (E.D. Tex.)*	Motion Granted
27	*United States ex rel. SCEF, LLC, et al. v. AstraZeneca, PLC, et al.*, No. 2:17-cv-01328 (W.D. Wash.)*	Motion Granted
28	*United States ex rel. SMSF, LLC, et al. v. Biogen Inc., et al.*, No. 1:16-cv-11379 (D. Mass.)*	Dismissed on Defendants' Motion
29	*United States ex rel. SAPF, LLC, et al. v. Amgen, Inc., et al.*, No. 2:16-cv-05203 (E.D. Pa.)*	Dismissed by Relator
30	*United States ex rel. Miller, et al. v. AbbVie, Inc.*, No. 3:16-cv-02111 (N.D. Tex.)*	Dismissed by Relator
31	*United States ex rel. Carle, et al. v. Otsuka Holdings Co., et al.*, No. 1:17-cv-00966 (N.D. Ill.)*	Dismissed by Relator

32	*United States ex rel. Harman, et al. v. BNSF Ry. Co., et al.*, No. 1:17-cv-00059 (D. Mont.)	Dismissed by Relator
33	*United States ex rel. Lubemba v. Garda*, No. 5:17-CV-286 (M.D. Ga.)	Dismissed by Relator
34	*United States ex rel. Haule v. Univ. of Texas Health Science Ctr.*, No. 19-cv-00033 (W.D. Tex.)	Dismissed by Relator
35	*United States ex rel. Haule v. Heggemeier, et al.*, No. 19-cv-00034 (W.D. Tex.)	Dismissed by Relator
36	*United States ex rel. Haule v. Southwest Housing Compliance Corp.* No. 19-cv-0035 (W.D. Tex.)	Dismissed by Relator
37	*United States ex rel. Haule v. Austin, et al.*, No. 19-cv-00036-RP-AWA (W.D. Tex.)	Dismissed by Relator
38	*United States ex rel. Vanderlan v. Jackson HMA, LLC, et al.*, No. 3:15-cv-00767 (S.D. Miss.)	Motion Pending
39	*United States ex rel. NHCA-TEV, LLC, et al. v. Teva Pharm., et al.*, No. 2:17-cv-02040 (E.D. Pa.)*	Motion Pending
40	*United States ex rel. Farmer, et al., v. The Republic of Honduras, et al.*, No. 1:17-cv-00470 (S.D. Ala.)	Motion Pending
41	*United States ex rel. Mikovits v. Whittemore Peterson Institute, et al.*, No. 3:15-cv-409 (D. Nev.)	Motion Pending
42	*United States ex rel. CIMZNHCA, LLC, et al. v. UCB, Inc., et al.*, No. 3:17-cv-00765 (S.D. Ill.)*	Motion Denied; Appeal Pending

[i] This list is based on a review of the Civil Division's records as of October 25, 2019. There are three additional *qui tam* actions that remain under seal for which the United States has filed a motion to dismiss pursuant to 31 U.S.C. 3730(c)(2)(A), of which two have been granted and one remains pending. Because these actions currently remain under seal, they are not listed.

[ii] The use of an asterisk (*) denotes an action filed by the *qui tam* investment group, Venari Partners LLC (dba National Healthcare Analysis Group).

EXHIBIT M

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

May 4, 2020

VIA ELECTRONIC TRANSMISSION
The Honorable William P. Barr
Attorney General
U.S. Department of Justice
Washington D.C., 20220

Dear Attorney General Barr:

I write in response to a recently filed brief to the Supreme Court by Solicitor General Noel J. Francisco in which the Department of Justice (DOJ) argues that their dismissal authority of a *qui tam* False Claims Act case is an unreviewable exercise of prosecutorial authority.[1] In doing so, DOJ asserts that the plain language of the law grants them unfettered discretion in the dismissal of any such claim.[2] As the original author of the 1986 amendments to the False Claims Act, I vehemently disagree with the Department's reading of the law.[3]

