

Startling omission of safety review: VRBPAC not informed that the US early vaccine safety warning system is effectively disabled because safety signals for all vaccines are masked by COVID-19 vaccine reports in VAERS: Urgent action required.

Vaccines and Related Biological Products Advisory Committee, May 28, 2026

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Abstract

Absent from the agenda of the May 28, 2026 VRBPAC meeting, is a review of COVID-19 vaccine safety. This absence is startling given the findings of a recent Majority interim report of the Permanent Subcommittee on Investigations of the US Senate Committee on Homeland Security and Governmental Affairs.

This report revealed that FDA was aware that its primary vaccine safety early warning system was effectively disabled for COVID-19 vaccines because of a phenomenon called masking. The report documents FDA’s refusal to implement available solutions and its attempts to silence those raising concerns about masking.

Hundreds of safety signals were lost, representing potential risk FDA was required to consider for an EUA, without proving causality. The suppression of this largely uninvestigated potential risk by masking, including the failure to inform VRBPAC which was being asked to make recommendations on the “*totality of evidence*,” is both a scientific and a regulatory failure. It impugns the reliability of decisions regarding authorization, approval, and vaccine injury compensation.

So serious is the problem that the ability to detect VAERS safety signals for ALL OTHER vaccines is compromised because VAERS is inundated with COVID-19 vaccine reports across a wide variety of event types.

These findings challenge the core tenets of public policy on COVID-19 vaccination, and as former FDA and CDC officials Marks and Jernigan noted: “*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.*”

I recommend that VRBPAC ask HHS Secretary to provide a corrective action plan within 30 days.

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1. Introduction

The purpose stated in the agenda¹ for the VRBPAC meeting of May 28, 2026 is “to discuss and make recommendations on the selection of the 2026-2027 Formula for COVID-19 vaccines for use in the United States “

Although the agenda includes a presentation by CDC entitled: “*Updates on COVID-19 Vaccine Effectiveness*,” there is no agenda item related to safety. There is no mention of safety in FDA’s briefing document,² or in the voting question: “*For the*

¹ <https://www.fda.gov/media/192691/download>
² <https://www.fda.gov/media/192693/download>

2026-2027 Formula of COVID-19 vaccines in the U.S., does the committee recommend JN.1-lineage XFG variant as the preferred variant for an updated monovalent vaccine? “³

2. Startling omission of safety review

2.1. Senate Hearing: the US early warning system for vaccine safety is effectively disabled

The omission of any discussion of vaccine safety at this VRBPAC meeting is startling, given the findings contained in the recent interim report of Majority Staff of the Permanent Subcommittee on Investigations of the U.S. Senate Committee on Homeland Security and Governmental Affairs (PSI). (1) This report was released by the PSI with a number of documents provided under subpoena and in conjunction with a hearing on April 29, 2026,⁴ at which I testified on this topic. (2)

These findings highlighted the inability of the statistical algorithm (Empirical Bayesian Data Mining, EBDM) used by FDA to detect potential safety signals in VAERS, due to a phenomenon called masking. Masking occurs when statistical signals for one vaccine in a database are obscured by reports associated with other vaccines. Accordingly, VAERS, touted by CDC as “the nation’s early warning system for vaccine safety,” (3-7) was effectively disabled at the time of the nation’s greatest, the COVID-19 pandemic.

The report and associated documents revealed that FDA was warned repeatedly about the masking problem in connection with COVID-19 pro-vaccines by its own Dr. Ana Szarfman. Dr. Szarfman has been much lauded for her work on EBDM and might be considered the “mother”⁵ of EBDM, having introduced the method and associated Empirica™ Signal software into FDA after collaborating with its “father,” Oracle’s Dr. William DuMouchel.

Often conveying analyses performed by Dr. DuMouchel, Dr. Szarfman noted:

“I am not astonished that [FDA’s data mining system] was unable to detect these signals [identified by Dr. DuMouchel as being masked]”

Although FDA acknowledged and confirmed the problem, these warnings were ignored, met with a “cease and desist” notice, and the refusal by senior FDA officials to implement solutions available⁶ to FDA to overcome masking. This reticence is perhaps best encapsulated by FDA’s Dr. Zinderman,⁷ writing to Dr. Szarfman “Results from adjusting parameters that raise or lower sensitivity of the alerts as the vaccination campaign is underway could lead to confusion and have unintended consequences (e.g. regarding vaccine confidence).”

As we shall see (Section 4) the problem extends beyond COVID-19 pro-vaccines.

