National Vaccine Information Center

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January 25, 2023

Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration,
10903 New Hampshire Avenue, Bldg. 71
Silver Spring, MD 20993-0002
Via: Regulations.gov

Re: Docket No. FDA-2022-N-2810 for "Vaccines and Related Biological Products Advisory Committee (VRBPAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments" Federal Register Citation 87 FR 77617.

The National Vaccine Information Center (NVIC) provides the following as our public comment for the above referenced docket. We note that the meeting's public notice in the Federal Register was issued December 19, 2022 by the Food and Drug Administration (FDA), with a very vague agenda "to discuss the future vaccination regimens addressing COVID-19." As of January 19, 2023, no background materials had been provided to the public. The lack of agenda and background materials prior to the deadline denies the public meaningful input to VRBPAC and hinders the ability of members of the public to provide relevant public comments and presentations. This lack of transparency appears to violate the spirit of the Federal Advisory Committee Act (FACA) governing VRBPAC meetings.

NVIC requests that the FDA provide the public with reasonable access to background materials for the meeting and a more detailed agenda, with deadlines for public comment set after the availability of these items to allow the public meaningful access to the VRBPAC public comment process.

Below are NVIC's comments in relation to "future vaccination regimens addressing COVID-19".

Unlicensed mRNA COVID-19 Vaccines Rushed to Market Without Demonstrating Adequate Efficacy

Following the declaration of a novel coronavirus public health emergency in March 2020 and the fast-tracked development of COVID-19 vaccines,[1] in December 2020, the FDA granted an Emergency Use Authorization (EUA) to Pfizer/BioNTech to distribute an unlicensed mRNA COVID-19 vaccine for use in persons over 16 years old, followed by an EUA granted to Moderna to distribute an unlicensed mRNA COVID-19 vaccine for use in persons over 18 years old.[2] [3] It is the fastest development and mass administration of an experimental vaccine to humans in history.[4]

Typically, the development, testing, and licensing process for most vaccines is about 10 years before receiving approval from the FDA.[5] The EUA status granted by FDA officials to the two manufacturers of mRNA COVID-19 vaccines has resulted in an initial release of unlicensed vaccines using novel technology, which have been aggressively promoted by federal health officials for widespread use by the American public with less than a year of testing.[6] [7] [8] The clinical trials that were conducted on mRNA COVID-19 vaccines prior to FDA officials granting manufacturers an EUA failed to answer basic questions about the ability of the vaccines to prevent SARS-CoV-2 infection and transmission, with the FDA only requiring manufacturers to demonstrate the vaccines had at least 50 percent efficacy in prevention of severe symptoms of COVID disease.[9] [10] [11]

As early as April 2021, officials at the U.S. Centers for Disease Control and Prevention (CDC) reported 10,262 cases, 995 hospitalizations and 160 deaths among persons who had been fully vaccinated, while also acknowledging that infection rates within vaccinated populations were likely much higher, due to passive reporting systems in use.[12] In late April 2021, CDC officials announced that they would only be tracking breakthrough cases resulting in hospitalizations and death,[13] which had the effect of skewing published data on vaccine effectiveness and denying the public adequate information upon which to make informed vaccine decisions.

By July 2021, CDC officials issued a health alert stating that the fully vaccinated were still at risk for infection and were able to infect others.[14] In a peer-reviewed study published in November 2021, effectiveness at six months had waned for the Moderna mRNA COVID-19 vaccine and was demonstrated to be only 58 percent and Pfizer reported a 43.3 percent effectiveness.[15] In November 2022, CDC officials reported that mRNA COVID-19 bivalent vaccines were less than 50 percent effective in all adult populations in preventing symptomatic infection.[16]

As of January 8, 2023, health officials have warned that, while there is evidence that COVID-19 vaccines can prevent symptomatic COVID-19 disease, there is a lack of evidence that the vaccines are effective in preventing infection and transmission of SARS-CoV-2.[17] [18] [19] [20] [21] [22] Pfizer company officials have acknowledged that, prior to receiving an EUA to distribute their COVID-19 mRNA vaccine, clinical trials were not conducted to determine whether the vaccine would stop transmission of the SARS-CoV-2 virus.[23]

