Consequences of underestimated statistical safety signals, potential risks and suspected adverse reactions from VAERS associated with COVID-19 and other vaccines

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"*Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals*"

Permanent Subcommittee on Investigations
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1 OPENING STATEMENT

Distinguished Chairman, Ranking Member, and Committee Members. I am honored to discuss critical limitations in statistical safety signal and potential risk detection in VAERS, touted by CDC as *"the nation's early warning system for vaccine safety"* and credited by former CBER Director Dr. Peter Marks with *"detecting both potential and actual safety issues and informing vaccine policy decisions.*" Among limitations undermining detection of statistical safety signals is the problem of masking.

Certain data challenges often necessitate deploying surrogate methods for signal detection. CDC was required by VAERS' COVID-19 Standard Operating Procedures to use the straightforward Proportional Reporting Ratio (PRR) method, while FDA would employ Empirical Bayesian modeling, requiring sophisticated software such as Oracle's Empirica Signal™.

Masking occurs when statistical signals for one vaccine in a database are obscured by reports associated with other vaccines. For example, Moderna's myocarditis signal becomes hidden if its comparison baseline is artificially inflated by including Pfizer's myocarditis reports.

In a simple analogy, hemlock and arsenic appear equally toxic when compared separately with a non-toxic baseline control such as tea. However, if hemlock's baseline data include arsenic data, hemlock's signal is drowned out or masked, appearing innocuous.

As Chairman Johnson recently highlighted, regulators were well aware of the masking problem. Nonetheless, officials claimed ignorance on how to address masking, and that developing solutions exceeded FDA's capabilities. They considered it *"problematic to use a brand new, possibly unvalidated tool in the context of an EUA."*

FDA's failure to use tools already at their disposal challenge these assertions. In their own 2024 paper about tinnitus, regulators discussed masking, citing a 2022 seminal publication in the leading journal *Drug Safety,* noteworthy for three reasons.

Firstly, its authors included Oracle's Dr. William DuMouchel, developer of the Bayesian method and Empirica Signal software, along with FDA biostatistician Dr. Ana Szarfman.

Secondly, it detailed a demasking protocol they developed and available within the same Empirica software used by FDA.

Thirdly, it applied this protocol to unmask hundreds of statistical signals for the COVID-19 vaccines; a result consistent with my analysis.

Despite citing this *Drug Safety* paper and possessing both software and in-house expertise, regulators failed to implement this solution to correct their analyses for masking.

This omission impeded detection of perhaps hundreds of signals, including myocarditis and ischemic stroke; a striking failure given the accelerated, population-scale deployment by Operation Warp Speed of a novel and most complex class of drugs ever - mRNA.

Signals surviving masking warranted, perforce, urgent investigation. Yet in FDA's 2025 FOIA release, 163 Janssen signals evoked minimal discussion.

Compounding the problem, CDC considered that its PRR analyses were rendered *"basically redundant"* by FDA's Bayesian work, ignoring its responsibility to generate PRRs, with relatively simple demasking methods. Accordingly, the United States lacked a fully functional *"early warning system"* at the time of its greatest need.

Separately, statistical signals were apparently trivialized by a reluctance to use the term "signal" and recognize a "statistical signal" as a potential safety signal.

This hedging is incompatible with the *"enhanced surveillance"* required by VAERS' Standard Operating Procedures, hindering investigation of potential risks FDA was legally obliged to consider, even without proven causality. Such shortcomings impugn decisions regarding authorization, approval, and vaccine injury compensation, and the marginalization of those apparently injured after receiving a COVID-19 vaccine.

The notion that focusing on VAERS' shortcomings distracts from current public health priorities is mistaken. Not only did the system fail to perform as advertised, but, as the *Drug Safety* paper presciently warned —the COVID-19 vaccine reporting deluge likely created masking effects that now compromise signal detection for other vaccines.

Regulators must swiftly correct masking and other VAERS deficiencies, heeding earlier warnings of their former colleagues, Drs. Marks and Jernigan: *"failure to detect and communicate a serious health issue related to a vaccine could impact confidence not only in COVID-19 vaccines but in all vaccines."*

Thank you. I welcome questions.