2.2. How big is the problem of masking?

Although the Majority Interim Report (1) referred to 49 examples of “extreme masking” identified in one of Dr. DuMouchel’s analyses transmitted to FDA officials via Dr. Szarfman, a 2022 publication (Harpaz et al., (8)) whose authors included DuMouchel and Szarfman⁸ in the journal *Drug Safety*, used a demasking protocol to unmask hundreds of statistical signals for the COVID-19 vaccines, a result consistent with my analysis of EBDM signals released by FDA under FOIA. (9)⁹

My analysis, appended (9) to my Senate testimony, (2) suggested that, conservatively, as of April 29, 2022, 763 (range 487-1898) signals were lost from FDA’s EBDM analysis of VAERS data due to masking, threshold filtering, or other factors. These signal losses delayed recognition of safety signals and represent still largely uninvestigated potential risk FDA was required to consider in issuing the EUAs for COVID-19 pro-vaccines.

³ <https://www.fda.gov/media/192694/download>

⁴ <https://www.hsgac.senate.gov/subcommittees/investigations/hearings/unmasked-how-biden-health-officials-purposely-turned-a-blind-eye-toward-covid-19-vaccine-safety-signals/>

⁵ Dr. Szarfman’s email signature line includes:

“Medical Officer, Safety Data Mining Developer and Medical Informatics Analyst, Celebrating nearly a quarter of a century of successful implementation of safety data mining, interactive patient profiles, and other automated analytical tools.”

⁶ The RGPS method was available to FDA in the same Empirica Signal software it was using for its EBDM analyses. FDA claimed that this was new and unvalidated. DuMouchel had worked on this since about 2012. Even if FDA did not want to use this method, it could have adapted the EBDM method to adjust for masking. Indeed. This is what FDA’s Dr. Menschik did in a special data mining run, where he confirmed a muting trend.

⁷ May 7 2021, p186/ part 3 of April 29, 2026 release

⁸ Writing in her private capacity.

⁹ 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).

Most startling in FDA's EBDM analyses was the large, use-normalized imbalances of 76-123 times (IQR) the number of safety signals for the Janssen COVID-19 pro-vaccine compared with the Pfizer and Moderna products. The large imbalance of signals is strikingly evident in Figure 1.

Even after correcting for masking and filtering, there appear to be 4.8 and 8.8-fold true signal excesses associated with the Janssen over the Pfizer and Moderna products, respectively. These anomalies persisted for at least the 18 months covered by the FOIA disclosure. Most concerning is that these anomalies and the signal imbalance were never presented at any of the public VRBPAC or ACIP meetings, a critical omission given that these committees were being asked to make recommendations about the COVID-19 vaccines based on “a totality of evidence.”

Further, the anomaly of Janssen excess signals should have warranted regulatory actions at least as extensive and transparent as those executed for Thrombosis with Thrombocytopenia Syndrome (TTS) associated with the Janssen product.

Figure 1: Illustrative examples of data mining alerts (EB05 >2) in the FOIA dataset (highlight added)

