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Confidential Pfizer Document Shows the Company Observed 1.6 Million Adverse Events Covering Nearly Every Organ System

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Region: Europe
Theme: Science and Medicine

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Over 10,000 categories of nearly 1.6 million adverse events – many of them serious and debilitating – brought to you by Pfizer!

You might not have heard it in the news, but in recent months, Pfizer's pharmacovigilance documents requested by the European Union's drug regulator, the European Medicines Agency, have been released. They show that Pfizer knew about a sickening level of injury early on. An August 2022 document shows that the company already had observed the following scope of vaccine injury:

- 508,351 individual case reports of adverse events containing 1,597,673 events;
- One-third of the AEs were classified as serious, well above the standard for safety signals usually pegged at 15%;
- Women reported AEs at three times the rate of men;
- 60% of cases were reported with either "outcome unknown" or "not recovered," so many of the injuries were not transient;

Highest number of cases occurred in the 31-50 year age group, and 92% did not have any comorbidities, which makes it very likely it was the vaccine causing such widespread, sudden injury.

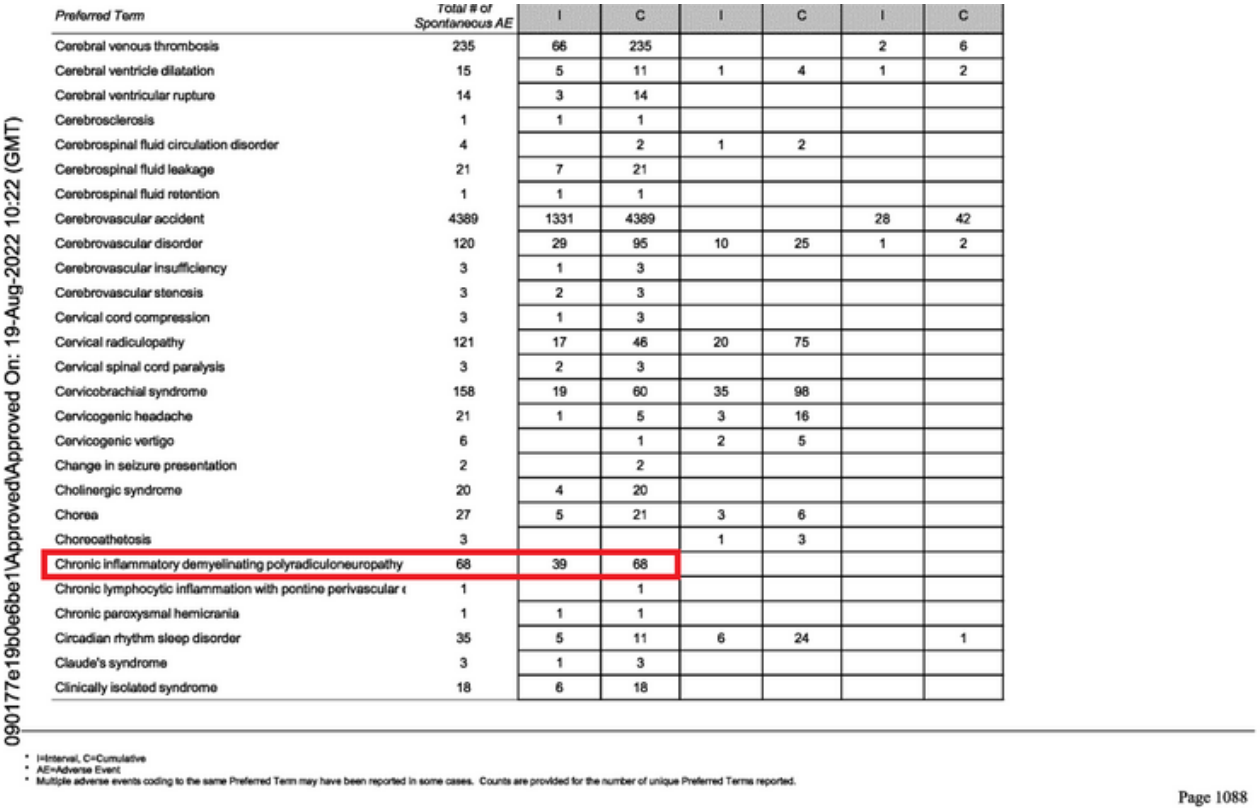
These numbers alone suggest that all COVID shots should be defunded and Congress must immediately remove liability protections from the manufacturers. But a more recent document released by the Europeans is even more devastating, because it breaks down the 1.6 million adverse events observed by Pfizer by category and subcategory of ailment and injury.