2 ANNOTATED VERSION

Distinguished Chairman, Ranking Member, and Committee Members. I am honored to discuss critical limitations in statistical safety signal and potential risk detection in VAERS, (1-3) touted by CDC as *"the nation's early warning system for vaccine safety"* (4-8) and credited by former CBER Director Marks with *"detecting both potential and actual safety issues and informing vaccine policy decisions.*" (9)[1] [2] Among (e.g. (10)) limitations undermining detection of statistical safety signals (p18/43 of (11)) is the problem of masking.(12) [3]

Empirical Bayesian Data Mining and detection of COVID-19 vaccine safety signals

Certain data challenges often necessitate deploying surrogate methods[4] for signal detection. CDC was required by VAERS' COVID-19[5] Standard Operating Procedures to use the straightforward Proportional Reporting Ratio (PRR) method,(13) while FDA would employ Empirical Bayesian modeling,(14,15) requiring sophisticated software such as Oracle's Empirica Signal™.

What is masking and why is it a problem with Empirical Bayesian Data Mining analyses?

Masking occurs when statistical signals for one vaccine in a database are obscured by reports associated with other vaccines. (12) For example, Moderna's myocarditis signal becomes hidden if its comparison baseline is artificially inflated by including Pfizer's myocarditis reports.

Simplified analogy of how masking could prevent detection of COVID-19 vaccine safety signals

In a simple analogy, hemlock and arsenic appear equally toxic when compared separately with a non-toxic baseline control such as tea. However, if hemlock's baseline data include arsenic data, hemlock's signal is drowned out or masked, appearing innocuous.

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[1] Notably, myocarditis for the modRNA vaccines, and blood clotting issues for Janssen. FDA's Marks and CDC's Jernigan proffered: *"While not without limitations, VAERS has proven to be vital in detecting both potential and actual safety issues and informing vaccine policy decisions that protect the health of the American public. That's a job the CDC and the FDA take seriously. "We know that failure to detect and communicate a serious health issue related to a vaccine could impact confidence not only in COVID-19 vaccines but in all vaccines. Bottom line: VAERS works and has a track record that proves it."*

[2] These descriptions dispatch the popular canard of VAERS' alleged nonutility due to passive and lay reporting. Another canard is that VAERS is unreliable because it does not prove causality. Indeed, raw VAERS data do not prove causality. However, causality may be determined after further investigation, including the examination of statistical signals generated from VAERS data. Proof of causality is not required for the issuance (or non-issuance) of an Emergency Use Authorization (EUA) which requires only FDA's ***reasonable belief*** "*that the product **may be** effective"* based on a *"**totality**"* standard which is lower than the regular "safe and effective" standard. This standard requires FDA to consider "*known **and potential risks,**"* even without proving causality. (Food, Drug and Cosmetic Act, Section 564(c) (2)(B) www.govinfo.gov/content/pkg/COMPS-973/pdf/COMPS-973.pdf) Emphasis added.

[3] These methods are termed "Disproportionality Signal Analyses" (DSA). There are other forms of masking possible with DSA. Additionally, since DSA methods were developed primarily for signal detection involving classical small-molecule drugs with limited pharmacological effects, the inherent assumptions underlying the use of DSA may be violated for complex products involving several potential toxicants. This would certainly be true of the modRNA COVID-19 vaccines, for which toxic effects might arise from the modRNA itself, the lipid nanoparticles (and their components), RNA-lipid adducts, frameshift proteins, dsRNA, residual DNA, and elicited spike protein. Other issues in the conduct of DSA include the setting of statistical thresholds. These issues are beyond the scope of this presentation.

[4] Because the number of people receiving a drug, and the number of doses they have received is often unknown, it is difficult to calculate an occurrence rate for a particular adverse event. Accordingly, the total number of adverse events reported is used as a surrogate for the number of doses or people receiving doses of drug.

