STAND FOR HEALTH FREEDOM | IS CO-ADMINISTRATION OF RSV, COVID-19, AND FLU VACCINE/PRODUCTS SAFE?

In an OPEN LETTER sent October 14, 2024, Stand for Health Freedom asked Dr. Caitlin Newhouse, Medical Director, Vaccine-Preventable Diseases & Immunization Program, Tennessee Department of Health (TDH) for information (the five points listed below) to support her recommendation for the co-administration of RSV, COVID-19, and flu vaccine/products. Since Dr. Newhouse failed to provide the information, we are providing it.

Note that there is no health benefit to co-administration of vaccine products. Co-administration increases risk of adverse reactions due to additive and synergistic effects that are never properly studied. Convenience and taking advantage of an "opportunity to vaccinate" are the only reasons proffered by public health proponents.

1.) (***Information requested)*** **All clinical trials on which your claims of safety are based for the co-administering of RSV, COVID-19, and influenza products to babies, pregnant women, and others.**

- **None exist.** The CDC admits that "there is no clinical trial data on getting all three vaccines at the same time." [1]

2.) ***(Information requested)*** **Details about each trial:** Since no trials with all three exist, we searched product inserts, clinicaltrial.gov, and Pubmed [2] for co-administration clinical trials that included two of the three, or one with any other vaccine.

- **MRESVIA** by Moderna [3] (age 60+):
  - **No co-administration safety trials found.**
  - The Phase 2/3 trial of just MRESVIA: "Individuals were not eligible for inclusion in the Per-Protocol Efficacy Set if they received any other vaccine within 28 days before or after administration of the study injection."
- **AREXVY** by GSK-SA [4] (60+, high risk 50-59):
  - **AREXVY and FLUARIX QUADRIVALENT co-administration**
    - Adverse events include: **"Acute disseminated encephalomyelitis (ADEM) was reported in 2 participants enrolled in a study site in South Africa; the onset of the symptoms was 7 and 22 days post vaccination, respectively. One event was fatal and the other non-fatal. These participants received AREXVY concomitantly with FLUARIX QUADRIVALENT. "**
    - **"Data are not available for concomitant administration with other vaccines"**
  - In a study of just AREXVY: "Within 30 days after vaccination, **atrial fibrillation** was reported in 10 participants who received AREXVY and 4 participants who received placebo (**of which 7 events in AREXVY arm and 1 event in placebo arm were serious**); the onset of symptoms ranged from 1 to 30 days post vaccination. **The currently available information on the atrial fibrillation is insufficient to determine a causal relationship to the vaccine."**

    - Another study of just AREXVY: **"Guillain-Barré syndrome** beginning 9 days after AREXVY vaccination was reported in a participant enrolled in a study site in Japan."
- **ABRYSVO by Pfizer** [5] (Pregnant women; 60+, high risk 18-59):
    - **"Concomitant administration of Tdap with ABRYSVO in pregnant individuals has not been studied."**
    - In a study with just ABRYSVO: Study 2 evaluated "115 pregnant individuals who received ABRYSVO and 117 who received placebo. **A numerical imbalance in preterm births in ABRYSVO recipients was observed compared to placebo recipients in these two clinical studies. Available data are insufficient to establish or exclude a causal relationship between preterm birth and ABRYSVO."**
    - **ABRYSVO and a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)**
        - Study 6 (NCT04071158) in a concomitant administration study in non-pregnant women, no safety concerns were identified. [This was a phase 2b Study. Of 709 participants, **14 withdrew and their outcomes were lost to follow-up. One SAE of spontaneous abortion was reported** and was considered to be unrelated to the vaccine. Safety was monitored for just 1 month. [6]
    - **ABRYSVO and FLUAD QUADRIVALENT**
        - Study 5 (NCT05301322) was a Phase 3 study conducted in Australia in adults ≥65 years of age compared adverse reactions of subjects who received ABRYSVO and FLUAD QUADRIVALENT at the same time to subjects who received the vaccines one month apart. **Participants were followed for just one month after final dose**. No SAEs (Serious Adverse Events) were considered related to vaccination. [7]
- **BEYFORTUS (nirsevimab) by AstraZeneca [8] (Neonates and infants born during or entering their first RSV season)**
    - **A search did not locate any co-administration studies with either COVID-19 or flu vaccines.**
    - **Product insert: "There is limited experience with co-administration of BEYFORTUS with vaccines. In clinical trials, when BEYFORTUS was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone."** A search located no clinical trials that included BEYFORTUS and routine childhood vaccines, seeming to indicate that the co-administration referred to was not directly studied during BEYFORTUS trials. We are still seeking data.