Originally enacted in 1863, the False Claims Act allows the government to recover triple damages and impose fines against those who knowingly defraud the government.[4] This is the government's most powerful tool to prevent and deter fraud—it is responsible for the recovery of more than $59 billion since 1986.[5] The key feature of the highly successful, modern False Claims Act is the *qui tam* provision, which allows whistleblowers (referred to as relators) privy to inside information about fraudulent conduct to sue on the government's behalf.[6] For their efforts, successful relators may receive a reward of up to 30% of funds recouped by the government.[7] The statute requires that the relator file a claim under seal and allow DOJ 60 days to investigate the allegations raised in the complaint.[8] DOJ may also request an extension if an investigation is likely to go past the 60-day mark. If no extension is requested, after the 60 days, DOJ may prosecute the

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[1] Brief for the United States at 9, United States *ex rel.* Schneider v. JPMorgan Chase, N.A, No. 17-7003 (D.C. Cir. 2017) (No. 19-678) [hereinafter Brief].
[2] *Id.* at 9 (stating that the legislative text is "best read to preserve the Executive Branch's usual unfettered discretion to dismiss an action that is brought in the name of the United States to remedy a wrong done to the United States…").
[3] 31 U.S.C. §§ 3729 -3733 (2012); *See* U.S. Dep't of Justice, *The False Claims Act: A Primer* (Apr. 22, 2011), *available at* https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.
[4] *Id.*
[5] Civil Div., U.S. Dep't of Justice, *Fraud Statistics – Overview: October 1, 1986 – September 30, 2018* (Dec. 21, 2018), *available at* https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.
[6] 31 U.S.C. § 3730(c).
[7] *Id.*
[8] 31 U.S.C. § 3730(b).

case itself by "intervening" in the case.[9] Relators who alerted the government of the fraud through their *qui tam* claim remain eligible for a reward regardless of DOJ's involvement.[10]

On January 10, 2018, Michael D. Granston, Director of the Commercial Litigation Branch at DOJ, issued new guidance on when to seek dismissals of *qui tam* claims.[11] Prior to the memo, motions to dismiss by the government were extremely rare.[12] Since the Granston memo was issued, DOJ has moved to dismiss approximately 45 cases pursuant to authority contained in the False Claims Act under 31 U.S.C § 3730(c)(2)(A).[13] In seeking dismissal, DOJ argues that the plain text of the law grants DOJ unfettered discretion to dismiss a case over the objections of the relator.[14] Regrettably, some courts have agreed with this erroneous interpretation.[15]

Debate over whether DOJ possesses unfettered discretion in the dismissal of a *qui tam* claim centers on the following provision, including the statutory meaning of the word "hearing." The False Claims Act provides that:

> *The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.*[16]

DOJ contends that in this context a hearing does not impose any substantive limitations on the government's dismissal authority and simply requires that the court grant the relator an opportunity to "be heard."[17] The D.C. Circuit Court of Appeals has agreed with DOJ's narrow reading of this section, stating that the purpose of a hearing in this context is to grant the relator an opportunity to publicly persuade DOJ to change course.[18] I can confidently say this narrow reading of the False Claims Act is erroneous and contrary to congressional intent. Moreover, the statutory cannons of

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[9] *Id.*
[10] 31 U.S.C. § 3730(c); *see also* Paden M. Hanson, *True Damages for False Claims: Why Gross Trebling Should Be Adopted*, 104 IOWA L. REV. 2093, 2099 (2019).
[11] Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, to Atty.'s in the Commercial Litig. Branch, Fraud Section (January 10, 2018), *available at* https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.
[12] Schooner, Steven L., *FALSE CLAIMS ACT: Greater DOJ Scrutiny of Frivolous Qui Tam Actions?* (April 2018) 32 NASH & CIBINIC REP. ¶ 20 at 60 (2018) (citing that only a single reported instance between 1986 to 1996 in which the DOJ has sought to dismiss a qui tam suit on the ground that the suit lacked substantive merit or otherwise contradicted the interests of the United States), *available at* https://scholarship.law.gwu.edu/cgi/viewcontent.cgi?article=2593&context=faculty_publications.
[13] Letter from Stephen E. Boyd, Assistant Attorney General, United States Department of Justice, to Charles E. Grassley, United States Senator (Dec. 19, 2019) (on file with author). *See also* Joshua M. Gilbert & Jeremy R. Morris, *DOJ Moves to Dismiss 11 False Claims Act Cases*, Bricker & Eckler Attorneys at Law (Jan. 16. 2019), *available at* https://www.bricker.com/insights-resources/publications/doj-moves-to-dismiss-11-false-claims-act-cases (Eleven of the cases DOJ moved to dismiss were brought by whistleblowers backed by the National Health Care Analysis group. DOJ described this group as a "professional relator" and argued that NHCA gathered information from witnesses under false pretense. NHCA denies these allegations and argues they are safeguarding taxpayer dollars).
[14] *Brief* at 9.
[15] *e.g.*, *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003).
[16] 31 U.S.C. § 3730(c)(2)(A).
[17] *Brief* at 7, 12.
[18] *Swift*, 318 F.3d at 253.