[5] I use the term "vaccine" to refer to all COVID-19 vaccine types. Although for the Pfizer, Moderna and Jannsen products, the term "pro-vaccine" more accurately describes their character and distinguishes them from conventional vaccines. Unlike conventional vaccines, these pro-vaccines do not contain target antigens. Rather, they contain the genetic instructions read by a vaccinee's body to produce the target spike protein antigen. This is somewhat analogous to the activation of a pro-drug that lacks the desired pharmacologic action, but is converted by the body to an active form.

Were federal health officials able to adjust their data analyses to account for masking?

As Chairman Johnson recently highlighted,(2,16,17)[6] regulators were well aware of the masking problem. (footnote 89 in (2))[7] Nonetheless, officials claimed ignorance on how to address masking, and that developing solutions exceeded FDA's capabilities.(p108 in document 4 of (3)) They considering it *"problematic to use a brand new, possibly unvalidated tool in the context of an EUA."* [8] [9]

[6] Chairman Johnson cites David Menschik MD, MPH who, as of January 2021, was Associate Director for Surveillance Informatics, Division of Epidemiology/Office of Biostatistics and Epidemiology, CBER, FDA (p179 document 3 of 2026 Johnson release). He authored most of the weekly email EBDM alerts from January 2021 to mid-2022. The recently released documents contain several drafts for limitation language relating to masking for the paper by Rosenblum et al. This was included in the preprint version, but removed in the Lancet version, along with mention of EB data mining. Three versions of this language are contained in an email found on p146 of document 9 from the March 2026 Johnson release. (Bates PSI-HHS-000008252047, in pertinent part)

From: Menschik, David To: Baer, Bethany Subject: FW: [EXTERNAL] 6 month safety review- approval for CDC clearance- please review and respond. Date: Thu, 23 Sep 2021

"Attached is the new clean manuscript and there is no redline version per below. I created a "blackline version" of the manuscript (comparing previous clean version with this clean version; attached) and it appears that there are substantive changes that will require re-clearance.

I'm not satisfied with the late changes to the data mining limitation section. Recent version said:

> *EB data mining has multiple limitations[22] including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionality scores (which are adjusted by year to control for time-dependent confounders, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.*

New version says:

> *A limitation of EB data mining[22] is low sensitivity; that is, absence of a disproportionality alert does not rule out a possible adverse event. A new concern with disproportionality scores, which are adjusted by year to control for time-dependent confounders, is that during the study period most VAERS reports were for COVID-19 vaccinations. As all VAERS reports are used for vaccine-event comparisons in EB data mining, potential associations with mRNA COVID-19 vaccines plausibly could be missed.*

This is inadequate since there are many limitations to data mining and they are only pointing out 'low sensitivity' which is not accurate. If you agree, would advise revising to:

> *EB data mining has multiple limitations[22,23] including that the absence of a disproportionality alert does not rule out a possible corresponding adverse event. A new concern with disproportionality scores, which are adjusted by year to control for time-dependent confounders, is that during the study period most VAERS reports were for COVID-19 vaccinations. As all VAERS reports are used for vaccine-event comparisons in EB data mining, potential associations with mRNA COVID-19 vaccines plausibly could be missed.*

I'm ok with the other data mining parts (including slimming down the results section) and deferring on non-data mining parts of the paper (for which we were not involved).

Any additional edits or thoughts welcome. Thanks, David"

[7] Indeed, they were cautioned by FDA's Dr. David Menschik against *"placing excess value on… the absence of specific data mining alerts."*

[8] Bates PSI-HHS-000001136460. In pertinent part. The tinnitus paper referred to is Yih et al.

Email from Nair, Narayan (FDA), Friday, October 27, 2023. To: Su, John (CDC), Bazel, Samaneh (FDA). Cc: Shimabukuro, Tom (CDC) Subject: FDA coauthor for tinnitus paper

"Hi John,

She does bring up a good point. As you know, data mining has all the limitations of passive surveillance as well as others. However, during the COVID vaccine era there is an additional limitation. Since most reports received involve COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be driven towards the null by COVID-19 vaccine reports contributing substantially to the comparator group. This would could occur in the setting if there was some type of class-effect (e.g., if both mRNA COVID-19 vaccines are associated with the same adverse event).