Drug	Event	Drug	Event	Drug	Event
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	COVID19 (COVID19 (JANSSEN))	Fall	COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	COVID19 (COVID19 (JANSSEN))	Feeling cold	COVID19 (COVID19 (JANSSEN))	Adverse drug reaction
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	COVID19 (COVID19 (JANSSEN))	Loss of consciousness	COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	COVID19 (COVID19 (JANSSEN))	Syncope	COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	COVID19 (COVID19 (JANSSEN))	Syringe issue	COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy
COVID19 (COVID19 (JANSSEN))	Interchange of vaccine products	COVID19 (COVID19 (JANSSEN))	Vital signs measurement	COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	COVID19 (COVID19 (JANSSEN))	Body temperature	COVID19 (COVID19 (JANSSEN))	Body temperature
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism			COVID19 (COVID19 (JANSSEN))	CSF protein increased
COVID19 (COVID19 (JANSSEN))	Syncope			COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage
COVID19 (COVID19 (JANSSEN))	Thrombosis			COVID19 (COVID19 (JANSSEN))	Cerebral mass effect
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal			COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis
COVID19 (COVID19 (MODERNA))	Injection site pruritus			COVID19 (COVID19 (JANSSEN))	Computed tomogram head abnormal
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation			COVID19 (COVID19 (JANSSEN))	Computed tomogram thorax abnormal
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue			COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue			COVID19 (COVID19 (JANSSEN))	Fibrin D dimer
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain			COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight			COVID19 (COVID19 (JANSSEN))	Gaze palsy
p34/153, April 27, 2021				COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	COVID19 (COVID19 (JANSSEN))	International normalised ratio normal
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	COVID19 (COVID19 (JANSSEN))	Onitis	COVID19 (COVID19 (JANSSEN))	Off label use
COVID19 (COVID19 (JANSSEN))	Computed tomogram head abnormal	COVID19 (COVID19 (JANSSEN))	Computed tomogram thorax abnormal	COVID19 (COVID19 (JANSSEN))	On and off phenomenon
COVID19 (COVID19 (JANSSEN))	Computed tomogram head abnormal	COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	COVID19 (COVID19 (JANSSEN))	Peripheral embolism
COVID19 (COVID19 (JANSSEN))	Computed tomogram thorax abnormal	COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	COVID19 (COVID19 (JANSSEN))	Platelet count
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	COVID19 (COVID19 (JANSSEN))	Platelet count normal
COVID19 (COVID19 (JANSSEN))	Dysmenorrhea	COVID19 (COVID19 (JANSSEN))	Gaze palsy	COVID19 (COVID19 (JANSSEN))	Platelet factor 4
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	COVID19 (COVID19 (JANSSEN))	Poor quality product administered
COVID19 (COVID19 (JANSSEN))	Gaze palsy	COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	COVID19 (COVID19 (JANSSEN))	Pulmonary embolism
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	COVID19 (COVID19 (JANSSEN))	Therapy non-responder
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	COVID19 (COVID19 (JANSSEN))	Thrombocytopenia superficial
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	COVID19 (COVID19 (JANSSEN))	Off label use	COVID19 (COVID19 (JANSSEN))	Thrombosis
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	COVID19 (COVID19 (JANSSEN))	Peripartum embolism	COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	COVID19 (COVID19 (JANSSEN))	Platelet count	COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler
COVID19 (COVID19 (JANSSEN))	Platelet count	COVID19 (COVID19 (JANSSEN))	Platelet count normal	COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal
COVID19 (COVID19 (JANSSEN))	Platelet count normal	COVID19 (COVID19 (JANSSEN))	Platelet factor 4	COVID19 (COVID19 (JANSSEN))	Ultrasound scan
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal
COVID19 (COVID19 (JANSSEN))	Syncope	COVID19 (COVID19 (JANSSEN))	Pyrexia	COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	COVID19 (COVID19 (JANSSEN))	Thrombocytopenia superficial	COVID19 (COVID19 (JANSSEN))	Venogram
COVID19 (COVID19 (JANSSEN))	Thrombosis	COVID19 (COVID19 (JANSSEN))	Thrombocytopenia superficial	COVID19 (COVID19 (JANSSEN))	Venogram abnormal
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	COVID19 (COVID19 (JANSSEN))	Thrombosis	COVID19 (COVID19 (JANSSEN))	Venogram normal
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	COVID19 (COVID19 (MODERNA))	Accidental exposure to product
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	COVID19 (COVID19 (MODERNA))	No adverse event
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	COVID19 (COVID19 (MODERNA))	Poor quality product administered
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	COVID19 (COVID19 (JANSSEN))	Ultrasound scan	COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation
COVID19 (COVID19 (MODERNA))	Poor quality product administered	COVID19 (COVID19 (JANSSEN))	Venogram	COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	COVID19 (COVID19 (JANSSEN))	Venogram abnormal	COVID19 (COVID19 (PFIZER-BIONTECH))	Weight
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	COVID19 (COVID19 (MODERNA))	Poor quality product administered		
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	COVID19 (COVID19 (MODERNA))	Product temperature excursion issue		
COVID19 (COVID19 (PFIZER-BIONTECH))	Off label use	COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective		
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation		
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue		
COVID19 (COVID19 (PFIZER-BIONTECH))	SARS-CoV-2 test	COVID19 (COVID19 (PFIZER-BIONTECH))	Weight		
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain				
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight				
p37/153, May 11, 2021		p42/153, June 1, 2021		p53/153, July 6, 2021	

Several examples of EBDM signal alert listings (before usage normalization) circulated within FDA and CDC by FDA, derived from the EBDM FOIA disclosure. (10) These examples were selected because their length was suitable for display on a printed page. Only the first two columns of each report are displayed here. Pink (Janssen), yellow (Moderna), and green (Pfizer) highlights have been added here. Each row represents an adverse event (Preferred Term, PT) for which an EB05>2 signal was present for at least one of the stratifications used.

