EXPERT REPORT

in the case
of

Sam White & Others

V

MHRA

PJH Law
18a Maiden Lane
Stamford
Lincolnshire
PE9 2AZ

Dated 28th December 2021 **Alexandra Latypova**

Contents:

1-3 - Introduction

4 - Background and Experience

5-8 - Personal Reasons for This Analysis

9 - Methodology

10-11 - Questions Examined in My Analysis

12 - The Covid19 Vaccine Dataset

13-14 - The Flu Vaccine Dataset

15-16 - Summary of Findings

17-21 - Limitations of this Analysis

22-25 - Results for Finding 1

26-38 - Results for Finding 2

39-43 - Additional Information

44 - Declaration of Responsibilities

Introduction:

1. Mass vaccination with covid vaccines has been under way for nearly a year now in the US and worldwide. Millions of doses have been administered, majority are the so-called mRNA vaccines manufactured by Pfizer, Moderna, Janssen, Astra Zeneca and others.
2. Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/about.html is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.
3. As stated on the CDC website: "VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern".

Background and Experience:

4. I am a retired business executive with 20+ years of experience in pharmaceutical and medical device Research and Development (R&D) industry as well as in a broader data analytics field. Throughout my career my primary expertise was collection and analysis of data from global clinical trials. My experience covers all therapeutic areas of drug development. I was senior executive at several clinical research organizations (CROs) conducting data collection and analysis on behalf of pharmaceutical companies for the purpose of clinical trial data submissions to regulatory authorities such as FDA, EMA and other relevant agencies. I left the Pharmaceutical R&D industry in 2014. Prior to working in the CRO field, I worked as analytical consultant in the area of econometrics and litigation support, working primarily for pharmaceutical and medical device clients. I hold Master of Business Administration degree from Dartmouth College, Hanover, NH.

Personal Reasons for This Analysis:

5. I personally have never been against vaccines in general. I received many vaccines during my life, and my children have always been up to date on

childhood vaccinations. Prior to 2020 I did not know anyone personally who have died or was injured by the vaccines. I now know several people who have been injured by the Covid 19 vaccines, and I have witnessed a young man (late 20's – early 30's) falling unconscious immediately post Covid 19 vaccine injection at my local Safeway Pharmacy. I saw his CDC issued vaccination card lying on the floor next to him. I do not know whether this young man survived.

6. Prior to 2020 and while working in the pharmaceutical industry I had general trust in the scientific method and I observed most people in the industry, including staff at the FDA working honorably and following their own procedures and guidelines.
7. In 2020 I was following the industry news closely, and I decided to use my own skills and experience and publicly available VAERS data to evaluate for myself and my family whether these vaccines are safe and reliable products as now advertised broadly in media.
8. The following analysis is all my own work. Everything I say below is based on fact and data. My analysis is easily reproducible and can be checked by anyone with intermediate skills in Microsoft Excel software. I have included files that I downloaded from VAERS and used in this analysis in the Technical Appendix.

Methodology:

9. Since most people believe that vaccines in general are very safe, I decided to study the patterns of VAERS data for Covid 19 vaccines manufactured by Pfizer, Moderna and Janssen in comparison to the seasonal flu vaccines from a variety of manufacturers. Seasonal flu vaccines are some of the most widely used vaccine products and are given annually to approximately 50% of the US population (according to CDC). Thus, they represent a reasonable comparison for Covid 19 vaccines. I decided to examine the data in relation to specific manufacturing lot numbers.

Questions Examined in My Analysis:

10. Are Covid 19 vaccines similar to the seasonal flu vaccines in regard to the overall patterns of Severe Adverse Events and Death Reports?
11. Are there unusual patterns in manufacturing lot-to-lot variability for Covid 19 vaccines in comparison to the seasonal flu vaccines?