construction support the notion that hearing implies an adjudicative procedure where the court acts as an arbiter.[19]

Both the ordinary meaning and technical meaning of the word "hearing" denote a proceeding in which a judge makes a determination based on evidence and the law.

A key principle of statutory construction provides that we should understand words that are not expressly defined in a statute according to their ordinary, everyday meanings – unless the context indicates the word carries a technical meaning.[20] Often called the "technical meaning exception" or "term of art" exception, a word takes the meaning of the field from which it derives.[21] As Justice Frankfurter stated: "[I]f a word is obviously transplanted from another legal source, whether the common law or other legislation, it brings the old soil with it."[22]

Although the term "hearing" can have multiple meanings in common parlance, in the legal field it is commonly understood to mean a proceeding in which a judge makes a determination based on arguments or evidence presented by the parties. For example: *Black's Law Dictionary* defines hearing in the first instance as a "judicial session…held *for the purpose of deciding issues of fact or of law[.]*"[23] Applying this legal definition is appropriate considering that the Senators who drafted this language in the Senate Judiciary Committee are primarily lawyers who also employ lawyers on their staffs—all of whom have a common understanding of the legal meaning of "hearing."[24] There is also nothing in the text of the law that would suggest an alternate meaning to this commonly understood legal term.

Further, while *Black's Law Dictionary* provides a clear definition of the legal meaning of the word "hearing," a plain non-legal definition suggests a similar meaning. Putting the word "hearing" in the context of a court proceeding, the vast majority of Americans would presume that "hearing" implies a forum wherein a judge has decision-making authority. In statutory construction, as well as everyday life, reading words in context is critical to understanding what the author meant. For example, the word, *run*, has over 800 meanings depending on context; one can *run a company, run for office,* or *run late*.[25] In each of those examples, the same exact word evokes vastly different meanings. In the context of a court proceeding, the term "hearing" immediately brings to mind a proceeding where a judge decides issues of fact or law. For example: someone who is not legally trained would correctly presume if summoned for a hearing based on a traffic violation, that the hearing would provide more than just an opportunity to be heard, and that the Judge would have the authority to make a determination. Likewise, an administrative hearing carries a similar understanding. Finally, any movie patron can describe the scene of a criminal bail hearing in which the prosecutor and defense argue over the conditions of a suspect's bail, only to have it ultimately decided by the presiding judge. Ironically, one of the few instances

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[20] Antonin Scalia & Brian Garner, *Reading the Law: The Interpretation of Legal Text* at 69 -73 (1st ed. 2012).
[21] *Id.*
[22] Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. Rev. 527, 537 (1947).
[23] *Hearing*, BLACK'S LAW DICTIONARY (11th ed. 2019) (emphasis added); *see also id.* (defining "*Administrative law.* Any setting in which an affected person presents arguments to a decision-maker . . . ."); *Hearing*, BLACK'S LAW DICTIONARY (5th ed. 1979) (defining as a "proceeding of relative formality . . . with definite issues of fact or of law to be tried . . . .").
[24] S. Rep 99-345, the False Claims Reform Act of 1985, to accompany S.1562 (1986).
[25] Scalia & Garner, *supra* note 19, at 70.

in which a hearing carries the definition promoted by DOJ is in the context of a legislative hearing. Undoubtedly, local city councils and Congressional Committees routinely hold hearings in which the only purpose is to "be heard." Yet, few examples exists of such a notion in the context of a court of law. The very nature of a court evokes a strong connection to its adjudicatory nature.

