C19 Vax Lot Variability as Evidence of Toxicity and Fraud

Key findings from the VAERS data analysis by manufacturing lot number, **March 8, 2022**

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Introduction and Background

- “Team Enigma” is a collaboration on the unique topic of interest: adverse events in VAERS data by “vaccine” lot (batch) number
- Howbad.info - publish our analyses and let users research specific lot numbers for themselves
- Speakers today:
  - Craig Paardekooper, computer scientist, life sciences researcher, https://howbad.info founder
  - Sasha Latypova, pharmaceutical R&D and clinical research professional

Why Vax Lot Variability is Relevant?

Most people assume a pharmaceutical product is not variable:

- This assumption is valid for "normal" medicines, but is not valid in case of an adulterated product
- We detected extreme variability lot-to-lot in C19 injections (compared to traditional products like flu vaccines)

Adulterated products are HARMFUL and FRAUDULENT:

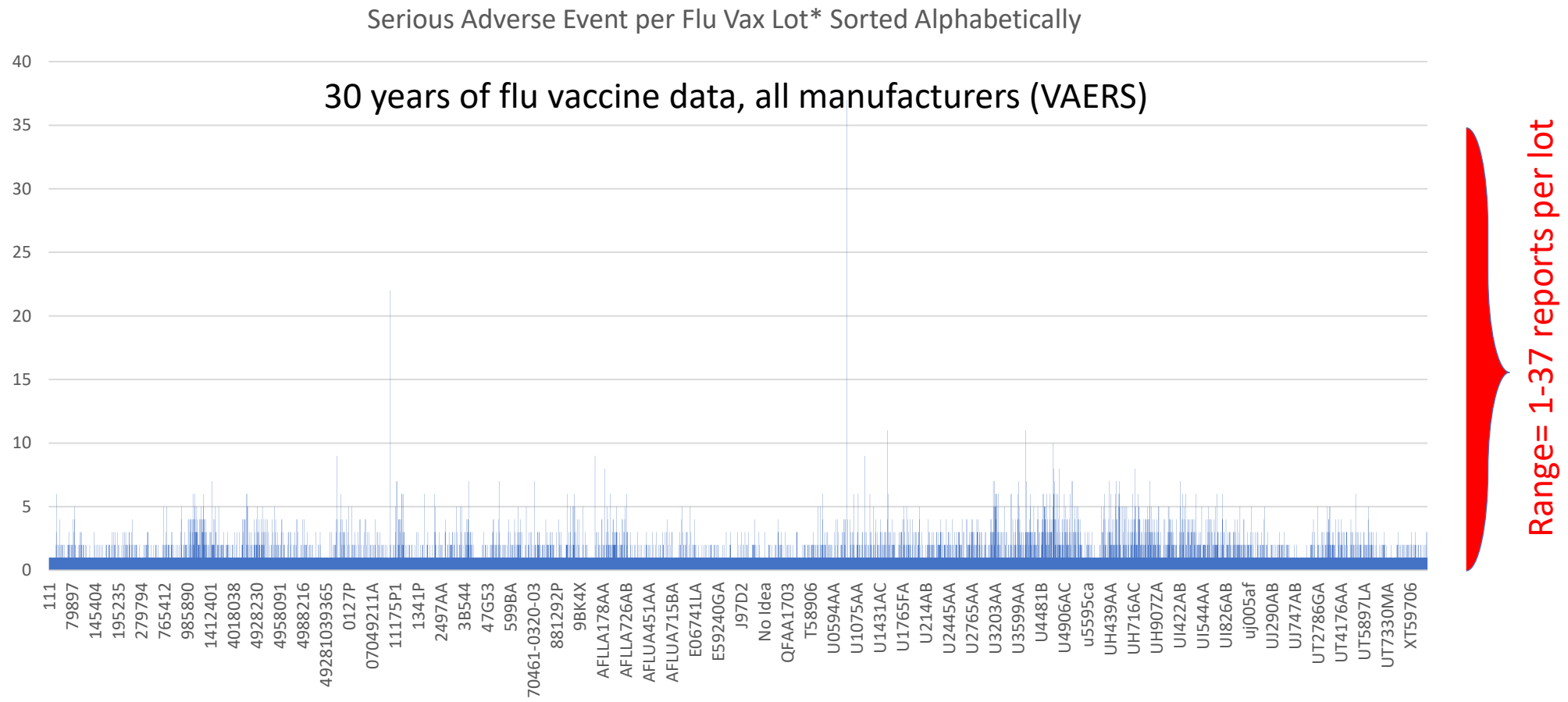
- Toxicity and lethality of C19 injections is indisputable, however, the manufacturers are generally not liable (the claims, if any, will get paid by their insurers, our governments = we all - unless we can prove their intent)
- Fraud is not indemnified – the manufacturers are liable directly, personally and will get dismantled by claims