We were aware of this limitation before and during the pandemic. There are many data mining tools and there was some discussion about utilizing a novel tool to adjust for this. However, we thought it would be problematic to use a brand new, possibly unvalidated tool in the context of an EUA. We ended up using the same EBGM data mining we use for all vaccines and has a long history of use rather than take an experimental approach. As new non-COVID vaccine reports are added we think this limitation will be mitigated to some degree.

As far as the paper goes there are several options to address this:

- *We could report our data mining findings and just acknowledge this as a limitation (this is what we have done in other papers)*
- *We could not include any data mining findings*
- *You could develop another tool that would compensate for the greater number of COVID vaccine reports. I am not sure how to do this but you would need a statistician with DM experience. This would be beyond our capabilities at FDA."*

[9] *If this is taken to mean that it might not be possible to validate a new tool, this suggestion is untenable in the light of many examples of FDA accepting the use of unvalidated, unverified, or low--quality data, such as: a) use of immunobridging methods with no establishment of am immune correlate of protection to authorize booster for new-variant COVID-19 vaccine authorizations (see comments of Dr. Ofer Levy at the VRBPAC meeting of October 13, 2021; b) At the VRBPAC meeting of October 26 2021, FDA accepted clinical data it had not verified; c) At the VRBPAC meeting of June 15, 2022, FDA accepted clinical data it considered "preliminary, imprecise, and potentially unstable" () but nonetheless "based on the totality of evidence [..] we do feel very confident that the evidentiary standard for benefit for EUA has been met here. "*

It is difficult to understand why validating a statistical method should take more than a few weeks, given the pace of Operation Warp speed that was able to solve far more challenging issues.

FDA's failure to use tools already at their disposal challenge these assertions. In their own 2024 paper about tinnitus,(18) regulators discussed masking,[10] citing a 2022 seminal publication (12) in the leading journal *Drug Safety,* noteworthy for three reasons.

Firstly, its authors included Oracle's Dr. William DuMouchel, developer of the Bayesian method (19) and Empirica Signal software, along with FDA biostatistician Dr. Ana Szarfman.[11]

Secondly, it detailed a demasking protocol they developed (20) and available within the same Empirica software used by FDA.

Thirdly, it applied this protocol to unmask hundreds of statistical signals for the COVID-19 vaccines; a result consistent with my analysis. (21) [12] [13]

Despite citing this *Drug Safety* paper and possessing both software and in-house expertise,(22)[14] (p56 of Document i1 in (3)),[15] (reviewed in (21)),[16] regulators failed to implement this solution to correct their analyses for masking.

Other data mining limitations

This omission impeded detection of perhaps hundreds of signals,(21) including myocarditis[17] (Figure 1) and ischemic stroke;[18] a striking failure given the accelerated, population-scale deployment by Operation Warp Speed of a novel and most complex class of drugs ever - mRNA.

What is the significance of signals that survive masking?

Signals surviving masking warranted, perforce, urgent investigation. Yet in FDA's 2025 FOIA release, 163 Janssen signals evoked minimal discussion. (21)

[10] "*VAERS is a system used primarily for signal detection. Since COVID-19 vaccines became available, the majority of VAERS reports have been for COVID-19 vaccines, which is unprecedented compared to pre-pandemic reporting. This might limit signal detection capability for COVID-19 vaccines using Empirical Bayesian data mining because disproportionality scores may be driven towards the null [35 – citing Harpaz et al].*"

[11] Writing in her personal capacity.

[12] For the seven events that were the focus of the *Drug Safety* paper, Harpaz et al. detected, before demasking, Empirical Bayesian Data Mining safety signals for eight out of a possible 21 vaccine-adverse event pairs, from the global VAERS database. Using US data, FDA only detected one of these, missing seven out of eight, a statistically significant failure (p=0.02). See Wiseman, 2025.

[13] In addition to demasking, Harpaz et al., used a threshold of 1, instead of the arbitrary threshold of 2. Discussion of this also significant issue with PRR, Bayesian, and related methods, is beyond the scope of this presentation (see Wiseman, 2025).

[14] In addition to Dr. Szarfman, other FDA data mining experts include Drs. Travis Canida (current) and John Ihre (former), statisticians who developed open-source software for Empirical Bayesian Data Mining.