The 393-page confidential Pfizer document, dated Aug. 19, 2022, shows that Pfizer observed over 10,000 categories of diagnosis, many of them very severe and very rare. For example:

- Pfizer was aware of 73,542 cases of 264 categories of vascular disorders from the shots. Many of them are rare conditions.
- There were hundreds of categories of nervous system disorders, totaling 696,508 cases.
- There were 61,518 AEs from well over 100 categories of eye disorders, which is unusual for a vaccine injury.
- Likewise, there were over 47,000 ear disorders, including almost 16,000 cases of tinnitus, which even Mayo Clinic researchers observed as a common but often devastating side effect early on.
- There were roughly 225,000 cases of skin and tissue disorders.
- There were roughly 190,000 cases of respiratory disorders.
- Disturbingly, there were over 178,000 cases of reproductive or breast disorders, including disorders you wouldn't expect, such as 506 cases of erectile dysfunction in men.
- Very disturbingly, there were over 77,000 psychiatric disorders observed following the shots, lending credence to Dr. Peter McCullough's research observing case studies showing psychosis correlating with vaccination.
- 3,711 cases of tumors – benign and malignant
- Of course, there were almost 127,000 cardiac disorders, running the gamut of about 270 categories of heart damage, including many rare disorders, in addition to myocarditis.
- There were over 100,000 blood and lymphatic disorders, for both of which there's a wealth of literature linking them to the spike protein.

When reading what Pfizer knew early on juxtaposed to independent studies, it's clear that nobody could have mistaken most of these AEs for mere incidental ailments. Here is a list of 3,129 case studies chronicling vaccine injury in every organ system observed in this Pfizer document.

What is so jarring is that there are hundreds of very rare neurological disorders that reflect something so systemically wrong with the shots, a reality that was clearly of no concern to the manufacturers and regulators alike. One of the infamous cases of vaccine injury was Maddie de Garay, an Ohio teen who became disabled for life immediately after participating in the Pfizer clinical trial. Her story is chronicled in chapter 16 of my book. I checked this confidential document and found that they knew of 68 cases of her rare diagnosis, chronic inflammatory demyelinating polyneuropathy.



Preferred Term	Total # of Spontaneous AE	I	C	I	C	I	C
Cerebral venous thrombosis	235	66	235			2	6
Cerebral ventricle dilatation	15	5	11	1	4	1	2
Cerebral ventricular rupture	14	3	14				
Cerebrosclerosis	1	1	1				
Cerebrospinal fluid circulation disorder	4		2	1	2		
Cerebrospinal fluid leakage	21	7	21				
Cerebrospinal fluid retention	1	1	1				
Cerebrovascular accident	4389	1331	4389			28	42
Cerebrovascular disorder	120	29	95	10	25	1	2
Cerebrovascular insufficiency	3	1	3				
Cerebrovascular stenosis	3	2	3				
Cervical cord compression	3	1	3				
Cervical radiculopathy	121	17	46	20	75		
Cervical spinal cord paralysis	3	2	3				
Cervicobrachial syndrome	158	19	60	35	98		
Cervicogenic headache	21	1	5	3	16		
Cervicogenic vertigo	6		1	2	5		
Change in seizure presentation	2		2				
Cholinergic syndrome	20	4	20				
Chorea	27	5	21	3	6		
Choreoathetosis	3			1	3		
Chronic inflammatory demyelinating polyradiculoneuropathy	68	39	68				
Chronic lymphocytic inflammation with pontine perivascular	1		1				
Chronic paroxysmal hemicrania	1	1	1				
Circadian rhythm sleep disorder	35	5	11	6	24		1
Claude's syndrome	3	1	3				
Clinically isolated syndrome	18	6	18				

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Page 1088

The broad scope of injuries affecting every single organ system is simply extraordinary. Yet to this day, the FDA continues to criminally label the Pfizer shot as safe and effective. To this day, the label indicates the shot is a fully protective vaccine and also fails to mention all of these side effects, as required by law.