Additional sources of evidence (other than VAERS):

- We have ~600 valid lot numbers from CDC and other gov sources – "typos" in VAERS no longer an issue
- Average manufacturing lot sizes for all manufacturers are known from internal documents
- Manufacturing and regulatory review documents, as well as internal email communications in our possession evidence fraud and can guide future investigations/ legal discovery efforts

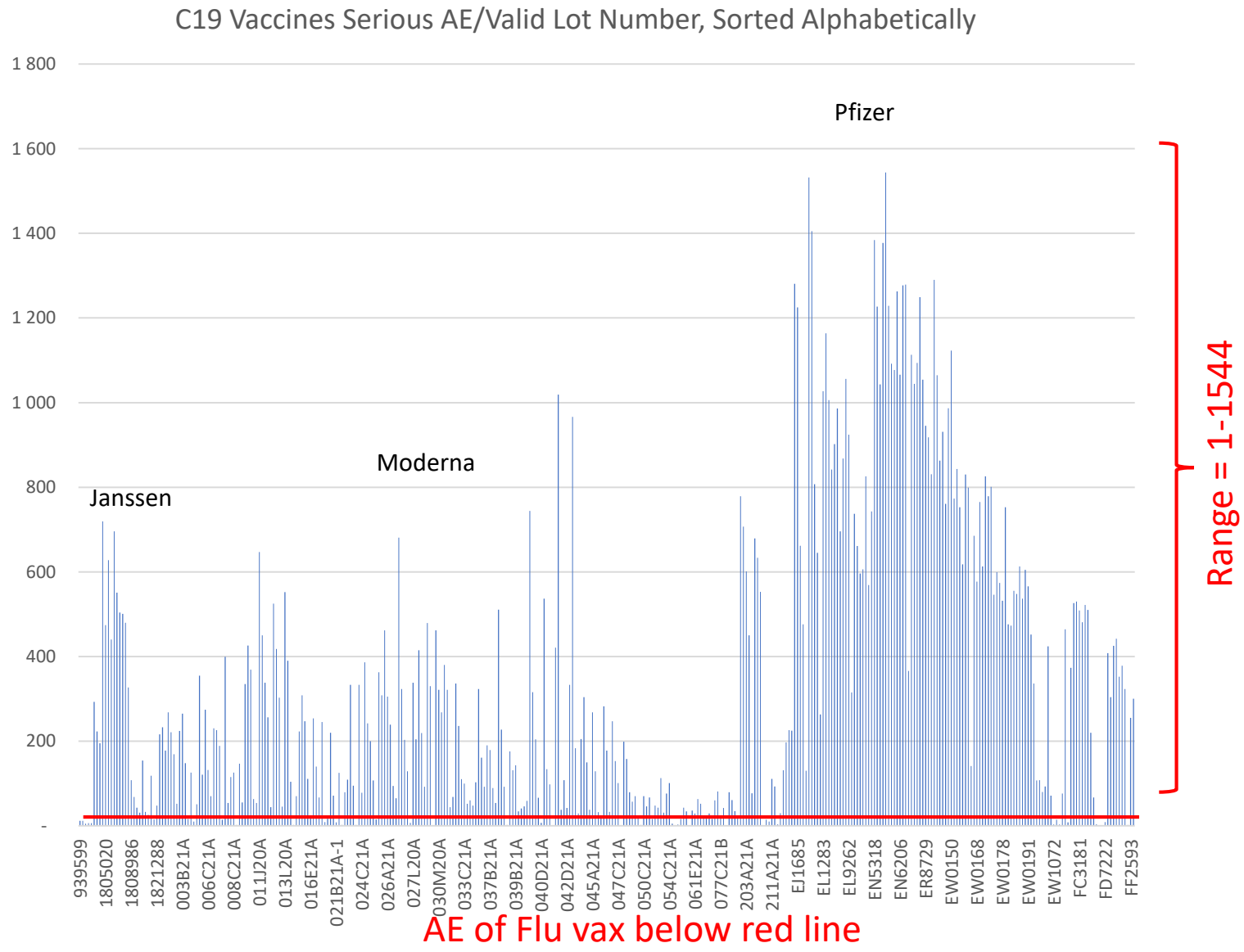
Excessive Lot-to-Lot Variability

Flu Vaccines: Consistent product across many manufacturers, lots, years, only 2 outliers