[15] Dr. Brendan Day, working on Empirical Bayesian Data Mining analysis for pneumococcal vaccines, described consideration of data from both the USA and worldwide, similar to that used in the *Drug Safety* (Harpaz et al.) paper. Although FDA's disclosed analysis only considered US reports, both analyses contribute to the totality of evidence on vaccine safety.

[16] Although the Empirica Signal software is able to calculate PRR values, it is unknown which software CDC used to calculate PRR values disclosed under a FOIA request. These analyses were limited in the time period covered, and in the comparisons made (Pfizer and Moderna were combined and no analyses were provided for Janssen). These analyses did however substantively account for masking by a) combining the Pfizer and Moderna reports, and b) comparing these combined data against non-COVID vaccines, presumably excluding Janssen data from the comparator. (see 8.4.2 in Wiseman, 2025) CDC's analysis also appears to avoid a different kind of masking that would have been problematic had CDC complied with its own Standard Operating Procedure. (see 10.1.1 in Wiseman, 2025) How these analyses were used to inform regulators' decisions has not been disclosed, but it appears that for the most part they were not. (see p144 in Document 8 of Johnson 2026 release)

[17] Taking myocarditis as an example, after demasking Harpaz et al. detected a Bayesian safety signal for Pfizer in the dataset around May 28, 2021, and for Moderna, February 18. When adjustment was also made for a separate statistical problem in which the threshold is set too high, a Pfizer myocarditis signal was evident March 5, and a Moderna signal for February 5, 2021. Compare these dates with the requests for information from Israel on February 28, 2021 (p14 in Document 2 submitted to the PSI 5/21/25) and FDA and CDC statements (p 153 in Document 2 submitted to the PSI 5/21/25). (see Figure 1).
https://www.hsgac.senate.gov/subcommittees/investigations/hearings/the-corruption-of-science-and-federal-health-agencies-how-health-officials-downplayed-and-hid-myocarditis-and-other-adverse-events-associated-with-the-covid-19-vaccines/
Regarding Pfizer's EUA for its teenage dose, ACIP were told on May 17, 2021 over two months after a signal was evident according to Harpaz et al., that myocarditis did *"not differ[ed] from expected baseline rates."* Finally, a myocarditis signal was announced May 27, 2021. (see Wiseman, 2025)

[18] CDC's substantively demasked PRR analysis (see 8.4.2 in Wiseman, 2025) identified signals for ischemic stroke at least as early as July 2022, despite representations made in early 2023, regarding the VSD signal that there were *"no excess reports of stroke from VAERS"* and that *"Other safety monitoring systems have not observed similar findings."* (see 9.1.3 in Wiseman, 2025)

Compounding the problem, CDC considered that its PRR analyses were rendered *"basically redundant"* by FDA's Bayesian work, (p144 in Document 8 of (3)),[19] ignoring its responsibility to generate PRRs, (11) with relatively simple demasking methods.(21) Accordingly, the United States lacked a fully functional *"early warning system"* (4-7) at the time of its greatest need.

Separately, statistical signals were apparently trivialized [20] by a reluctance to use the term "signal" (p62 12/1/22 in Document 1 of (3))[21] [22] and recognize a "statistical signal" as a potential safety signal. (eg p2 of (1,8)) [23]

This hedging is incompatible with the *"enhanced surveillance"* required by VAERS' Standard Operating Procedures,(11) hindering investigation of potential risks FDA was legally obliged to consider, even without proven causality. Such shortcomings impugn decisions [24] regarding authorization, approval, and vaccine injury compensation, and the marginalization of those apparently injured after receiving a COVID-19 vaccine.

Ongoing implications

The notion that focusing on VAERS' shortcomings distracts from current public health priorities is mistaken. Not only did the system fail to perform as advertised, but, as the *Drug Safety* paper presciently warned (12)[25]—the

[19] In pertinent part: Email from Dr. Tom Shimabukuro to CDC colleagues (CDC), June 23, 2022. To: Martha Sharan, John Su, cc Kristen Nordlund, Perstephanie Thompson, Paige Marquez.
"Okay, but the main reason we didn't do PRR is b/c FDA EB data mining is the 'gold standard' for disproportionality analysis so we had a better and more efficient way of doing disproportionality analysis at a time when we were occupied trying to monitor an onslaught of reports. There really isn't a reason for CDC to do PRR if FDA is conducting EB data mining b/c it's basically redundant. Now that we are further along in the pandemic and we better understand some of the limitations of FDA's EB data mining for COVID-19 vaccines we are doing some exploratory work with PRR, but it's still not a major component of our monitoring."