Had the FDA required COVID-19 vaccine manufacturers to adhere to a higher standard for proof that the mRNA COVID vaccines were effective in preventing infection and transmission of SARS-CoV-2, the coronavirus pandemic may not have been as severe and lawmakers would have reconsidered implementing draconian lockdown policies, which could have resulted in far less damage to the economy, child development, and the mental health of Americans.[24] At the very least, more honesty and transparency about mRNA COVID-19 vaccine effectiveness would have allowed the public to make better informed decisions about vaccination and coronavirus disease prevention.

Unlicensed mRNA COVID-19 Vaccines Rushed to Market Without Demonstrating Adequate Safety

The rush to market mRNA COVID-19 vaccines by December 2020 did not allow for adequate study of long-term adverse effects. Considering that the mRNA technology and nanoparticle delivery system for vaccine production had never been licensed,[25] [26] FDA's laissez-faire approach to requiring mRNA COVID-19 vaccine manufacturers to prove safety over the short and long term is disturbing. For example, FDA officials used vague caveats when granting Pfizer an EUA based on the *"totality of the scientific evidence available"* that the *"known and potential benefits…outweigh the known and potential risks of the vaccine."*[27] Those kinds of caveats clearly demonstrate that an EUA allows a lower standard for scientific evidence of the product's safety and effectiveness than full licensure.[28,29] In fact, it is not unreasonable to conclude that the Pfizer COVID vaccine is still an investigational product for younger age groups.

In the Phase 2/3 clinical trials Pfizer conducted on its mRNA COVID-19 vaccine, before FDA officials granted the company an EUA to distribute, the majority of vaccinated participants experienced a local or systemic reaction, with younger people more often reporting side effects like pain at the injection site, headache, fatigue, fever and swollen lymph glands that occurred more often after the second dose and lasted for several days. The few serious adverse events recorded after vaccination in the trial, such as cardiac arrhythmia and a death from cardiac arrest, were dismissed by investigators as unrelated to the vaccine.[30] Unfortunately, the choice by investigators to engage in the unscientific "it's just a coincidence" denial of serious adverse events after vaccination - without objection from VRBPAC or FDA officials - has had catastrophic consequences for people receiving mRNA COVID-19 vaccines.

Published reanalysis of Pfizer's pre-EUA clinical trial data revealed a 36 percent higher risk of serious adverse events, including myocarditis/pericarditis, in adult vaccinated participants in comparison to placebo participants.[31] National Institutes of Health officials acknowledge that mRNA COVID-19 vaccines can cause myocarditis in 1 in 50,000 vaccinations,[32] and there are questions being raised about FDA's delayed release of information on the frequency of myocarditis after receipt of the Pfizer mRNA COVID-19 vaccine,[33] and lack of transparency about autopsy results of patients who have died after COVID vaccinations.[34]

According to research published in the medical literature since December 2020, mRNA vaccines stimulate a very strong inflammatory response that can cause, for example, inflammation of the heart and brain.[35] [36] [37] [38] If inflammation does not resolve in the body,[39] it can lead to chronic inflammation, disability and ongoing health problems or death. There are now multiple reports and analyses in the medical literature, which reveal a spectrum of immune mediated serious health problems associated with the mRNA COVID-19 vaccines.[40] [41] [42] [43] [44] [45] [46] [47] [48] [49] [50] [51] [52] [53] [54] [55] [56]

By January, over 80 percent of the U.S. population, including 98 percent of those over age 65, had gotten at least one dose of COVID-19 vaccine and about 70 percent had completed the primary series.[57] [58] At the same time, as of January 13 2023, there have been over 1.5 million COVID vaccine-related adverse event reports made to the federal Vaccine Adverse Event Reporting System (VAERS), with 93 percent of those adverse events associated with mRNA COVID vaccines.[59] This means that over half of the 2.4 million vaccine adverse event reports filed with VAERS since it became operational in 1990 are associated with mRNA COVID vaccines, which have only been on the market for about two years. This shocking statistic is even more concerning because,

historically, there has been acknowledged gross underreporting of vaccine-related adverse events to VAERS, which some have estimated to be as a low as between one and 10 percent.[60] [61]