*Includes lots with non-zero SAE Reports only

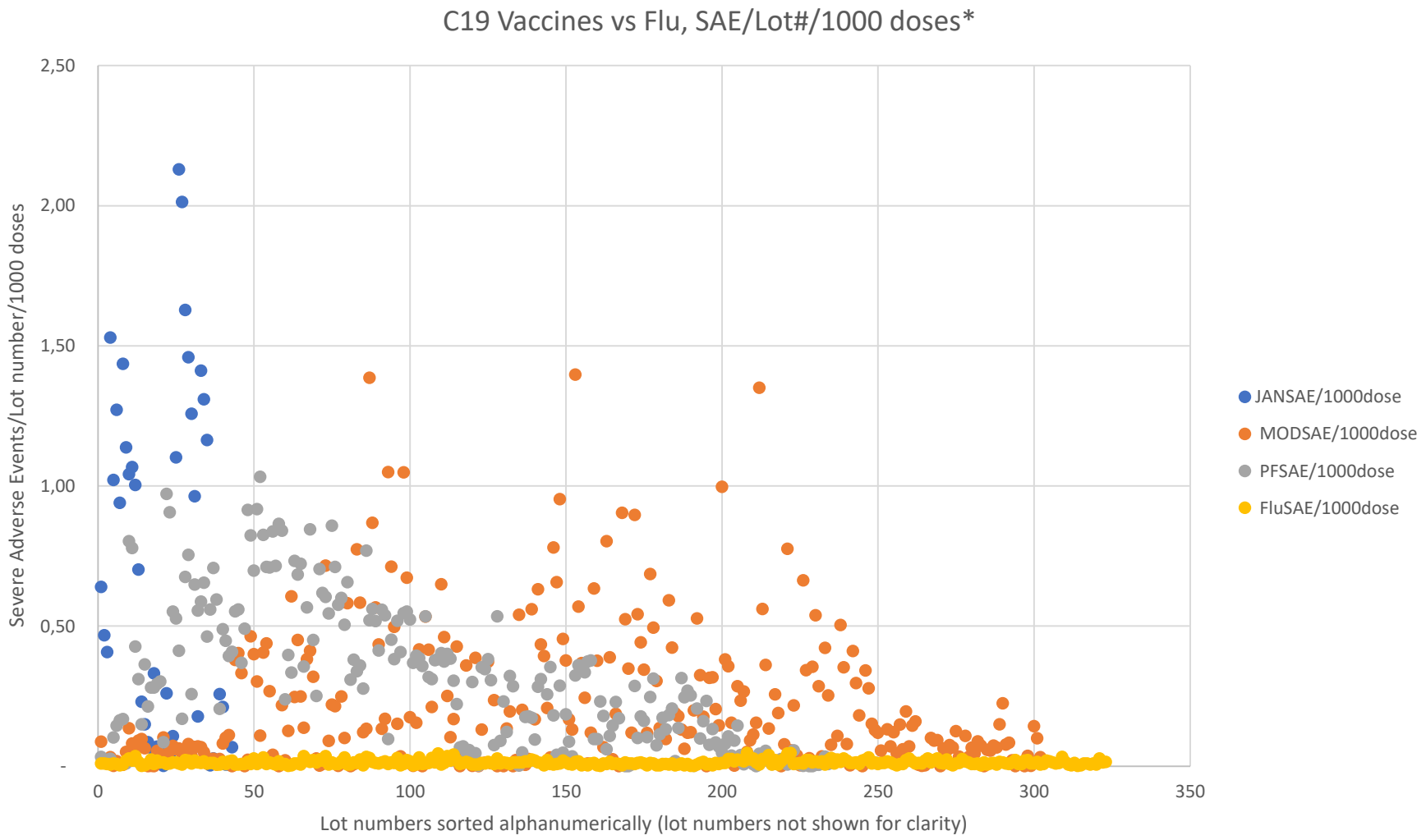
C19 Vaccines, Valid Lot Numbers Only*



*Includes 371 Lot numbers from CDC list, US data only

*C19 Vaccines, valid lot numbers (N~600)
vs
Flu vaccines (323 lots for 2019)