[20] The VAERS Standard Operating Procedure (p18/43) clearly refers to PRR or EBDM findings as safety signals*: "MedDRA terms identified as safety signals due to elevated PRR and/or a statistically significant finding on data mining will be reviewed as appropriate."*
In the context of Investigational New Drugs, the term "*Suspected adverse reaction"* appears appropriate, per 21 CFR §312.32 (a):
"Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug." at www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-B/section-312.32

[21] In pertinent part (emphasis added). From: Nair, Narayan (FDA) December 1, 2022.
To: Moro, Pedro (CDC) Cc: Alimchandani, Meghna (FDA); Zinderman, Craig E (FDA)
Subject: RE: RE: Weekly data mining
"Hi Pedro,
I hope you are well. FYI - we have shifted some of our responsibilities in our Division so David will no longer be responsible for fielding questions about data mining. Feel free to contact me if questions come up. With regard to Alison's question, we have not had any disproportionality alerts from Data Mining for the mRNA COVID-19 vaccines for any new safety concerns (including none for Parsonage Turner Syndrome.)
[…] We generally ***try and avoid referring to disproportionality/data mining alerts as "signals" or "safety signals".*** *From a regulatory perspective the terms signal and/or safety signal have certain connotations and may trigger actions so we try not conflate data mining alerts with signals."*

[22] In meetings held between the React19.org Patient Advocacy group, and FDA officials, frequent mention is made of the inability to detect signals of interest from VAERS data. For example see:
https://static.therealpetermarks.com/assets/01_04_22_FDA_PeterMarks_FollowUp_transcript.pdf
https://icandecide.org/wp-content/uploads/2025/04/03_03_2022_FDA_transcript.pdf
https://icandecide.org/wp-content/uploads/2025/04/05_25_22_FDA_transcript.pdf
https://icandecide.org/wp-content/uploads/2025/04/React19-FDA-Transcript-12_14_2022.pdf

[23] The 2026 paper by Anyalechi et al., co-authored by CDC and FDA scientists, uses the term "SDR' which it defines as a *"Statistic of disproportional reporting"* and qualifies by saying *"SDRs are not necessarily safety signals and should be considered hypothesis- generating. "* Two points are noteworthy. Firstly, the acronym "SDR" is used throughout pharmacovigilance literature to mean "signal of disproportionate reporting." The term *"statistic of disproportional reporting"* does not appear. Secondly, in noting that *"A strength of our analysis is that VAERS is a large national database designed to detect early signals of potential vaccine safety concerns,"* the paper acknowledges that SDRs as a type of signal.

[24] Importantly, the failure to identify potential safety risks, represented by the masked signals means that FDA failed to adequately inform VRBPAC and ACIP committees, being asked to consider the "totality of scientific evidence" to make COVID-19 vaccine recommendations that would inform public policy authorization, approval, and vaccine injury compensation decisions. This extended to health providers and ultimately to American citizens who would be given these products. Because many countries relied on FDA decisions to make their policy decisions, these failures affect millions of people around the world.

[25] *"Furthermore, the volume of reporting for COVID-19 vaccines is likely to influence future statistical associations with other new vaccines. This suggests that masking may become more frequent and should be carefully considered."*

COVID-19 vaccine reporting deluge likely created masking effects that now compromise signal detection for other vaccines. (23),[26] (24),[27].(25),[28] (p17 in document 5 of (3))[29]

Regulators must swiftly correct masking and other VAERS deficiencies, heeding earlier warnings of their former colleagues, Drs. Marks and Jernigan: *"failure to detect and communicate a serious health issue related to a vaccine could impact confidence not only in COVID-19 vaccines but in all vaccines."* (9)**Error! Bookmark not defined.**