It is widely acknowledged that not every adverse event report made to VAERS is causally associated with the vaccine received. However, the fact that more than half of all vaccine adverse event reports filed with VAERS over the past three decades are associated with mRNA COVID vaccines should not be ignored by FDA and should be followed up with methodologically sound basic science research to determine the biological mechanisms and genetic, epigenetic and other biological high-risk factors for mRNA COVID vaccine adverse events.

Lack of Data to Justify EUA to Administer mRNA COVID-19 Vaccines to Children

By early 2022, the CDC acknowledged that about 75 percent of U.S. infants and children from birth to 17 years of age had already been infected with COVID-19,[62] and that the majority of children only *"experience asymptomatic or mild illness"* from SARS-CoV-2 infections, with a small number of children with certain underlying health conditions having an increased risk for severe illness and serious complications.[63] [64] Additionally, research continues to accumulate that demonstrates natural immunity as being robust and protective. A pre-print study published January 19, 2023 found *"previous SARS-CoV-2 infection induced strong immunity against future infection".*[65] This finding is similar to existing peer-reviewed research that demonstrates natural immunity in children is protective and enduring.[66] [67] [68] [69]

Even so, when FDA officials granted an EUA to distribute mRNA COVID-19 vaccines in June 2022 for use in children as young as six months old, and extended an EUA to booster shots in January 2023, they did so with questionable safety data falling well below the previously established COVID-19 vaccine clinical trial guideline published by FDA in 2020 of demonstrating at least 50 percent efficacy in symptomatic disease prevention. [70] [71] At the time, little was known about long-term side effects of the vaccines [72] [73] or their ability to reduce severe symptoms of COVID disease.[74]

Acknowledged Risks and Lack of Additional Analyses

Additionally, the CDC has not performed adequate analyses of reported COVID-19 vaccine events as promised to the public to determine if there are additional safety signals of concern.[75]

There is inadequate scientific documentation of mRNA COVID-19 vaccine safety and effectiveness to make the assumption that benefits outweigh the risks, especially when the vaccine fails to prevent infection and transmission.
Adhering to the precautionary principle and with respect for the informed consent ethic, the National Vaccine Information Center calls on the FDA to ask Pfizer/BioNTech and Moderna to voluntarily withdraw mRNA COVID vaccines from the market.

There is historic precedent for withdrawal of a previously licensed and recommended vaccine that was subsequently found to be associated with a serious complication. RotaShield rotavirus vaccine was withdrawn by its manufacturer in 1999 when intussusception was identified as a serious but rare complication of that vaccine, a reaction which could injure and kill those who received RotaShield.[76]

In light of the known risks and failures of mRNA COVID vaccines, the public is waiting for the FDA to do its job and exercise appropriate regulatory authority over manufacturers of a vaccine that has yet to be fully licensed for all age groups.

Sincerely,

Barbara Loe Fisher

Barbara Loe Fisher,
Co-Founder & President

Theresa Wrangham

Theresa Wrangham,
Executive Director

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[1] Tregoning JS, Brown ES. Vaccines for COVID-19. *Clin Exp Immunol* November 2020; 202(2): pp.162-192.
[2] U.S. Food and Drug Administration. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Dec. 11, 2020.
[3] U.S. Food and Drug Administration. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. Dec. 18, 2020.