Recently, Peter Doshi, editor of the British Medical Journal, wrote a letter to the FDA requesting that the agency update its labeling to reflect the reality of what we've learned about the shots. Specifically, he asked that they include the following side effects on the label: multisystem inflammatory syndrome in children, pulmonary embolism, sudden cardiac death, neuropathic and autonomic disorders, decreased sperm concentration, heavy menstrual bleeding, and detection of vaccine mRNA in breast milk. The causal relationship of all these AEs to the vaccine is backed by substantial research, surveys, and adverse event reporting systems.

Unfortunately, the FDA denied the causal relationship between any of these side effects and the COVID shots. Even with regard to the request that officials clarify on the label that the shots don't stop transmission, the FDA replied, "We are not convinced that there is any widespread misconception about this."

"Product labeling should be informative and accurate, not promotional. The law requires it, and following the law shouldn't be optional," bemoaned Doshi and the other authors in a piece at TheHill.com.

The question is whether Republicans in the House will force the FDA to comply with the law by using the leverage of the appropriations bills for the FDA and HHS. So far, there has been no reckoning for their false marketing and the devastating human toll it has cost. Oh, and that is just the short-term human toll.

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Featured image: A hand holding an mRNA vaccine vial. (Spencer Davis / Unsplash)

Annex: Periodic Safety Update Report # 3 for COVID-19 mRNA Vaccine (BNT162b2)

PERIODIC SAFETY UPDATE REPORT #3
for
ACTIVE SUBSTANCE: COVID 19 mRNA vaccine (nucleoside modified) (BNT162b2)[1]

ATC CODE: J07BX03[2]

AUTHORISATION PROCEDURE in the EU: Centralised

INTERNATIONAL BIRTH DATE (IBD)[3]: 19 DECEMBER 2020

EUROPEAN UNION REFERENCE DATE (EURD): 19 DECEMBER 2020

INTERVAL COVERED BY THIS REPORT:

19 DECEMBER 2021 through 18 JUNE 2022

DATE OF THIS REPORT: 18 AUGUST 2022

SIGNATURE: [redacted] **Date: 18 August 2022**

NAME AND CONTACT DETAILS OF THE QPPV:	
EU Qualified Person Barbara De Bernardi, MD [redacted]	telephone: [redacted] fax number: [redacted] email: [redacted]
EU Qualified Person Deputy [redacted]	telephone: [redacted] fax number: [redacted] email: [redacted]

Marketing Authorisation Holder:
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany

Please note that this report may contain unblinded clinical trial information.

[1] Change of the name of the active substance from COVID-19 mRNA Vaccine (nucleoside modified) to Tozinameran in EU (EMEA/H/C/005735/X/0044/G).
[2] Implementation as new ATC code starting from 01 January 2022.
[3] Earliest conditional approval date.

EXECUTIVE SUMMARY

This is the 3rd Periodic Safety Update Report (PSUR) for COVID-19 mRNA vaccine (nucleoside modified) (Coronavirus disease 2019 [COVID-19] mRNA Vaccine, COMIRNATY®, also referred to as BNT162b2)[4], covering the reporting interval 19 December 2021 through 18 June 2022.

A product description is provided in Table 1.