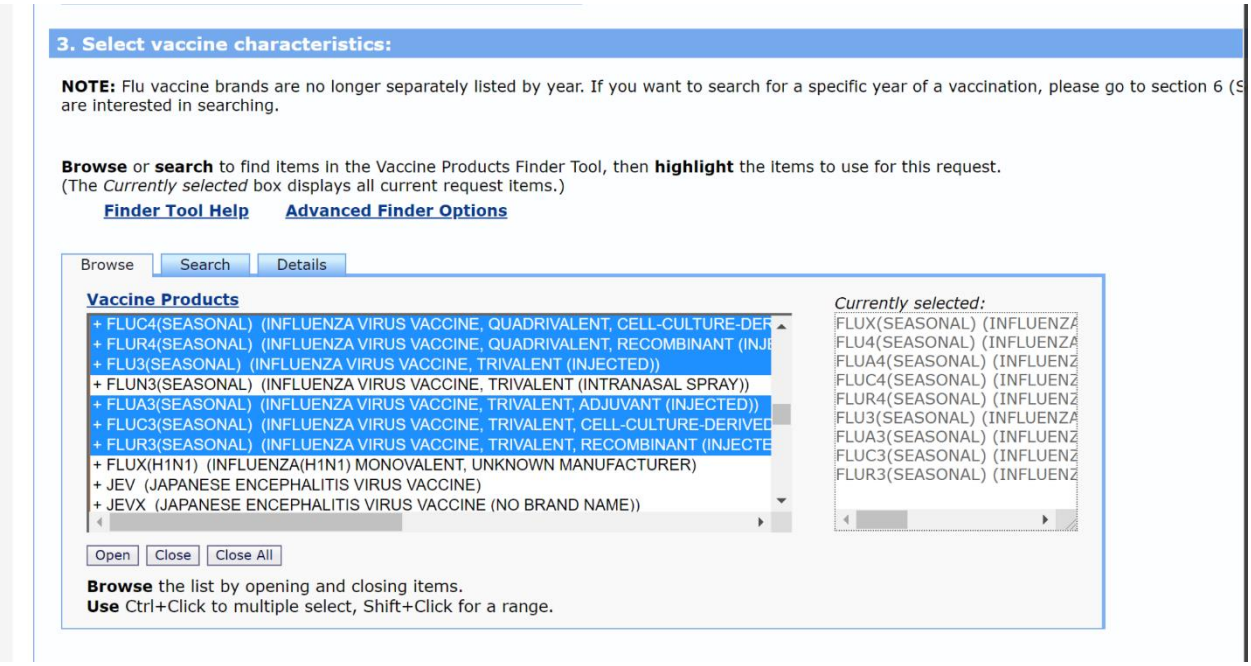
The Covid19 Vaccine Dataset:

12. The dataset for my analysis was downloaded from the VAERS website (as of December 10, 2021), limited to the reports submitted from the United States only. The final dataset was merged from several files available in VAERS with the following information:

    - Vaccine Lot Number
    - Manufacturer
    - Number of Adverse Event (AE) Reports that contained this Lot Number
    - Number of Severe Adverse Event (SAE) Reports that contained this Lot Number. In my analysis Severe Adverse Events were identified by checking "Severe" tab in Section 5 of VAERS search engine.
    - Number of Death reports that contained this Lot Number

The Flu Vaccine Dataset:

13. The dataset with the same parameters as above was downloaded from VAERS for the following 9 flu vaccine products.



14. Intranasal sprays and H1N1 products were not included. I downloaded all available manufacturers and all available years of data, for the United States only.

Summary of Findings:

15. My analysis revealed two findings for covid vaccines:

- Finding 1: The total number of adverse events, serious adverse events and deaths reported in lots of COVID-19 vaccines over the period of less than 12 months appear to be much higher than the total number of these events reported in lots of seasonal flu vaccines over the total available time (approx. 30 years).
    - A very large difference exists for every assessed category: total as well as maximum and average per lot adverse events, serious adverse events, and deaths.
- Finding 2: A dramatic variation of adverse events, serious adverse events, and deaths between lots of COVID-19 vaccines appears to stand in stark contrast to much lower variation of adverse events associated with the lots of the seasonal flu vaccines reported over a 30-year period.
    - This latter finding puts in question whether the manufacturing process for Covid 19 vaccines conforms to the Current Good Manufacturing Practice (CGMP) requirements from the FDA and EMA.

16. These results indicate unusual and alarming data patterns in the adverse event and deaths reporting from covid vaccines associated with specific lot numbers. These findings are easy to detect and obvious, yet no regulatory or public health agency have "detected" these signals to date. This willful inaction speaks even louder than my numbers do.