Average lot size:
Pfizer = 1.6m
Moderna = 1.1m
Janssen = 500k
Flu = 500k



We cannot assume the “same formulation” in every lot, vial or dose with this degree of variation

mRNA Injections are **Fraudulent Products** *(and regulators know this)* – Documented Evidence

FDA Good Manufacturing Practices (GMP): 21CFR210.1

- High quality, consistency and purity standards for drugs/vaccines:
  - Expectation that every new lot/batch is "almost the same" as all previous lots
  - Expectation that vaccines from different manufacturers for a disease indication are "the same" or interchangeable product
- Current FDA GMP regulations were developed after several adulterated or poorly tested products poisoned and killed 100s of people (early 1900's to 1960's)
- "The failure to comply …shall render such drug to be adulterated …shall be subject to regulatory action".

Opinion of the European Regulators (EMA) on Nov 30, 2020:

- Pfizer/BioNTech manufacturing processes (at all sites) were NOT GMP compliant:
  - Not able to produce consistent product
  - No plan/deadline as to when they were going be in compliance
- 117 Major Objections and Concerns listed by the regulators on 30+ pages:
  - For any normal product, all would need to be resolved before authorization would happen

If non-GMP compliant production is allowed, ANY ingredient or process step can be manipulated accidentally or on purpose!

33 Pfizer C19 Vaccine Lots for 28 million doses had been produced before EMA Opinion. They were shipped anyway.

Data From VAERS as of 12/2021

Lot (batch)	# Vials	Date manuf	All AE	Perm Disabil	Life Threat	Deaths
ED3938	19,010	16-Jul-20	-	-	-	-
EE3813	30,193	29-Jul-20	-	-	-	-
EE8492	67,665	5-Aug-20	656	123	9	2
EE8493	68,445	5-Aug-20	597	118	14	2
EG5411	201,258	3-Sep-20	-	-	-	-
EH9899	179,400	7-Oct-20	3,630	45	34	23
EH9978	304,869	23-Sep-20	-	-	-	-
EJ0553	164,580	25-Sep-20	476	74	19	20
EJ0701	200,265	26-Sep-20	-	-	-	-
EJ0724						8
EJ1685						4
EJ1686						8
EJ1688						2
EJ1691						-
EJ6795						7
EJ6796						5
EJ6797						3
EK1768						4
EK2808						-
EK4175						7
EK4176	131,625	16-Oct-20	1,339	39	26	34
EK4237	140,985	5-Nov-20	122	18	1	2
EK5730	191,295	22-Oct-20	4,102	37	40	24
EK9231	230,685	4-Nov-20	3,860	63	46	49
EL0140	155,610	29-Oct-20	1,856	24	28	61
EL0141	156,195	29-Oct-20	499	68	12	14
EL0142	138,060	29-Oct-20	1,802	28	36	42
EL0725	272,073	30-Oct-20	919	68	20	50
EL0739	294,239	3-Nov-20	1,023	131	33	19
EL1283	245,895	11-Nov-20	2,492	48	51	60
EL1284	214,305	17-Nov-20	2,790	40	34	45
EL1484	277,608	4-Nov-20	1,478	152	32	37
EL3246	204,360	19-Nov-20	2,417	54	24	43
Total	5,724,844		40,097	1,614	747	1,025