Table 1. Product Description[a]

Therapeutic class	The active substance of the COVID-19 mRNA vaccine is a highly purified single-stranded, 5'-capped mRNA produced using a cell-free *in vitro* transcription from the corresponding DNA template, encoding the viral spike (S) protein of SARS-CoV-2.		
Mechanism of action	The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralising antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.		
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 years of age and older.		
Formulation and route of administration	The vaccine is a white to off-white frozen solution, is administered intramuscularly in the deltoid muscle and is available in 3 presentations.		
	Purple cap (for 12 years of age and older)	*Grey cap (for 12 years of age and older)*	*Orange cap (for age 5 years to <12 years)*
	Concentrate for dispersion for injection	Dispersion for injection	Concentrate for dispersion for injection
	30 micrograms/dose	30 micrograms/dose	10 micrograms/dose
	Requires dilution	Do not dilute	Requires dilution
	PBS/Sucrose presentation	Tris/Sucrose presentation	Tris/Sucrose presentation
Posology	Individuals aged 12 years and older The 2 formulations (purple cap and grey cap) are administered as 30 µg/dose as a primary series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart. A booster dose (third dose) may be administered approximately 6 months after the second dose in individuals 16 years of age and older. Individuals aged 5 through 11 years The Tris/Sucrose formulation (orange cap) is administered after dilution as a primary series of 2 doses (0.2 mL) at greater than or equal to 21 days (preferably 3 weeks) apart. A booster dose may be administered at least 6 months after the second dose.		

a. As per information reported in the Core Data Sheet version 13.0 dated 10 May 2022, in effect at the end of the reporting period. Since 17 June 2022, BNT162b2 is approved in individuals 6 months of age and older, as the paediatric Tris/Sucrose presentation - maroon cap was approved in the United States. Please refer below for details on this new formulation.

Abbreviations: COVID-19 = coronavirus disease 2019; DNA = deoxyribonucleic acid; LNP = lipid nanoparticle; mRNA = messenger ribonucleic acid; PBS = phosphate buffered saline; RNA = ribonucleic acid; S = spike; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

[4] Also referred to as Pfizer-BioNTech COVID-19 vaccine in other Company's documents.

On 17 June 2022, an additional formulation was approved first in the United States (US): the paediatric Tris/Sucrose presentation - maroon cap (3 micrograms/dose) for individuals aged between 6 months and 4 years. This is a concentrate for dispersion for injection, to be administered after dilution intramuscularly in the anterolateral aspect of the thigh (or in the deltoid muscle in individuals 1 year of age and older) as a primary series of 3 doses (0.2 mL). The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose.

Cumulatively, it is estimated that 66,656[5] participants have received BNT162b2 in sponsor initiated clinical trials worldwide, with 59,260 participants exposed to BNT162b2, 1836 participants exposed to clinical candidates developed as variant vaccines based on BNT162b2 (BNT162b2 [B.1.351], BNT162b2 [B.1.1.7 + B.1.617.2], BNT162b2 [B.1.617.2] and BNT162b2 [B.1.1.7]) and 633 participants exposed to other early development candidates (including BNT162a1 [30], BNT162b1 [411] to, BNT162b3 and BNT162c2 [96 participants each]). There were 7044 participants exposed to blinded therapy and 5871 to placebo.

There were 372 participants who received BNT162b2 as a study vaccine or as a comparator in another Pfizer clinical development program (B747).

From the receipt of the first temporary authorisation for emergency supply on 01 December 2020[6] through 18 June 2022, approximately 3,555,998,805 doses of BNT162b2 were shipped from BioNTech and Pfizer worldwide, corresponding to 2,693,922,584 estimated administered doses.

During the current reporting interval (19 December 2021 through 18 June 2022), approximately 1,115,282,160 doses of BNT162b2 were shipped from BioNTech and Pfizer worldwide, corresponding to 843,724,061 estimated administered doses.[7]

Overall, through 18 June 2022, a total of 143,844,450 adult Tris/Sucrose doses and a total of 229,269,400 paediatric Tris/Sucrose doses were shipped worldwide.

Additionally, as per data provided by license partner (LP) in Hong Kong, Macau, and Taiwan, 27,314,884 doses of BNT162b2 were administered cumulatively through 21 June 2022 and 12,126,713 dose were administered from 19 December 2021 through 21 June 2022.

[5] Participants to more than one clinical trial (e.g., extension study) are counted once when receiving the same treatment in the parent study.