Limitations of this Analysis:

17. VAERS database is set up for spontaneous voluntary reporting, and significant under-reporting factors have been found in the past, ranging from 10-100x under-reporting of significant adverse events. A Columbia University study found that vaccine related deaths were under-reported by a factor of 20x: (PDF) COVID vaccination and age-stratified all-cause mortality risk (researchgate.net)
18. I do not have access to a definitive list of manufacturing lot numbers. This limitation is not relevant to the lot numbers that have hundreds or thousands adverse event reports associated with them, since it is impossible to mistype a lot number in the same way thousands of times from various geographic locations. Therefore, lot numbers associated with at least several adverse events should be considered valid lot numbers.
19. I do not have the complete information about the lot sizes in terms of doses for these datasets. However, it is highly unlikely that manufacturing process for these products produces lots in the range of sizes that would explain ~1000% lot-to-lot variability that I have detected in the adverse event reports. Something else must be going on to fully explain these highly unusual patterns.

20. VAERS database contains many "lot numbers" with 1 adverse event reported that are apparent typos. This problem applies to both flu vaccine and covid 19 vaccine datasets, therefore it is unlikely to significantly affect my conclusions. Note that when these typos are corrected and an event is correctly attributed to a lot with larger number of events, the variability lot-to-lot increases. Thus, if all typos were corrected, the variability for the Covid 19 vaccines would likely be even worse than I detected in my analysis. Additionally, I removed most obvious typos from both datasets prior to performing my analyses, and I further tested my conclusions when all 1- and 2 – event lots are removed from the dataset, and this does not change the conclusions.
21. Factors such as person's age and co-morbidities, temperature control for the vaccine products, distribution, transportation and storage issues, possible errors in administration, and other similar parameters can affect adverse event analysis. This limitation does not matter when looking at the total lot-to-lot variability, since both flu vaccines and Covid19 vaccines are by these possible issues. Furthermore, it is manufacturers' responsibility to endure that the product can be delivered and administered safely throughout the supply and distribution chain. My analysis looks at the total variability on the output of the system – how many people are affected, and how these negative events are distributed between 2 types of products when we look at the real-world data.

Results for Finding 1:

22. The datasets after data downloaded from VAERS and obvious typos and missing values are removed.

Seasonal Flu Vaccines	Covid 19 mRNA Vaccines
9 injectable products	3 injectable products
10+ manufacturers	3 manufacturers (Pfizer, Moderna, Janssen)
~30 years of data	<12 months of data
22,334 manufacturing lots*	24,945 manufacturing lots*
123,651 Adverse Events**	483,400 Adverse Events**
11,025 Serious Adverse Events**	48,270 Serious Adverse Events**
906 deaths**	7,457 deaths**

*Unvalidated – i.e. lots that are present in VAERS database, contains typos. This does not matter when comparing two datasets that have similar population and methods of data collection. This does not affect lot numbers that are associated with high numbers of adverse events and deaths.

**Numbers of events reported to VAERS in each category. Remove "unknown", "none", reports with missing data and some obvious typos. Not 100% of typos were removed – discussed in "Limitations".

23. As of December 3, 2021, the data comparing COVID-19 vaccine lots to seasonal flu vaccine lots from over 30 years show the following:

		AllC19Vaccines		
Range of Reports		AE Reports*	SAE**	Deaths***
>5000		1	0	0
4000	4999	3	0	0
3000	3999	8	0	0
2000	2999	50	0	0
1000	1999	124	0	0
500	999	70	3	0
100	499	109	177	5
50	99	73	54	25
25	49	156	43	72
10	24	539	68	80
5	9	1,136	102	67
1	4	22,676	3,606	624
Total Nmbr of Lots		24,945	4,053	873

		All Flu Vaccines		
Range of Reports		AE Reports*	SAE**	Deaths***
>5000		0	0	0
4000	4999	0	0	0
3000	3999	0	0	0
2000	2999	0	0	0
1000	1999	0	0	0
500	999	0	0	0
100	499	10	0	0
50	99	150	0	0
25	49	896	1	1
10	24	2883	6	0
5	9	2588	219	6
1	4	15,807	6,381	764
Total Nmbr of Lots		22,334	6,607	771