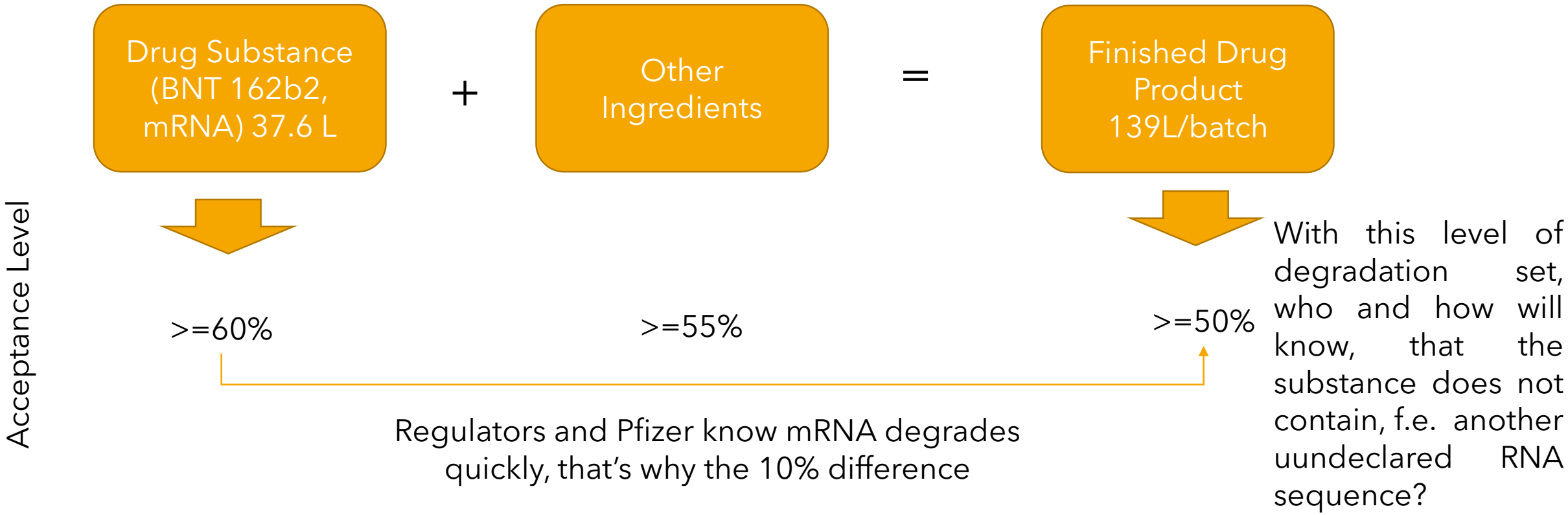
- 40,000+ Injuries
- 1,600+ Permanent Disabilities
- 747 Life Threatening Events (we don't know if later survived)
- 1,025 Deaths
- Includes 1 death of a child (5yo)

Overall Batch Analyses %RNA integrity

EUROPEAN MEDICINES AGENCY

Company	Drug Substance batch number	%RNA integrity	Mean %RNA integrity	Drug Product batch number	%RNA integrity	Company	Mean %RNA integrity
	?			COVVAC/270320 69	69		
BNT	R427-P020.2-DS	77	81	BCV40420-A	75	Polymun	78
	R438-P020.2-DS	80		BCV40620-A	85		
	R438-P020.2-DS	80		BCV40620-B	86		
	R438-P020.2-DS	80		BCV40620-C	83		
	R438-P020.2-DS	80		BCV40620-D	77		
	R438-P020.2-DS	80		BCV40620-E	85		
	R443-P020.2-DS	81		BCV40720-A	71		
	R443-P020.2-DS	81		BCV40720-B	72		
	R443-P020.2-DS	81		BCV40720-C	69		
	R443-P020.2-DS	81		ED3938	62	Pfizer, Puurs (S2S2)	63
	R445-P020.2-DS	86		EE3813	63		
Pfizer, Andover	20Y513C101	62	62	EE8492	55	Pfizer, Puurs (WSL5)	55
	20Y513C101	62		EE8493	55		

Arbitrary Acceptance Standard Set at >=50% for mRNA Integrity



EMA/Pfizer Nov 26, 2020: „In addition, we are revising the RNA integrity specification for drug substance to >=60%, drug product release to >=55%, and drug product shelf life to >=50%."

139L of stratified bulk product cannot be equally filled into 0.45ml vials

"Particles have been observed …across many lots spanning multiple manufacturing sites, …Particles are light in density and have a tendency to float. Because sterile bulk drug product flows from the bottom of the vessel to the filling line, floating particles tend to be observed more frequently in vials filled towards the end of the filling process."

A way to vary toxicity of the product by having varied concentration of mRNA?

Source: Pfizer document "Responses to FDA Queries, Nov 19, 2020"

-----Original Message-----
From: Wathion Noel <Noel.Wathion@ema.europa.eu>
Sent: Thursday, 19 November 2020 19:12
To: Cooke Emer <Emer.Cooke@ema.europa.eu>; Sweeney Fergus <Fergus.Sweeney@ema.europa.eu>; Nolte Alexis <Alexis.Nolte@ema.europa.eu>; Boone Hilde <Hilde.Boone@ema.europa.eu>; Dias Monica <Monica.Dias@ema.europa.eu>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Subject: Some reflections after today's TC with the Commissioner

Dear all,

Since Alexis and Monica were no longer connected when we had our short discussion after today's TC with the Commissioner, a brief summary of what I already said together with some additional reflections.