[4] Cohen S. The fastest vaccine in history. *UCLA Health* Dec. 10, 2020.
[5] Pronker ES, Weenen TC, Commandeur H et al. Risk in Vaccine Research and Development Quantified. *PLOS One* 2013; 8(3).
[6] U.S. Food and Drug Administration. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Dec. 11, 2020.
[7] U.S. Food and Drug Administration. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. Dec. 18, 2020.
[8] Fisher BL, What Mothers Should Know About COVID and COVID-19 Vaccine for Children. *National Vaccine Information Center* Mar. 11, 2022.
[9] FDA. Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry. Efficacy Considerations Pages 13-24. Revised June 2020.
[10] Doshi P. Will covid-19 vaccines safe lives? Current trials aren't designed to tell us. *BMJ* October 2020; 371:m4037.
[11] U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines. June 20, 2020.
[12] U.S. Centers for Disease Control and Prevention. COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. *MMWR* May 28, 2021;70:792–793.
[13] U.S. Centers for Disease Control and Prevention. Identifying and investigating hospitalized or fatal vaccine breakthrough cases. In: COVID-19 Vaccine Breakthrough Case Investigation and Reporting. Apr. 16, 2021.
[14] U.S. Centers for Disease Control and Prevention. Vaccination to Prevent COVID-19 Outbreaks with Current and Emergent Variants — United States, 2021. In: Emergency Preparedness and Response. July 27, 2021.
[15] Cohn BA, Cirillo PM, Murphy CC, et al. SARS-CoV-2 vaccine protection and deaths among US veterans during 2021. Science Jan 21, 2022;375(6578):331-336.
[16] Link-Gelles R, Ciesla AA, Fleming-Dutra KE, et al. Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection — Increasing Community Access to Testing Program, United States, September–November 2022. *MMWR* ePub: November 22, 2022.
[17] Sky News Australia. WHO doesn't have evidence vaccines prevent people transmitting virus to others. Dec. 29, 2020.
[18] Kim S. Dr. Fauci on Mandatory COVID Vaccines: 'Everything Will Be on the Table. *Newsweek* Jan. 1, 2021.
[19] Fisher BL. WHO and Fauci Warn COVID-19 Vaccines May not Prevent Infection and Disease Transmission. *The Vaccine Reaction* Jan. 4, 2020.
[20] Caceres B. COVID Vaccines Not Proven to Prevent SARS-CoV-2 Infection or Transmission. *The Vaccine Reaction* Aug. 9, 2021.
[21] Johnson & Johnson. Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA for Emergency Use – First Single Shot Vaccine in Fight Against Global Pandemic. Feb. 27, 2021.
[22] Stokel-Walker C. What do we know about covid vaccines and preventing transmission? *BMJ* Feb 4, 2022;376:o298.
[23] Phillips J. Pfizer Exec Concedes COVID-19 Vaccine Was Not Tested on Preventing Transmission Before Release. The Epoch Times Oct. 13, 2022.
[24] Alexander PE. More Than 400 Studies on the Failure of Compulsory Covid Interventions (Lockdowns, Restrictions, Closures). *Brownstone Institute* Nov. 30, 2021. /
[25] Trilingiris D, Vallianou NG, Karampela I et al. Potential implications of lipid nanoparticles in the pathogenesis of myocarditis associated with the use of mRNA vaccines against SARS-CoV-2. *Metabolism Open* 2022; 13: 100159.
[26] Dwivedi R. Research looks at inflammatory nature of lipid nanoparticle component in mRNA vaccines. *News-Medical.net* May 15, 2021.
[27] O'Shaughnessy JA. Letter to Amit Patel, Pfizer Inc. amending EUA to authorize use of COMIRNATY (Covid-19 Vaccine, mRNA) as a single booster dose in individuals 12 through 15 years of age. *U.S. Food & Drug Administration* Jan. 3, 2022.
[28] Sherkow JS, Quellette LL et al. What's the Difference Between Vaccine Approval (BLA) and Authorization (EUA)? *The Petrie-Flom Center* June 15, 2021.
[29] Siri A. Federal law prohibits employers and others from requiring vaccination with a Covid-19 vaccine distributed under an EUA. *STAT* Feb. 23, 2021.
[30] Polack FP, Thomas SJ, Kitchin N et al. Safety and Efficacy of the BNT162B2 mRNA COVID-19 Vaccine. *N Engl J Med* Dec. 10, 2020.
[31] Fraiman J, Erviti J, Homes M, et al. Serious adverse events of special interest following. mRNA COVID-19 vaccination in randomized trials in adults. *Vaccine* 2022; 40(4)): 5798-5805.
[32] National Institutes of Health. *COVID-19, Vaccines and Myocarditis*. July 1, 2022.
[33] Stieber Z. Deadline Passes for Pfizer to Submit Results of Post-Vaccination Heart Inflammation Study to US Regulators. *The Epoch Times* Jan. 11. 2023.