Further discussion of masking and related issues welcome

Thank you I welcome questions.[30]

[26] *"To mitigate the masking effect of COVID-19 vaccines in post-marketing SRS analyses, we recommend utilizing COVID-19-corrected versions for a more accurate assessment."*

[27] *"The impact of COVID-19 vaccine ADR reports on current signal detection practices requires further evaluation and solutions to tackle masking issues in EudraVigilance may need to be developed."*

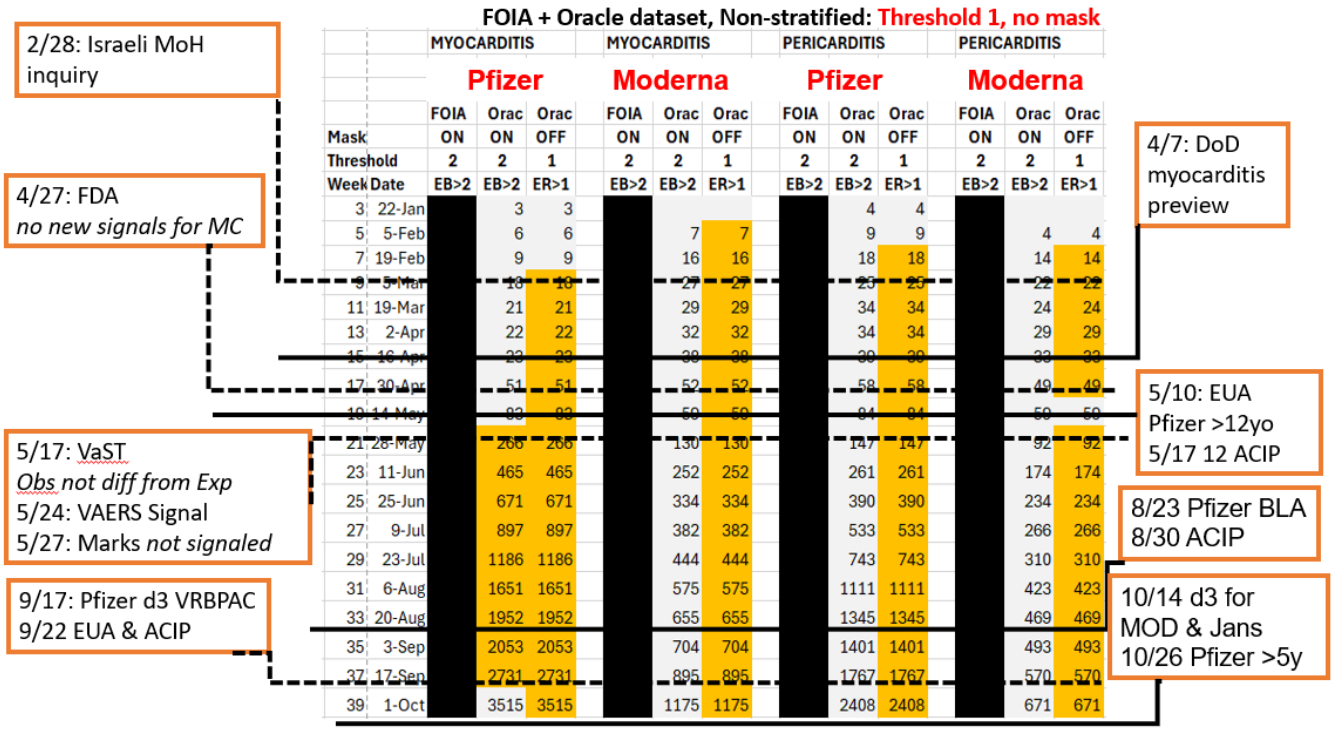
[28] *"COVID-19 vaccines caused substantial masking in both databases."* (Dutch - Lareb database, Spanish – FEDRA database)