*All Lot Numbers within the Range of Adverse Event Reports
**"Serious" tag in VAERS search, included in AE Reports
*** Deaths are included in AE and SAE Reports

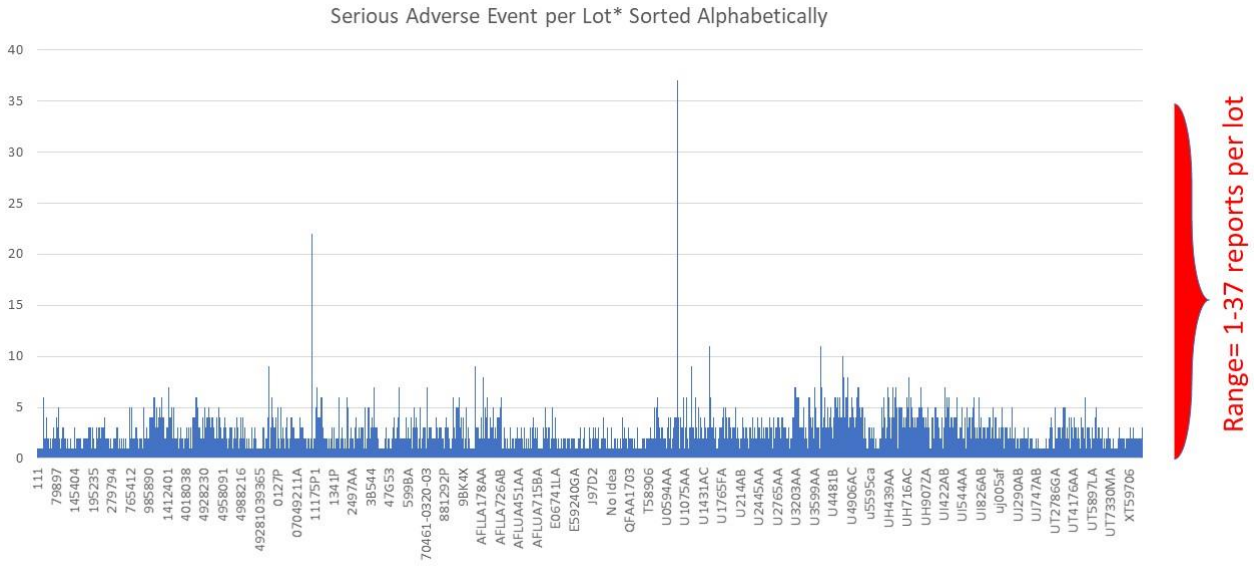
24. I found that over 30 years, the seasonal flu vaccine has never had more than 137 adverse events reported for a single lot. However, according to VAERS data, in less than one year, 5,297 adverse events were associated with one lot of the COVID-19 vaccines (Moderna 039K20A). In addition, over 1,000 reports of adverse events were linked to 186 COVID-19 vaccine lots, and another 500-999 reports of adverse events were associated with 70 lots. The analysis further shows that approximately 80% of U.S.-only adverse events reported on VAERS for COVID-19 vaccines are associated with approximately only 1% of vaccine lot numbers, and approximately 80% of serious adverse events (those involving emergency room visits, hospitalization, or death) are associated with approximately only 5% of vaccine lot numbers.

25. In conclusion, the significant differences between COVID-19 and seasonal flu vaccines on VAERS, both in terms of absolute numbers of reported adverse events and lot variation, should be raising major alarms with the vaccine manufacturers and regulatory health agencies. However, it remains unclear the extent to which vaccine manufacturers and regulatory health agencies have reviewed or conducted robust safety investigations based on the COVID-19 VAERS data.