3.) ***(Information requested)*** **A summary of types and numbers of adverse reactions reported to the Vaccine Adverse Event Reporting Systems (VAERS) and MedWatch for individually and co-administered RSV, COVID-19, and influenza products.**

[VAERS only makes initial reports available to the public. If a filed report is updated to reflect new or escalating symptoms, or death, the public has no way of knowing.]

[For lists of reported adverse reactions per product, see the product insert [9]. RSV products are new, and so are licensed COVID shots. Product inserts will not yet reflect all serious reported adverse reactions. FDA labelling law [10] requires vaccine manufacturers to update product inserts as needed and include: "Adverse reactions. This section must describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. **This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.**" (emphasis added)]

- **RSV**
  - **MRESVIA – Data Not Yet Available in VAERS**
  - **AREXVY – VAERS**
    - Total Reports: 5795 [11]
    - Serious: 468 [12]
    - Fatal: 47 [13]
  - **ABRYSVO** – Data Not Yet Available in VAERS
  - **BEYFORTUS/**nirsevimab – MedWatch Search – Limited Data Available Publicly
    - Total Reports: More than 100 [14]
    - Life Threatening: More than 25 [15]
    - Death: More than 10 [16]
- **Flu – Data is an aggregate of all flu vaccines administered individually and with other vaccines.**
  - Total Reports: 227,578 [17]
  - Serious: 24,415 [18]
  - Fatal: 2,540 [19]
- **COVID-19 – Data is an aggregate of all COVID vaccines administered individually and with other vaccines.**
  - Total Reports: 1,648,532 [20]
  - Serious: 317,707 [21]
  - Fatal: 37,966 [22]

4.) ***(Information requested)*** **The states in the United States and the countries which no longer recommend COVID-19 vaccines for children, adolescents, young adults, pregnant women, or for anyone.**

- **Florida: Does not recommend mRNA vaccines to anyone of any age.** [23] "Based on the high rate of global immunity and currently available data, the State Surgeon General advises against the use of mRNA COVID-19 vaccines. Any provider concerned about the health risks associated with COVID-19 for patients over the age of 65 or with underlying health conditions should prioritize patient access to non-mRNA COVID-19 vaccines and treatment.
  - Additionally, the Florida Department of Health sets an excellent example by encouraging health care providers to stay current on vaccine information and provide patients with informed consent, providing details about safety and efficacy concerns, and encourages Floridians to eat healthy and get outdoors "to support necessary vitamin D levels."

- **Idaho: Idaho's Southwest District Health voted to stop promoting and offering COVID-19 shots.** [24]
- Global policies can be hard to track down, but overall they have been changing in the direction of backing away from recommending COVID shots to young and healthy individuals. The information provided may not be up-to-date.
  - In 30 European nations, **only 3 recommend COVID shots to babies age 6 months** [25]
  - **These EU nations do not recommend COVID shots for children under age 5** [26]. [Ages in brackets are updates to recommended minimum age]: Austria, Belgium, Bulgaria, Croatia (65), Cyprus (not at all), Czechia, Denmark (65 for specific groups), Estonia, Finland (12), France (65), Hungary, Iceland (60), Italy (12), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden.
- **Australia no longer recommends to children under 18** (18 primary, 65 booster) [27] Nearly all travel restrictions based on COVID-19 vaccination status have been lifted worldwide. [28]
- The most important stakeholders: consumers. Americans are increasingly saying no to COVID-19 vaccines. Per the CDC, as of October 19, 2024, 4.8% of children were reported to be up to date with the 2024-25 COVID-19 vaccine, 7.3% of pregnant women, and 13.5% of adults [29].