3. Masking concerns raised to FDA in the context of BLA approval, vaccine mandates, and patient dialog

Many of the interactions between Dr. Szafrman and her colleagues at FDA regarding her (and Dr. DuMouchel's) concerns about masking took place in 2021. That FDA was aware of these problems and refused to correct them is all the more egregious given that the public was being assured of the safety and efficacy of the COVID-19 vaccines in the run-up to the full BLA of COMIRNATY in August 2021, the imposition of Federal vaccine mandates shortly thereafter, and the authorization of booster and children's doses in October 2021. The validity of these decisions and recommendations made by VRBPAC or ACIP advisory committees must be questioned.

Even worse, in meetings held with the React19.org Vaccine Injury Patient Advocacy group, FDA officials frequently stated that despite their best efforts, they were unable to detect safety signals in VAERS or other datasets.¹⁰

¹⁰ 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

4. Consequences for ALL vaccines, beyond COVID-19

The problem extends beyond what FDA knew about within-class masking, namely the interference, for example, by VAERS reports associated with the Pfizer product, with signal detection for the Moderna product. The ability to detect VAERS safety signals for ALL OTHER vaccines is compromised because VAERS is inundated with COVID-19 vaccine reports across a wide variety of event types. This problem is noted by DuMouchel and Szarfman in their *Drug Safety* (Harpaz et al.) paper: (8)

“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.”

The problem extends to similar databases outside the US of spontaneously reported adverse events, as documented by three other papers. (11-13)

A large contributor to this problem is the wide variety of adverse event types associated with the COVID-19 pro-vaccines, which contain several components that may elicit adverse events. These include the modified modRNA itself, Lipid Nanoparticles, residual DNA, lipid adducts, N1-methyl pseudouridine, as well as the elicited spike protein. Frameshift proteins,(14,15) which are aberrant proteins elicited by the modRNA may differ with each patient, giving rise to different types of adverse events. All of these effects have the potential to raise the baseline of many different types of adverse events, reducing the ability to detect a signal for any vaccine.

Although FDA had access to the *Drug Safety* paper, the topic came up in FDA’s Dr. Menschik’s “special project” (p180 of Part 3 of 042926 document release¹¹): *“the concern is that COVID case reports contribute a significant enough portion in the VAERS database, where it may affect the EBGM scores of other vaccine/product event combinations”* (031821)

5. Public health implications of FDA’s refusal to correct for masking: Early warning for ALL vaccines is currently compromised

Safety signals represent potential risk FDA was required to consider to issue an EUA, even without proving causality.¹² The suppression of this largely uninvestigated potential risk because signals were masked is both a scientific and a regulatory failure. It impugns the reliability of decisions regarding authorization, approval, and vaccine injury compensation.

These findings challenge the core tenets of public policy on COVID-19 vaccination, particularly that there were robust systems in place to monitor COVID-19 vaccine safety. Even more concerning is the fact that because VAERS is inundated with COVID-19 vaccine reports across a wide variety of event types, the current ability to detect VAERS safety signals for ALL OTHER vaccines is compromised. It is possible that drug safety databases may also be compromised (FAERS, AEMS).

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.”* (16)

6. Corrective action needed from Secretary HHS

Immediate corrective action is warranted by the Secretary of HHS. I recommend that VRBPAC ask the HHS Secretary to provide a corrective action plan within 30 days that includes the following elements:

- An explanation as to why VRBPAC and ACIP were not informed of safety signal imbalances evident from FDA’s EBDM analyses.
- An explanation as to why FDA failed to inform VRBPAC and ACIP that it was aware of the masking issues compromising its EBDM analyses.
- The establishment of an independent inquiry to assess:
 - the degree of compromise since 2021 of EBDM (or other) VAERS and FAERS signal detection due to the presence of COVID-19 vaccine reports in VAERS, or as concomitant drugs in FAERS.
 - the likely future compromise in VAERS and FAERS/AEMS.

¹¹ <https://www.hsgac.senate.gov/subcommittees/investigations/hearings/unmasked-how-biden-health-officials-purposely-turned-a-blind-eye-toward-covid-19-vaccine-safety-signals/>