[6] BNT162b2 received first temporary authorisation for emergency supply under Regulation 174 in the UK on this date.

[7] License Partner data are not included in the reported amount.

Details about BNT162b2 marketing authorisation by type of formulation, and population include:

- The PBS/Sucrose 30 µg formulation for individuals aged 16 years and older has received approvals in 103 countries[8] including full (5), conditional (49), emergency use authorisation (EUA) and other type of approvals (52).
- The PBS/Sucrose 30 µg formulation for individuals aged between 12 and 15 years has received approvals in 81 countries[9] including full (2), conditional (46), EUA and other type of approvals (34).
- The Tris/Sucrose 30 µg formulation for individuals aged 12 years and older has received approvals in 73 countries[10] including full (3), conditional (44), EUA and other type of approvals (28).
- The Tris/Sucrose 10 µg formulation for individuals aged between 5 and 11 years has received approvals in 79 countries[9] including full (2), conditional (43), EUA and other type of approvals (35).
- The Tris/Sucrose 3 µg formulation for individuals aged between 6 months and 4 years has received EUA approval in the US.
- The booster dose has received approvals in 83 countries[11] including full (3), conditional (46), EUA and other type of approvals (36).

The use of BNT162b2 in individuals aged 12 years and older is under EUA in Hong Kong and under a special import permit in Macau and Taiwan. In Hong Kong only the PBS/Sucrose – Purple cap formulation was approved.

The marketing authorisation holders (MAHs) of BNT162b2 are the following: BioNTech (56 countries); Pfizer (40 countries), the local Ministry of Health (MoH) and local Government (3 countries each), the LP Fosun Pharma (2 countries), and the LP Hemas (1 country).

In addition, World Health Organization (WHO) had approved the Emergency Use Listing (EUL) of BNT162b2.

There were no marketing authorisation withdrawals for safety reasons during the reporting interval.

[8] For this population, both conditional and EUA approvals were granted in the United Kingdom (UK), full and EUA approvals in Singapore and the US.

[9] Both conditional and EUA approvals for this population were granted in the UK.

[10] For this population, both conditional and EUA approvals were granted in the UK, full and EUA approvals in the US.

[11] For this population, both conditional and EUA approvals were granted in the UK, full and EUA approvals in Singapore.

During the reporting period, no actions have been taken with respect to BNT162b2 for safety reasons, either by a Health Authority (HA) or by the MAH. Although not considered by definition a regulatory action taken for safety reasons because it does not significantly impact the benefit risk balance of use of the product in authorised populations, due to the receipt of spontaneous reports of Guillain-Barré syndrome (GBS) after vaccination with mRNA COVID-19 vaccines including BNT162b2, Pharmaceuticals and Medical Devices Agency (PMDA) in Japan has required class changes to include GBS in the important precautions section of the Japan package insert[12] and inclusion of GBS as an important potential risk in the Japan Risk Management Plan (RMP)[13]. It should be noted that based on PMDA assessment, the frequency of reported cases of GBS was not significantly higher than the background incidence in any gender or age group and a mechanism is not known.

The reference safety information (RSI) for this PSUR is the COVID 19 mRNA vaccine Core Data Sheet (CDS) version 13.0 dated 10 May 2022, in effect at the end of the reporting period.

Four (4) previous CDS versions (version 9.0 dated 02 December 2021[14], version 10.0 dated 21 December 2021, version 11.0 dated 14 January 2022 and version 12.0 dated 23 March 2022[14]) were also in effect during the reporting period.

Safety-related changes included updates of the following sections: 4.2 *Posology and method of administration* (CDS version 13.0), 4.8 *Undesirable effects* (CDS versions 10.0, 11.0 and 13.0), 5.1 *Pharmacodynamic properties* (CDS versions 10.0 and 11.0), Appendix A, Appendix B (CDS version 10.0).