5

.) **Guidance for reporting adverse reactions and filing for compensation for injuries or death due to co-administration when each product has a different legal liability status for manufacturers and healthcare providers who administer them.**

- COVID-19, RSV, and flu products all have a different legal status. Co-administration makes it impossible to know which product or combination of products caused the injury or death, making reporting difficult, and compensation almost impossible.
- COVID-19 products are under the PREP ACT [30]. Everyone involved with making, distributing, promoting, and administering the shots are shielded from liability when they cause harm - except in the case of "willful misconduct", but the ACT contains two statutory defenses to claims of willful misconduct.
- A lawsuit has been filed challenging the constitutionality of the PREP ACT. [31]
- The compensation program for COVID products, CICP, has very limited qualifications and a one year statute of limitations. Only a handful of victims have been compensated for out-of-pocket medical expenses not covered by the individual's insurance, and there is no coverage for future medical expenses, temporary or permanent inability to work, etc. CICP [32] covers no legal costs or fees for professional help with the application.
- For children under 12, COVID shots are still under Emergency Use Authorization and by law, this is supposed to be disclosed in all promotions of the product and prior to administration.
- Seasonal Flu vaccines are under the 1986 NCVIA [33] and pandemic flu shots are under the PREP Act. NCVIA shields the manufacturers and healthcare providers from liability, except in the case of fraud.

- Filing with the VICP [34] and getting through "Vaccine Court" is an arduous, multi-year process that leads most often to failure, except for the attorneys who are paid even if compensation is denied the victim. Recent decisions can be read online at the U.S. Court of Federal Claims.[35] A recent successful claim led to significant compensation to a man who developed Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP") from a flu vaccine. [36]
- The manufacturers of RSV products and healthcare providers who administer them are not yet shielded from liability by any government program. That means victims can sue the makers and the healthcare providers who administer them.
- Given the above complex legal situation that leaves consumers on their own to deal with injuries or deaths resulting from any vaccine administration, let alone the triple combination being recommended, it is incumbent upon the state of TN, and the General Assembly, to ensure that citizens are given full information about vaccine products so that they can either give informed consent or informed refusal.

No RSV, COVID-19 or flu vaccine/product prevents infection or transmission. All the products are designed to reduce severity of symptoms, or in the case of RSV products, reduce risk of lower respiratory tract disease. Level and duration of protection are varied and limited. Long-term risks are unknown.

Other proven approaches exist that can prevent infection, transmission, reduce severity and duration of symptoms for respiratory infections, while still allowing the individual to acquire durable and superior natural immunity. Such approaches include ensuring optimal Vitamin D [37] and glutathione levels [38], and nasal spray and gargling protocols with iodine or hydrogen peroxide [39], but these are not promoted by Dr. Newhouse or the Tennessee Department of Health.

ENDNOTES

[1] https://www.cdc.gov/ncird/whats-new/getting-vaccines-at-same-time.html Be aware that CDC web pages are designed to market products and increase uptake. Many claims of safety and effectiveness are either not cited, or the citations do not support the claim, or the study cited is under-powered, or poorly designed, or the exclusion criteria make the results irrelevant to the general public.

[2] https://pubmed.ncbi.nlm.nih.gov/

[3] https://www.fda.gov/media/179005/download?attachment

[4] https://www.fda.gov/media/167805/download?attachment

[5] https://www.fda.gov/media/168889/download?attachment

[6] https://pmc.ncbi.nlm.nih.gov/articles/PMC9200146/#s8

7] https://clinicaltrials.gov/study/NCT05301322term=NCT05301322&rank=1&tab=results#-participant-flow

[8] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s005lbl.pdf

ENDNOTES (continued)

