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March 28, 2023

VIA EMAIL

National Academies of Sciences, Engineering, and Medicine
Committee Members c/o Kathleen Stratton, Responsible Staff Officer
vaccines@nas.edu

Re: Review of Relevant Literature Regarding Adverse Events Associated with Vaccines

Dear Kathleen Stratton, Chair George J. Isham, and Committee Members:

We write on behalf of Informed Consent Action Network ("**ICAN**") regarding the above-referenced review and your committee's charge concerning the causal association between certain vaccines and specific adverse events.[1] ICAN respectfully asks that you please take the following critical, real-world points into consideration as you meet and reach conclusions for your report.

I. Vaccine Injury, Generally

As noted, our firm represents ICAN, a 501(c)(3) organization founded with the mission of investigating and educating the public on the safety of medical procedures, pharmaceutical drugs, and vaccines. In addition to representing ICAN, our firm has extensive experience with vaccine-related matters with more than 30 professionals who handle vaccine injury, exemptions, and policy matters. In our robust vaccine injury practice, we represent children and adults in the Vaccine Injury Compensation Program ("**VICP**") who have been injured by vaccines. At your committee meeting in January, Dr. Grimes from HRSA spoke to you about the VICP.[2] While Dr. Grimes is correct that statistics show that most of the cases filed in the VICP in recent years are for shoulder injuries, including Shoulder Injury Related to Vaccine Administration ("**SIRVA**"), and for Guillain-Barré Syndrome ("**GBS**") after influenza vaccine, implying that this is a reflection of the injuries caused by vaccines is misleading.

While it is true that SIRVA and GBS cases are the most frequently filed cases, what Dr. Grimes did not disclose is that this is because the VICP is no longer a place for swift, flexible, and less adversarial litigation. Almost all vaccine injury cases are extremely complex and require the retention of multiple experts in specialties such as immunology, neurology, rheumatology, otolaryngology, orthopedics, cardiology, as well as other specialties. Congress' intention in

[1] *See* https://www.nationalacademies.org/our-work/review-of-relevant-literature-regarding-adverse-events-associated-with-vaccines#sectionCommittee.

[2] *See* https://www.nationalacademies.org/event/01-25-2023/review-of-relevant-literature-regarding-adverse-events-associated-with-vaccines-meeting-1.

creating the VICP was to provide vaccine injured individuals a "swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation."[3] The VICP was created with the intention that "close calls regarding causation would be resolved in favor of the injured petitioner" and recognized that the "purpose of the Vaccine Act's preponderance standard was to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."[4]

In the early years of the VICP, it appears the program worked as designed, however, for many years now, the VICP has not been operating as intended and many vaccine injured petitioners with cases in the VICP are required to go to great lengths to prove they have suffered a vaccine injury. Moreover, the attorneys from the Department of Justice ("**DOJ**") who represent The U.S. Department of Health and Human Services("**HHS**"), the Respondent in all vaccine injury cases in the VICP, are relentless when it comes to defending these cases. Catastrophic vaccine injury cases can linger for 5 to 8 years, or more, as injured petitioners' appeals wind their way through the system in a fight to get compensation. Even Table Injury cases, where vaccine causation is presumed, can take an average of two years to resolve.

For many firms taking on vaccine injury cases, it is much easier to focus exclusively on the Table Injury cases, such as SIRVA or GBS, in order to keep their practices running. We, too, have many cases of SIRVA and GBS after influenza vaccine but we also zealously represent children and adults who have died after receiving vaccines as well as individuals with catastrophic and life-altering injuries. Some of the injuries that have occurred after routine vaccinations include encephalopathy, seizures, anaphylactic shock, syncope, sensorimotor polyneuropathy, chronic inflammatory demyelinating polyneuropathy, ulnar neuropathy, tinnitus, vertigo, polymyalgia rheumatica, transverse myelitis, optic neuritis, transverse myelitis, Bell's Palsy, lichen planus, autoimmune hepatitis, hearing loss, and inflammatory arthritis. This is not an exhaustive list.

Critically, petitions filed by those injured are reviewed by HHS, which in turn sends recommendations to the attorneys at the DOJ handling these cases. After receiving the recommendation from HHS, the DOJ attorneys convey HHS's position through a written report to the presiding Special Master at the U.S. Court of Federal Claims Office of Special Masters. If HHS has decided to defend against a specific case, Petitioners must fight hard to prove they are entitled to compensation. While petitioners do not need certainty to prevail, often times reports from governmental committees on vaccine injury are submitted by HHS to support the contention that the vaccine was not responsible for the injury. Further, HHS's recommendations in vaccine injury cases are strongly guided by reports like the one your committee is being charged with drafting right now. As Dr. Grimes shared with you all at your January meeting, the last significant report from the Academies was issued in 2012. Dr. Grimes said:

> [T]he 2012 report has been something that we look at as truly one of the sentinel works in the field…. [I]t is really, really something we lean heavily on from the HRSA side as we make considerations and determinations of causality as it relates to our program…. This

[3] *See* https://www.uscfc.uscourts.gov/vaccine-program-readmore.