¹² 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

- the dearth of EBDM signals for modRNA COVID-19 pro-vaccines, excess of signals for Janssen in FDA's EBDM alerts, released under FOIA in 2025, and inaction by regulators on these findings.(9)
- how the selection of signaling criteria, signal thresholds, data stratifications, data mining query structures, and EBDM hyperparameters may have reduced the ability of EBDM to detect vaccine safety signals.
- why VSD signals for acute myocardial infarction and venous thromboembolism identified in May 2022 were only disclosed at the ACIP meeting of 9/12/23.(17) (see 13.1.5 in (9))
- Provision of a list of all signals related to any vaccine or drug that meet RGPS statistical signaling criteria (i.e. ER05>1, according to Harpaz et al.), along with its associated EB05 and PRR values. This list is to include all signals generated by date from the launch of the COVID-19 vaccines.
- Development of a plan to avoid interference of COVID-19 vaccines in signal detection in VAERS, FAERS (and now AEMS), possibly to include COVID-19 vaccine-free versions of these databases.
- Mandating that Federal agencies and sponsors use demasking procedures for vaccine and drug safety pharmacovigilance.
- Validation of RGPS Empirica™ Signal software to permit use by Federal agencies and sponsors for pharmacovigilance.
- Establishment of clear guidelines for the detection of safety signals by disproportionality or other methods, investigation of signal confounding, investigation of underlying case reports, determination of causality, and publication of the status of any safety signal investigation.
- Provision of MGPS, RGPS, and PRR values for each product-event pair, on public-facing VAERS, FAERS, and AEMS databases.
- Establishment of a research plan to examine ways to solve other forms of masking, and appropriateness of Disproportionality Signal Analysis methods for multi-toxicant drugs.
- Update current guidelines (18) as to the criteria for inclusion of black box warnings or related language in product labeling.¹³
- Improvement in VAERS functionality to reduce misreporting and reporting delays, and biases due to missing data or data that are inadequately captured in free-text rather than specific fields.(19)
- Hfull PRR reports for COVID-19 vaccines mandated by VAERS SOP,(20) including details of which systems were used to generate them.
- HHS to designate one agency that will assess vaccine safety (eg AHRQ, NIH), that is not conflicted due to its role in the approval process (e.g. CDC, FDA).
- Completion of the plan within 120 days.

7. **Chasing COVID-19 variants vaccines is “inadequate as a long-term strategy**

We have previously discussed the wisdom of chasing COVID-19 variants (21,22) including the problems of waning, imprinting, and use of immunobridging in the absence of an immune correlate of protection. Further, why this strategy is still being pursued is baffling in light of remarks by:

- Former CBER Director Marks: (23)
“Continuing along the current path of the generation and administration of variant-specific vaccine boosters is inadequate as a long-term strategy for addressing COVID-19 in populations globally.”
- Former NIAID Director Fauci: (24)
“Viruses that replicate in the human respiratory mucosa without infecting systemically, including influenza A, SARS-CoV-2, endemic coronaviruses, RSV, and many other “common cold” viruses, cause significant mortality and morbidity and are important public health concerns. Because these viruses generally do not elicit complete and durable protective immunity by themselves, they have not to date been effectively controlled by licensed or experimental vaccines. [...] if natural mucosal respiratory virus infections do not elicit complete and long-term protective immunity against reinfection, how can we expect vaccines, especially systemically administered non-replicating vaccines, to do so?”

¹³ “According the FDA itself, it only takes a single report to justify an investigation into a product’s safety and potentially initiate a labeling change. In the past, “black box” warning changes have occurred after around a mere 400 adverse event reports.(see testimony of David Gortler PharmD, to the Committee on Oversight and Accountability Select Committee on the Coronavirus Pandemic United States House of Representatives, March 21, 2024: [Comparing Historical Threshold for Labeling Changes Related to Adverse Events](https://oversight.house.gov/wp-content/uploads/2024/03/GortlerTestimony_COVIDSelectCommittee_FINAL57.pdf)”
https://oversight.house.gov/wp-content/uploads/2024/03/GortlerTestimony_COVIDSelectCommittee_FINAL57.pdf

8. **Nomenclature: pro-vaccine, engRNA**

Pro-vaccine: We use the term “pro-vaccine” since the modRNA products do not contain the target antigens as in a conventional vaccine. Rather they contain the genetic instructions that are read by a patient’s body to produce the target spike protein antigen by translation. Because this is somewhat analogous to the conversion of a pro-drug to an active form,(25) we employ the term “pro-vaccine.”

engRNA (engineered RNA): Although the term modRNA (nucleoside modified RNA) is used throughout regulatory documents, as we have proposed to the United States Pharmacopeia, (26) this term does not adequately describe the wide range of modifications made to the RNA molecule that include use of N1 methylpseudouridine, codon optimization, use of human gene sequences in the 5’ and 3’ untranslated regions and alteration of the code for spike protein sequence. We therefore propose that the term **engRNA (engineered RNA)** is more accurate, and should be used.

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10. **Revision history**

V1 As submitted to FDA 5/27/26

11. **References**

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