As a minimum we can say that the TC was interesting, the atmosphere was rather tense, at times even a bit unpleasant, and provides a hint on what EMA may expect if the expectations are not being met, irrespective if such expectations are realistic or not.

The real added value of today's TC in my view is that we have more clarity now on what may not be easily acceptable for the EC, ie a delay of several weeks between an authorisation granted by the FDA/ MHRA (under whatever form) and a CMA opinion issued by EMA. The political fall-out seems to be too high, even if the "technical" level at the MSs (as it was referred to by the Commissioner) could defend such a delay in order to make the outcome of the scientific review as robust as possible.

Although we know that whatever we do (speeding up the process to align as much as possible with the "approval" timing by FDA/MHRA versus taking the time needed to have robust assurance in particular as regards CMC and safety) EMA will have a very big challenge addressing questions and criticism from various parties (EC, MSs at political level, EP, media, the general public) in case of a delay of several weeks.

Even if it can not be excluded now that at the end we are aligned with the FDA/MHRA (both in the outcome of the scientific review and the timing), the opposite certainly can not be excluded at this moment so we need to prepare for the worst case scenario. So how do we go from here? Are the current measures enough? In my view, probably not. We will be overwhelmed from all fronts and be in the middle of the storm. And on who's support will we be able to count? I hope it will not be a rethorical question...

What can we do on top, without creating the perception that we are interfering outside our "technical" mandate?
A non-exhaustive list:
1. Explaining the EMA process and what it will deliver:
- A public event is organised on 11/12: I think we need to critically review if we will achieve what is needed, taking into account the already brought forward date and the content related aspects.
- Making better use of social media tools as referred to by Emer today: we urgently need a dedicated strategy. However the resources in Comms are so stretched already that they have at this moment enormous difficulties to cope with the high influx of (media) queries. Reaching out to a specialist company to help out?
2. Explaining the differences between US/U.K. EUA and CMA: although the general public and the media will not (necessarily) understand the nuances between the 2 concepts we have to finalise this exercise which is currently ongoing ASAP, and then, more importantly, decide how to make best use of it. CMC, responsibility and accountability are certainly elements to be considered in my view.
3. Making the CMA process adapted as much as possible to the current pandemic situation: this exercise is ongoing but (1) the time gained may be limited and (2) any changes may be too late for the Pfizer/BioNTech vaccine. Nevertheless I think we should finalise ASAP if only to demonstrate that we did our utmost.

I hope these reflections can contribute to coming to a decision how to best address the important challenges ahead.

KR,

Noel

Noel Wathion, Deputy Executive Director EMA Retired on 6/30/2021

Agnes Saint Raymond, EMA Head of the International Affairs Division

Wathion Noel
Mon 11/16/2020 12:42 PM
Inbox
Time for decision-making at EU; tomorrow phone call with Olga et al to prepare for EU Exe SG on Wednesday.
Wednesday EU Exe SG with HoAs.
Thursday TC with Commissioner.
The feasibility to "adapt" the CMA to these extraordinary circumstances will be key for determining the approach.

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Saint Raymond Agnes
Mon 11/16/2020 12:37 PM
Inbox
Azar is pro-Trump and still under his influence. Trump is still pulling strings ont his
Dr Agnès Saint-Raymond
Head of Division International Affairs
+31 (0)88781 7017
Office 17-S-27

Cavaleri Marco
Mon 11/16/2020 12:36 PM
Inbox
US Health secretary

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Wathion Noel
Mon 11/16/2020 12:35 PM
Inbox
AZAR is what?

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Cavaleri Marco
Mon 11/16/2020 12:34 PM
Inbox
FDA has a call with MHRA in 3 hours to discuss Biontech CMC aspects. They are going to rush into EUA.
FDA still unclear and not so easy for them to be faster than Xmas, but pushed hard by Azar and US GOV
Marco

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Saint Raymond Agnes
Mon 11/16/2020 12:20 PM
Inbox
This means MHRA is definitely going to issue an EUA or equivalent very soon…
Dr Agnès Saint-Raymond
Head of Division International Affairs

CHRONOLOGY

CHRONOLOGY

Noel Wathion, Deputy Executive Director EMA

Marco Cavaleri chair of the COVID-19 EMA pandemic Task Force.