[9] https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

[10] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201#201.56

[11] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=RSV

[12] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=RSV&SERIOUS=ON

[13] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=RSV&DIED=Yes

[14] http://fdable.com/advanced_aers_query/5bfd66531e9c0f5dc3c399c96fcc7911

[15] http://fdable.com/advanced_aers_query/18908176d42d4b6c780eeefcf7a02f4e

[16] http://fdable.com/advanced_aers_query/d9145add4e63f3351e72ca0506a900ff

[17]https://www.medalerts.org/vaersdb/findfield.phpTABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=FLU(H1N1)&VAX[]=FLU3&VAX[]=FLU4&VAX[]=FLUA3&VAX[]=FLUA4&VAX[]=FLUC3&VAX[]=FLUC4&VAX[]=FLUN(H1N1)&VAX[]=FLUN3&VAX[]=FLUN4&VAX[]=FLUR3&VAX[]=FLUR4&VAX[]=FLUX&VAX[]=FLUX(H1N1)&VAX[]=H5N1&VAXTYPES=Influenza

[18] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=FLU(H1N1)&VAX[]=FLU3&VAX[]=FLU4&VAX[]=FLUA3&VAX[]=FLUA4&VAX[]=FLUC3&VAX[]=FLUC4&VAX[]=FLUN(H1N1)&VAX[]=FLUN3&VAX[]=FLUN4&VAX[]=FLUR3&VAX[]=FLUR4&VAX[]=FLUX&VAX[]=FLUX(H1N1)&VAX[]=H5N1&VAXTYPES=Influenza&SERIOUS=ON

[19] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS = ON&VAX[]=FLU(H1N1)&VAX[]=FLU3&VAX[]=FLU4&VAX[]=FLUA3&VAX[]=FLUA4&VAX[]=FLUC3&VAX[]=FLUC4&VAX[]=FLUN(H1N1)&VAX[]=FLUN3&VAX[]=FLUN4&VAX[]=FLUR3&VAX[]=FLUR4&VAX[]=FLUX&VAX[]=FLUX(H1N1)&VAX[]=H5N1&VAXTYPES=Influenza&DIED=Yes

[20] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=COVID19&VAX[]=COVID192&VAXTYPES=COVID-19ENDNOTES

[21] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=COVID19&VAX[]=COVID192&VAXTYPES=COVID-19&SERIOUS=ON

[22] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=COVID19&VAX[]=COVID19-2&VAXTYPES=COVID-19&DIED=Yes

ENDNOTES (Continued)

[23] https://www.floridahealth.gov/newsroom/2024/09/20210912-UpdatedGuidanceCOVID-19.html

[24] https://childrenshealthdefense.org/defender/idaho-health-board-defy-cdc-fda-covid-vaccines-clinics/

[25] https://vaccine-schedule.ecdc.europa.eu/Scheduler/ByDisease?SelectedDiseaseId=52&SelectedCountryIdByDisease=-1

[26] https://vaccine-schedule.ecdc.europa.eu/Scheduler/ByDisease?SelectedDiseaseId=52&SelectedCountryIdByDisease=-1

[27] https://www.health.gov.au/sites/default/files/2024-09/recommended-covid-19-vaccine-doses.pdf

[28] https://www.travelandleisure.com/travel-news/vaccinated-americans-travel-to-europe

[29] https://www.cdc.gov/covidvaxview/weekly-dashboard/index.html

[30] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx

[31] https://icandecide.org/wp-content/uploads/2023/10/001-COMPLAINT.pdf

[32] https://www.hrsa.gov/cicp

[33] https://www.nvic.org/law-policy-federal/vaccine-injury-compensation/1986-national-childhood-vaccine-injury-act

[34] https://www.hrsa.gov/vaccine-compensation

[35] https://ecf.cofc.uscourts.gov/cgi-bin/CFC_RecentDecisionsOfTheSpecialMasters.pl

[36] https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2019vv1563-126-0

[37] https://www.informedchoicewa.org/wp-content/uploads/2023/11/Vit-D-Iodine-RSV-Vaccine-copy.pdf; and https://covidindex.science/index-entries?kb_search_multiple_fields=Vitamin+D&kb_advanced_search_selection=no&kb_index_entries_search_ordering__ie_page=kb_information_source_name%3Aasc&search=kb_index_entries_list_with_advanced_search&task=search

[38] https://www.informedchoicewa.org/glutathione-the-antiviral-you-need-now/

[39] https://healthyimmunitynow.org/efu-challenge