DOJ argues that "hearing," in its most basic definition, simply means an "opportunity to be heard."[26] Yet, if Congress had intended to provide an "opportunity to be heard,"[27] it would have used those **exact words** as it has done in numerous other statutes.[28] Similarly, if Congress intended for DOJ to have unfettered discretion in dismissing a *qui tam* claim, then the word hearing would have been omitted and a period would have been added earlier to make the language read, "*The Government may dismiss the action notwithstanding the objections of the person initiating the action.*" Congress means what it says – a hearing is a hearing.[29]

DOJ's narrow reading of the word "hearing" is not in harmony with other elements of the law and would undermine certain provisions.

One must also read a statute in the context of the entire text of the law and not in isolation. Often referred to as the "whole text cannon," this important tool guarantees that a specific provision is not taken out of context and read in isolation, thus ensuring the text is in harmony with other provisions in the same law.[30] The logic stems from the notion that Congress would not write a provision in law that directly or indirectly undermines another provision in the same law.

DOJ argues that the law grants them unfettered discretion because ultimately every *qui tam* claim is brought on behalf of the government.[31] Therefore, since it is ultimately the government's claim, the government has the unfettered discretion to dismiss it.[32] But, Congress did not write the False Claims Act that way. In fact, in other sections, Congress wrote the law to ensure DOJ could **not** unilaterally dismiss cases. While DOJ can dismiss claims that the government brings on their own, or intervened claims, the law places various limitations on DOJ's discretion once they allow a relator to proceed on his own.[33] For example, 31 U.S.C. § 3730(c)(3) requires that

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[26] Brief at 7, 12 (quoting United States *ex rel.* Schneider v. JPMorgan Chase Bank, N.A., No. CV 14-1047 (RMC), 2019 WL 1060876, at *2 (D.D.C. Mar. 6, 2019), *aff'd*, No. 19-7025, 2019 WL 4566462 (D.C. Cir. Aug. 22, 2019)).

[27] In any event, nothing about the term "hearing" or the phrase "opportunity to be heard" suggests that the presiding official—here, "the court"—lacks authority to decide the issue in dispute. *Cf.* Harrison v. Commissioner, 107 F.2d 341, 342 (6th Cir. 1939) ("The general rule is that a 'hearing' contemplates a reasonable opportunity to be heard in the presentation of evidence and argument. If petitioners had been afforded such an opportunity the Board [of Tax Appeals] might have concluded upon the record that the motion to dismiss should have been denied.").

[28] *See, e.g.*, Federal Magistrates Act, Pub. L. No. 90-578, sec. 101, § 631(h), 82 Stat. 1107, 1110 (1968) (codified as amended at 28 U.S.C. § 631(i)) (giving magistrate judges facing removal "an opportunity to be heard on the charges"); Internal Revenue Code of 1954, ch. 736, subtit. F, § 7458, 68A Stat. 3, 886 (codified as amended at 26 U.S.C. § 7458) (providing for an "opportunity to be heard" in Tax Court proceedings); *cf.* Miss. *ex rel.* Hood v. AU Optronics Corp., 571 U.S. 161, 169 (2014) (reasoning that if Congress had intended references to "persons" and "plaintiffs" in the Class Action Fairness Act's definition of "mass action" to mean "named and unnamed real parties in interest," it "easily could have drafted language to that effect").

[29] *See* Simmons v. Himmelreich, 136 S. Ct. 1843, 1848 (2016) ("Absent persuasive indications to the contrary, we presume Congress says what it means and means what it says.").

[30] Scalia & Garner, *supra* note 19, at 167.

[31] *Brief* at 15.

[32] *Id.*

[33] 31 U.S.C. § 3730(c)(3).