Results for Finding 2: Manufacturing Lot-to-Lot Variability for Covid-19 Vaccines vs Seasonal Flu Vaccines

26. This part of my analysis is primarily concerned with manufacturing quality, stability, reproducibility, and other factors that relate to the consistency of the manufactured product lot-to-lot.
27. Vaccine manufacturing is a regulated industry, in the United States relevant regulations include Current Good Manufacturing Practices (CGMP), 21CFR 210.1, and related FDA regulatory guidances https://www.fda.gov/vaccines-blood-biologics/general-biologics-guidances/cmc-and-gmp-guidances, including Chemistry Manufacturing and Controls (CMC) and other relevant guidances. These regulations are harmonized with other countries' regulatory bodies via International Conference on Harmonization (ICH). While under public health emergency, some of these requirements can be waived by the regulators, it is nonetheless expected that the products are manufactured in a high-quality manufacturing environment with conformity of the product lot-to-lot.
28. Pharmaceutical products such as vaccines are expected to fall within certain narrow limits of variability on a set of controlled parameters between production lots. There is expectation and assurance from the manufacturers and regulators that the product sampled from different production lots will be essentially the same. In addition, there is assurance from manufacturers and public health authorities that Covid-19 vaccines can be used interchangeably from different manufacturers. There are no clinical studies demonstrating this, however, the public is expected to take the manufacturers' and health authorities' word for it.
29. To investigate the lot-to-lot variability for Covid-19 vaccines in comparison to the seasonal flu vaccines, I first plotted Serious Adverse Events for all manufacturing lot numbers in the Seasonal Flu dataset, sorted alphabetically:

30. Seasonal Flu Vaccines, All Lots with Non-Zero Serious Adverse Events



*Includes lots with non-zero SAE Reports only, N= 6,607 Lot Numbers

31. The chart above illustrates several findings for seasonal flu vaccines:

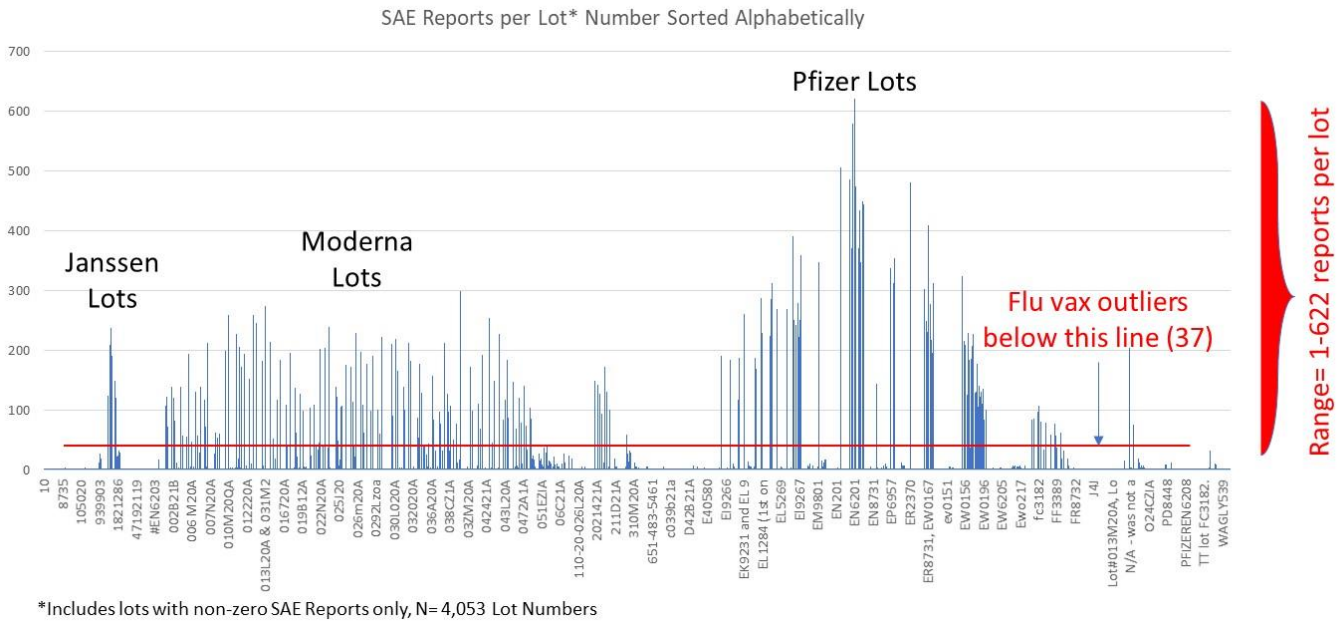
- Overall narrow range of Serious Adverse Events (SAE) per lot over the entire dataset. Nearly all lots are below 10 events per lot. Only 2 significant outliers (37 and 20+ events/lot) in the entire dataset.
- There are no significant patterns of lot-to-lot variability – the dataset looks homogeneous across all manufacturers.
- Maximum SAE observed in one lot over approx. 30 years is 37 reports/lot.