[34] Stieber Z. FDA Withholding Autopsy Results on People Who Died After Getting COVID-19 Vaccines. *The Epoch Times* Sept. 30, 2022.
[35] Myashita Y, Yoshida T, Talagi Y, et al. Circulating extracellular vesicle microRNAs associated with adverse reactions, proinflammatory cytokine, and antibody production after COVID-19 vaccination. *Vaccines* 2022; 7(16).
[36] Husby A, Hansen IV, Fosbol E et al. SARS-CoV-2 vaccination and myocarditis and myopericarditis: population based cohort study. BMJ 2021; 375.
[37] Finsterer J. Neurological side effects of SARS-CoV-2 vaccinations. Acta Neurol Scand 2022; 145(1): 509.
[38] The Vaccine Reaction. Canadian Government Approves Compensation for Man Paralyzed by Pfizer's COVID Shot. Jan. 22, 2023.
[39] Sugimoto MA, Souse LP, Pinho V et al. Resolution of Inflammation: What Controls Its Onset. *Frontiers in Immunology* 2018; 7(160).
[40] Shimabukuro T. COVID-19 Vaccine safety updates. U.S. Centers for Disease Control and Prevention June 23, 2021.
[41] Kim HW, Jenista ER, Wendell DC, et al. Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination. *JAMA* Cardiol. Oct 1, 2021;6(10):1196-1201.
[42] Barda N, Dagan N, Ben-Shlomo Y. et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *N Engl J Med* Sept. 16, 2021; 385:1078-1090.
[43] Krug A, Stevenson J, Hoeg T, et al. BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis. *Eur. J. Clin. Invest*. Feb. 14, 2022; 52 (5): e13759.
[44] Patone M, Mei XW, Handunnetthi L, et al. Risk of Myocarditis, Pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. *Nature Medicine* Dec. 14, 2021.
[45] Furer V, Zisman D, Kibari A, et al. Herpes zoster following BNT162b2 mRNA Covid-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series. *Rheumatology - Oxford* Apr. 12, 2021; keab345.
[46] Vera-Lastra O, Ordinola Navarro A, Cruz Domiguez MP, et al. Two Cases of Graves' Disease Following SARS-CoV-2 Vaccination: An Autoimmune/Inflammatory Syndrome Induced by Adjuvants. *Thyroid* September 2021;31(9):1436-1439
[47] Lee EJ, Cines DB, Gernsheimer T et al. Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination. Am J Hematol May 1, 2021;96(5):534-537.
[48] European Medicines Agency. Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021. May. 7, 2021.
[49] Hughes S. Thrombosis With Thrombocytopenia After mRNA COVID-19 Vaccine. *Medscape* June 28, 2021.
[50] Khayat-Khoei M, Bhattacharyya S, Katz J. et al. COVID-19 mRNA vaccination leading to CNS inflammation: a case series. *J Neurol* Sept. 4, 2021: 269, 1093–1106.
[51] European Medicines Agency. Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 30 August – 2 September 2021. Sept. 3, 2021.
[52] Blasius M. Unheard Concerns: Thousands blame COVID-19 vaccine for hearing problems. *ABC 15 Arizona* Sept. 17, 2021.
[53] Parrino D, Frosolini A, Gallo C, et al. Tinnitus following COVID-19 vaccination: report of three cases. *Int J Audiol* June 2022;61(6):526-529.
[54] Fujio K, Sung J, Nakatani S, et al. Characteristics and Clinical Ocular Manifestations in Patients with Acute Corneal Graft Rejection after Receiving the COVID-19 Vaccine: A Systematic Review. *J Clin Med* Aug. 2, 2022, 11(15), 4500.
[55] Alhumaid S, Rabaan AA, Dhama K. et al. Solid Organ Rejection following SARS-CoV-2 Vaccination or COVID-19 Infection: A Systematic Review and Meta-Analysis. *Vaccines (Basel)* Aug 10, 2022;10(8):1289.
[56] Nguyen Ly M. Rare Spinal Cord Condition Flagged as Potential Adverse Effect of COVID-19 Vaccines: EU Drug Regulator. *The Epoch Times* Jan. 15, 2022
[57] CDC. COVID-19 Vaccinations in the United States. Jan.18, 2023.
[58] Durkee A. Stunning Vaccine Stat: 98.5% of U.S. Seniors Have Had Shot. *Forbes* Apr. 21, 2022.
[59] MedAlerts. U.S. VAERS Database Search on Age and Vaccine. VAERS Data as of January 13, 2023.
[60] Rosenthal S, Chen R. The reporting sensitivities of two passive surveillance systems for vaccine adverse events. *Am J Public Health* 1995;85(12):1706–9.
[61] Harvard Pilgrim Health Care, Inc. Electronic System for Public Health Vaccine Adverse Event Reporting System. *AHRQ* 2011.
[62] U.S. Centers for Disease Control and Prevention. Seroprevalence of Infection-Induced SARS-CoV-2 Antibodies – United States, September 2021 – February 2022. MMWR Apr. 29 2022; 71(17): 606-608.
[63] Forrest CB, Burrows EK, Mejias A et al. Severity of Acute COVID-19 in Children under 18 Years Old March 2020 to December 2021. Pediatrics 2022; 149(4).
[64] U.S. Centers for Disease Control and Prevention. Severity and Underlying Medical Conditions. In: COVID-19 Information for Pediatric Healthcare Providers. Oct. 19, 2022.