During the reporting period, the following signals were addressed:

- Signals determined not to be risks: Appendicitis, Hemolytic anemia, Uveitis, Exacerbation and/or flare of underlying autoimmune disease or inflammatory disorders, Capillary leak syndrome (CLS), Corneal graft rejection, Vasculitis, Cerebral venous sinus thrombosis (CVST), Lymphocytic colitis, Chronic urticaria, Polymyalgia rheumatica (PMR), Subacute thyroiditis (SAT), Cerebrovascular accident (CVA)/stroke, Amenorrhea, Heavy menstrual bleeding, Loss of/altered taste and smell.
- Signal determined to be an identified risk (not important): Irritability.

[12] The Japan package insert was updated by the MAH during the current reporting period, on 10 June 2022.

[13] Guillain-Barré syndrome was added as important potential risk to the safety concerns in the Japan RMP after Data Lock Point (DLP) of this PSUR, on 22 June 2022.

[14] This version of the CDS did not include any safety-related changes.

- Signal determined to be an important identified risk: Myocarditis and pericarditis[15].
- Ongoing signal: Hearing loss.

Commitments to be addressed in this PSUR were received from European Medicines Agency (EMA), World Health Organization (WHO) and Health Canada. The Pharmacovigilance Risk Assessment Committee (PRAC) requests were included in the Assessment Reports (ARs) of the Summary Safety Reports (SSRs), in the Final AR of PSUR #2 and in signals' AR. The WHO requests were included in the EUL Procedure. Topics covered in these commitments are summarised in the table below.

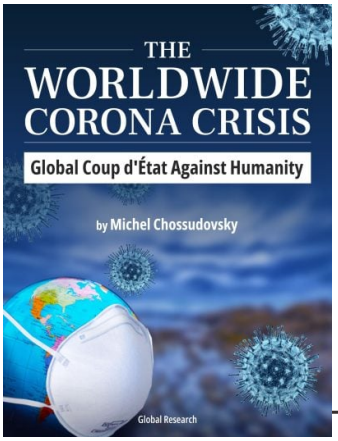
HA	Commitment(s)
PRAC	Closely monitoring multisystem inflammatory syndrome in children and in adults (MIS-C/A) and reporting of new cases of MIS.
	Observed vs Expected (O/E) analyses using at least no risk window, 14-day risk window and 21-day risk window and sensitivity O/E analyses which include the processed cases plus the backlog cases.
	Assessment of the used study methods in not (yet) peer-reviewed retrieved relevant literature to determine if the study results are valid or not.
	More effort in presenting/evaluating the cases considered to be confounded and present the risk factors for developing the respective conditions.
	Use of follow-up questionnaires anaphylaxis and vaccine associated enhanced disease/vaccine associated enhanced respiratory disease (VAED/VAERD).
	Presentation of all relevant literature concerning the safety of Comirnaty (also besides the database Medline and Embase) during the reporting period.
	Safety evaluation of sudden sensorineural hearing loss, tinnitus, glomerulonephritis and nephrotic syndrome, autoimmune hepatitis, dizziness, acquired haemophilia, IgA nephropathy.
	Continue to report on the number of processed cases downloaded from EudraVigilance.
	Estimate of the exposure of "third doses" in European economic area (EEA) countries, per country and by age group.
	Handling and dosing errors as result of different BNT162b2 formulations on the market.
WHO	Pregnancy outcome in clinical trials.
	Data on low- and middle-income countries (LMICs) populations with HIV, malnutrition and tuberculosis and other infectious diseases.
Health Canada	Review on the new variant "Omicron" and other variants.
	Safety evaluation of tinnitus and hearing loss.

According to the European Risk Management Plan (EU-RMP) version 4.0 adopted on 26 November 2021, in effect at the beginning of the reporting period, safety concerns for BNT162b2 are:

- Important identified risks: Anaphylaxis; Myocarditis and Pericarditis
- Important potential risk: Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)
- Missing information: Use in pregnancy and while breast feeding; Use in immunocompromised patients; Use in frail patients with co-morbidities (eg, chronic

[15] This refers to the company core list of safety concerns. Myocarditis and pericarditis were already important identified risks in the EU-RMP, US-PVP and many country-level RMP addendums.

Click here to read the full document.



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