32. Descriptive statistics for the Seasonal Flu Vaccine Dataset:

	#LOTS	AE REPORTS	SAE REPORTS	DEATHS
TOTAL	22,334	123,651	9,427	906
MAX/LOT		137	37	30
AVERAGE		6	0.4	0.04
MEDIAN		1	0.0	0.00
STD DEV		9	0.9	1
COEFF VAR		169%	224%	99%

33. Next, I created the same plot for the Covid-19 Vaccine dataset, looking at the Serious Adverse Events/manufacturing lot, sorted alphabetically.

34. Covid-19 Vaccines Dataset



35. The chart above illustrates several findings for the Covid-19 vaccines:

- Overall, extremely wide range of Reports/Lot (1-622), nearly 17 times broader range vs the flu vaccines data
- Visually clearly different patterns of data associated with each of the 3 manufacturers
- Unusual "clusters" of lots with high numbers of SAE reports and lots that have 1 report or only a few reports. Note that removing typos in lot numbers does not change this conclusion or pattern.

36. The table below provides Descriptive Statistics for the Covid-19 vaccines dataset:

	#LOTS	AE REPORTS	SAE REPORTS	DEATHS
TOTAL	24,945	483,410	47,239	7,335
MAX/LOT		5,307	622	139
AVERAGE/LOT		19	1.9	0.29
MEDIAN/LOT		1	0	0
STD DEV		178	19	4
COEFF VAR		916%	1019%	1195%

37. To summarize the differences in manufacturing lot-to-lot variability between these datasets, I compared coefficient of variation for each dataset. The coefficient of variation (CV) is a relative measure of variability that indicates the size of a standard deviation in relation to its mean. It is a standardized, unitless measure

that allows one to compare variability between disparate groups and characteristics. It is often expressed in percentages. The results demonstrate that the Covid-19 dataset the CV is up to 12 times greater that that for the seasonal flu vaccines dataset.

Coefficient of Variation for Each Dataset

Product Type	SAE Reports	Deaths
ALL COVID19 VACCINES	1019%	1195%
MODERNA ONLY	1005%	1159%
ALL FLU VACCINES	224%	99%

38. In conclusion, the Covid-19 vaccines do not demonstrate consistency in manufacturing lot-to-lot. This result puts in question whether manufacturing for these products that are being injected into millions of people, including young healthy adults, children and pregnant women are compliant or consistent with manufacturing quality standards expected from medicines. The public is under assumption that these vaccines are safe, effective, and produced with the highest standards of quality. My analysis demonstrates that this is not the case based on the real-world outcomes data. These findings are very alarming and require investigation into the drivers of these unusual, high variations lot-to-lot.

Additional Information:

39. Tables below summarizes the top lots for Pfizer and Moderna products with respect to the numbers of Serious Adverse Events and Deaths for reports submitted from the United States, and from Foreign Locations.

AllC19Vaccines, US Only

Manuf	Vaccine Lot	All AE Reports*	SAE**	Deaths***
Pfizer	EN6201	3020	622	139
Pfizer	EN6200	2638	580	110
Pfizer	EN5318	2935	507	108
Pfizer	EN6198	2497	486	103
Pfizer	el9261	2015	391	100
Moderna	039K20A	5297	299	97

Pfizer	EM9810	1308	348	94
Pfizer	EL3248	2085	286	90
Pfizer	EN6202	2457	474	87
Pfizer	EL9269	1585	360	87
Pfizer	EL3249	2177	313	79
Pfizer	EL3302	1622	270	75
Moderna	013l20a	3290	274	72
Pfizer	EL8982	2067	270	71
Moderna	012L20A	3175	260	69
Moderna	010m20a	2282	260	67
Pfizer	EN6208	2754	445	66
Pfizer	EL9267	1253	251	66
Pfizer	EN6199	2307	371	65
Pfizer	EL9264	1580	242	63
Pfizer	EL0140	1842	187	63
Moderna	037K20A	3007	212	60
Pfizer	EL1283	2457	287	59