DOJ show "good cause" to intervene in a case after more than 60 days have passed and the relator has proceeded with the case.[34] Applying the whole text cannon of statutory construction, it makes little sense that Congress would require DOJ to show good cause for intervening but grant them unfettered discretion for dismissing a case they have not yet joined.[35]

Allowing DOJ unfettered discretion to dismiss a claim would also undermine other provisions of the law which deal with dismissal by a relator. For example, 31 U.S.C. § 3730(b)(1) states:

> *A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.*[36]

In this provision, a relator may only dismiss a claim **if the court** and the Attorney General give written consent.[37] In that instance, DOJ would make its preference on dismissal clear, just as it would be in moving to dismiss without the relator. Yet, a court's consent is still required. Not only does this support the notion that DOJ does not have the unfettered right to dismiss a claim, it also presents a unique instance in which DOJ's reading of section (c)(2)(A) would effectively undermine provision (b)(1). Hypothetically, let's assume a relator moves to dismiss a claim with DOJ's consent. Under the (b)(1) provision, the court must also consent. Now, let's assume the court withholds its consent and requires the suit to proceed. DOJ would only need to issue a motion to dismiss themselves, and under the standard DOJ is advocating for, they would have unfettered discretion to override the court's previous ruling. In this hypothetical case, DOJ would clearly be undermining the judicial branch.

In closing, I have long denounced activist judges and career bureaucrats who attempt to undermine Congress' authority by reading legislative text to achieve desired outcomes in lieu of how the text reads. During your time as Attorney General, you have expressed the same concerns, and this Administration has made it a priority to clamp down on activist bureaucrats and fill judicial vacancies with individuals who will interpret the law as Congress intended by looking at the plain meaning of the text. I urge you to reconsider the Department's stance on dismissal authority in light of the overwhelming evidence that "hearing" indicates Congress intended a substantive process in which a judge hears arguments and decides whether a case should proceed or not. Relator's routinely spend hundreds of thousands of dollars in legal fees to litigate cases on behalf of the government, and since 1986, they have recovered more than $2.4 billion for the federal government via claims in which DOJ chose to not intervene.[38] Due to the large investment in time and money, Congress did not grant DOJ unfettered discretion to dismiss a relator's claim, which

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[34] *Id.*

[35] *Ridenour v. Kaiser-Hill Co. LLC*, 397 F.3d 925, 941 (10th Cir. 2005)(dissenting opinion, Judge Edgan, "[t]he context, design, and structure of the statute as a whole indicate that the government has unfettered discretion to dismiss if it intervenes within the sixty-day seal period, but not after."[35]).

[36] 31 U.S.C. § 3730(b)(1).

[37] *Id.*

[38] Civil Div., U.S. Dep't of Justice, *Fraud Statistics – Overview: October 1, 1986 – September 30, 2018*, (Dec. 21, 2018), *available at* https://www.justice.gov/civil/page/file/1080696/download.

is why the law requires an adjudicative process known as a hearing to take place. The very fact that a relator can proceed on their own shows that Congress intended for whistleblowers to play a very significant role, and it is partly what encourages reports of wrongdoing.

The False Claims Act is the government's most powerful tool in deterring fraud and recovering federal funds lost to fraud. To date it has helped the federal government reclaim more than $60 billion. What makes this law work is, and always has been, the support from whistleblowers who come forward with these claims. Having unfettered dismissal authority will create a chilling effect on future whistleblowers that will ultimately end up costing the taxpayers a lot more. Accordingly, please provide my staff with a briefing on DOJ's response to the concerns I have raised here and their plans moving forward. Should you have any questions, please contact Dario Camacho of my Committee staff at (202) 224-4515. Thank you for your attention on this important matter.

Sincerely,

Chuck

Charles E. Grassley
Chairman
Senate Finance Committee

Bill: I appreciate that you changed your mind on the constitutionality of the False Claims Act between 1992 and your confirmation to your present position.

But, there are other ways to neuter good legislation even if it's constitutional. I don't know the number of times the courts have ruled, or DOJ did something harmful, to carrying out the spirit of the False Claims. And, thank God, I, or Senator Leahy, have been successful passing legislation to correct such judicial or administrative mal-interpretation.

DOJ's action on Granston is just one more example. Don't do hurtful action to a very successful piece of legislation again. Successful?? It returned $63 B to the treasury. Yes, successful!!