[65] Yu Lin D, Xu Y, Gu Y, et al. Effectiveness of Vaccination and Previous Infection Against Omicron Infection and Severe Outcomes in Children Under 12 Years of Age. medRXiv Jan. 19, 2023.
[66] Dowell AC. Butler MS. Jinks E. et al. Children develop robust and sustained cross-reactive spike-specific immune responses to SARS-CoV-2 infection. Nat Immunol Dec. 22, 2021.
[67] Keeton R. Tincho MB. Ngomti A. et al. T cell responses to SARS-CoV-2 spike cross-recognize Omicron. Nature Jan. 31, 2022.
[68] Patalon T. Saciuk Y. Hadad HO, et al. Naturally-acquired Immunity Dynamics against SARS-CoV-2 in Children and Adolescents. medRXiv June 21, 2022.
[69] Alexander PE. 160 Plus Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted. Brownstone Institute Oct. 17, 2021.
[70] FDA. Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry. Efficacy Considerations Pages 13-24. Revised June 2020.
[71] Miller I. There Is No Basis for the FDA to Authorize Covid Vaccines For Toddlers. Brownstone Institute June 21, 2022.
[72] Fisher BL. U.S. Becomes First Country to Give mRNA COVID Vaccine to Babies. The Vaccine Reaction June 21, 2022.
[73] Hendler C. FDA Approves U.S. Babies and Young Children to Get Omicron COVID Booster Shots
[74] Kulldorff M. Should I Vaccinate My Child Against Covid? Brownstone Institute Mar. 8, 2022.
[75] Balmakov R. CDC Director Admits Agency Gave False Information to Epoch Times on Safety Monitoring | Facts Matter. Epoch Times Sept. 23, 2022.
[76] Delage G. Rotavirus vaccine withdrawal in the United States; The role of postmarketing surveillance. *Can J Infect Dis* 2000; 11(1): 10-12.