[29] The following email suggests that the earlier concern regarding the mutual masking of the mRNA products, now extends to the masking by the COVID-19 vaccines of vaccines in general.
Email (in pertinent part) from: Nair, Narayan [FDA]. Sent: March 15, 2024. To: Menschik, David [FDA] Zinderman, Craig [FDA] Baer, Bethany [FDA], Subject: Data mining question
"I know in the past we have discussed one of the possible limitations of data mining currently is the vast number of VAERS reports from the COVID vaccines may limit our ability to detect statistical alerts because disproportionality scores may be driven towards the null. Do you know if there is a public reference that discusses this limitation? I have found some references that discuss general limitations for data mining but not sure if there is one that talks about how a large volume of reports from a single class of products could masks results.
Narayan Nair, MD
Division Director, Division of Pharmacovigilance, Office of Biostatistics and Pharmacovigilance [CBER, FDA]"

[30] Since these highly technical issues are not easily discussed in this sort of forum, I am happy to do so off-line.

3 FIGURE: 1

Chronology of myocarditis and pericarditis signal generation by different methods, in comparison to key regulatory events



FOIA + Oracle dataset, Non-stratified: Threshold 1, no mask

		MYOCARDITIS			MYOCARDITIS			PERICARDITIS			PERICARDITIS		
		Pfizer			Moderna			Pfizer			Moderna		
		FOIA	Orac	Orac	FOIA	Orac	Orac	FOIA	Orac	Orac	FOIA	Orac	Orac
Mask		ON	ON	OFF	ON	ON	OFF	ON	ON	OFF	ON	ON	OFF
Threshold		2	2	1	2	2	1	2	2	1	2	2	1
Week	Date	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1
3	22-Jan		3	3					4	4			
5	5-Feb		6	6		7	7		9	9		4	4
7	19-Feb		9	9		16	16		18	18		14	14
9	5-Mar		13	13		27	27		25	25		22	22
11	19-Mar		21	21		29	29		34	34		24	24
13	2-Apr		22	22		32	32		34	34		29	29
15	16-Apr		33	33		38	38		39	39		33	33
17	30-Apr		51	51		52	52		58	58		49	49
19	14-May		83	83		59	59		84	84		59	59
21	28-May		266	266		130	130		147	147		92	92
23	11-Jun		465	465		252	252		261	261		174	174
25	25-Jun		671	671		334	334		390	390		234	234
27	9-Jul		897	897		382	382		533	533		266	266
29	23-Jul		1186	1186		444	444		743	743		310	310
31	6-Aug		1651	1651		575	575		1111	1111		423	423
33	20-Aug		1952	1952		655	655		1345	1345		469	469
35	3-Sep		2053	2053		704	704		1401	1401		493	493
37	17-Sep		2731	2731		895	895		1767	1767		570	570
39	1-Oct		3515	3515		1175	1175		2408	2408		671	671

Each panel contains three columns representing signals generated weekly by Empirical Bayesian Data Mining (EBDM). The first column of each panel shows that no signals were detected in FDA's analysis from US VAERS data using the EB05>2 criteria at a threshold of 2. (1) The second and third columns of each panel are the signals detected by Harpaz et al.,(12) The second column uses the same criteria as FDA, but for global data reported to VAERS. The third column uses the version of EBDM that accounts for masking, (ER05>1) at a threshold of 1.

Orange signifies the presence of a signal. No color, indicates no signal detected. Adapted from Wiseman, 2025 (21) Numbers in each cell are case counts.

4 ATTACHMENTS

The following two works are provided as attachments to this document.

Wiseman D. Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines. Research Gate 2025. Epub Sept 9 http://doi.org/10.13140/RG.2.2.16568.40961

Filename: Wiseman2025DSASignalLossVAERS-FOIA-090925PUB.pdf

Wiseman D, Gutschi, LM. Great expectations and generous reading of guidelines underestimate potential risk in oversight of COVID- 19 pro-vaccine quality, safety testing, and manufacturing: 248 questions for FDA. ResearchGate 2025. Epub Sept 13 http://doi.org/10.13140/RG.2.2.29026.80324

WisemanGutschi2025FDAIntrospection091325.pdf

An interactive version of this work is available at: https://248questions.com/

5 CONFLICT OF INTEREST

The author has acted as an expert witness or consultant in several legal cases related to COVID-19 vaccines.

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