Notes:
*All Lot Numbers within the Range of Adverse Event Reports
**"Serious" tag in VAERS search, included in AE Reports
*** Deaths are included in AE and SAE Reports

All C19V Manufacturers, Foreign Locations

Manuf	Vaccine Lot	All AE	SAE	Deaths
Pfizer	EK9788	2538	729	136
Pfizer	ER1741	2130	419	19
Pfizer	EM0477	1923	773	230
Pfizer	EW4109	1913	296	6
Pfizer	EJ6797	1885	413	73
Pfizer	ER1749	1756	313	9
Moderna	039K20A	1653	121	65
Pfizer	EP9605	1525	597	53
Pfizer	ET8885	1512	208	5
Pfizer	EW3143	1484	197	6
Pfizer	EL1484	1433	354	37
Pfizer	FD6840	1286	201	12
Pfizer	FE6208	1267	164	1
Pfizer	EJ6134	1229	464	90
Pfizer	FA1027	1229	154	1
Pfizer	EW2239	1220	431	70

Pfizer	EJ6136	1209	197	41
Pfizer	Ff3319	1207	141	0
Pfizer	EM4965	1197	212	2
Pfizer	EP2163	1159	509	68

40. Additionally, based on published news reports, in January 2021 the Orange County (CA) Health Care Agency recalled the use of a Moderna COVID-19 vaccine lot following reports of allergic reactions. https://www.ocbj.com/news/2021/jan/19/oc-recalls-moderna-vaccine-lot/
41. At the time of the recall, the injections from this lot were given to 5200 people in Orange County.
42. The news article indicated that the Moderna vaccine lot 041L20A was under investigation by the Centers for Disease Control and Prevention, U.S Food and Drug Administration and the manufacturer.
43. Nevertheless, this lot from Moderna was distributed in 40 US states and territories, where it was continued being administered, which resulted in the following total Adverse Events and Deaths (see attached file with all reports for this lot in Technical Appendix):
    - Adverse Events: 2796 reports (by date of vaccination from January 2021 to November 2021)
    - Serious Adverse Events: 193 reports (by date of vaccination from January 2021 to May 2021)
    - Death: 35 reports (by date of vaccination from January 2021 to March 2021)

Declaration of Responsibilities

44. I understand that my overriding duty is to the Court, both in preparing reports and in giving oral evidence and I have complied with this duty.

    I confirm that I am aware of the requirements of Part 35, practice direction 35 and the Protocol for Instruction of Experts to give evidence in Civil Claims.

    I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert is required.

    I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.

    I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own

knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

I have drawn to the attention of the Court all matters of which I am aware that might adversely affect my opinion.

Wherever I have no personal knowledge I have indicated the source of factual information.

I have not included anything in this report which has been suggested to me by anyone, including lawyers instructing me, without forming an independent view of the matter.

Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.

At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.

I understand this report will be the evidence I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.

I believe the facts I have stated in this report are true and that the opinions I have expressed are correct. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

A Latypova
28/12/2021 18:00:04

Signed: …Alexandra Latypova……. Date: 28th December 2021

Alexandra Latypova

Source files for all data downloaded from VAERS and examined in this report are available in Technical Appendix

Alexandra Latypova

326 Barrett Dr, P2981

Stateline, NV, 89449, USA

latypova@hotmail.com

Document Details

Title	ALEXANDRA LATYPOVA EXPERT REPORT.docx
Author	Broad Yorkshire Law (claims@broadyorkshirelaw.co.uk)
Document Created on	Tue, 28 Dec 2021 16:17:18
Digital Fingerprint	e65d3105-2554-421c-900f-a206b8911c44

Document Signers Scan/Click the QR Code to view signature information

Name	Alexandra Latypova
Email	latypova@hotmail.com
Status	**SIGNED** at Tue, 28 Dec 2021 18:00:05
Signature Fingerprint	728d2a14-ca72-417e-b746-24ff2aed70ae

Document History

Tue, 28 Dec 2021 18:00:06	**Alexandra Latypova** Signed the Document