[4] *See Althen v. Sec'y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005).

> current charge to the committee will be new in that it will be of particular import to the CICP as well as the VICP so just by doing the work, you are going to be filling a large need for us. The causality assessments and the structure you use in that report were really, really essential for us in being able to make these determinations…[5]

Additionally, Dr. Tom Shimabukuro, Director of the Immunization Safety Office at the CDC, told you that he relies upon the 2012 IOM report on a routine basis in his daily work, including when working on recommendations for updates to the injury table: "[The 2012 reports is] probably the reference I have used the most in my career in immunization safety and really think it's a, kind of a great blueprint on how to do a very thorough evidence review and come up with recommendations for HRSA… [I]t is an impressive piece of work."[6]

II. Covid-19 Vaccine Injury

Our firm has been directly contacted by thousands of people who have been injured by the Covid-19 vaccine as well as many family members whose loved ones have died after receiving a Covid-19 vaccine. The overwhelming majority of the injuries individuals contact our firm about are severe, life-changing, catastrophic injuries that have completely devastated these individuals' lives. These individuals have no doubt in their mind, and very often have compelling evidence, that a Covid-19 vaccine was the cause of their ailments. In most cases, these people were healthy, happy, gainfully employed or happily retired and were enjoying their lives. They report that following receipt of their Covid-19 vaccine, their entire lives have been forever altered. These individuals have reported bowel loss, stroke, brain bleed, death, severe and debilitating headaches, tremors, seizures, tinnitus, burning tongue syndrome,[7] severe joint pain, burning sensations, blurred vision, severe rash, anaphylaxis, GBS, SIRVA, myocarditis, tingling and burning in extremities, small fiber neuropathy, and other serious conditions. Attached is an appendix with just a sample of studies that this committee should review concerning adverse events following Covid-19 vaccination.

While our firm has undertaken representation of a select few cases in the Countermeasures Injury Compensation Program ("**CICP**"), the issues with this program are vast and include: a very short, one year statute of limitations from the date the vaccine was received to file a timely claim; an elevated burden of "direct proof" that the vaccine caused the injury (a somewhat impossible feat when the literature on adverse events and biological mechanisms is being studied

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[5] *See* https://www.nationalacademies.org/event/01-25-2023/review-of-relevant-literature-regarding-adverse-events-associated-with-vaccines-meeting-1 starting at 31:50.

[6] *Id.* at 34:22. While "very impressed with the rigor in which that review was conducted," *id.* at 34:11, Dr. Shimabukuro, when asked by Dr. Isham about the methodology used in writing the 2012 report and whether that could be updated, conceded that he "may have to go back and review the methods a little bit on that report. When [he] use[s] it, it's usually getting right to the assessments," *id.* at 1:02:36. He admitted that he was "not able to answer that question right now because [he] would need to refamiliarize [him]self with some of the specific methods that they used to come to their conclusions on both the epi and mechanistic evidence." *Id.* at 1:02:36. Dr. Grimes said the same held true for him and he would need to review the report before answering. *Id.* at 1:03:04.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8902844/.

simultaneously with the rollout and administration of these vaccines); the compensation available does not include pain and suffering; and the CICP is an administrative process with no avenue for the injured to prove their case in front of a judge or jury. Millions of Americans have been adversely affected by the Covid-19 vaccines. Many of those injured have lost their jobs and their ability to care for their families. Some have faced loss of their homes and their lives as they once knew them. They need fair and adequate compensation for these harms and your sponsor's, no doubt, are hoping to use your report to deny them that compensation.

III. Maddie de Garay

Let us provide you with one specific example. Maddie de Garay, a now-14-year-old girl, was seriously injured at age 12 after participating in Pfizer's Covid-19 clinical trial for 12-15-year-olds, which only included 1,131 children who received the Pfizer shot.[8] Maddie's injuries left her wheelchair-bound and reliant upon a feeding tube, yet Pfizer classified her severe injuries as mere "functional abdominal pain" in its emergency use authorization submission to the FDA.[9] On behalf of Maddie, our firm wrote to the FDA four separate times,[10] and provided her medical records, while the de Garays submitted their own comment to the FDA about this falsity.[11] Neither our firm nor the de Garays received any response until February 26, 2022, when Paul Richards, M.D., the Chief of the Consumer Affairs Brach of the FDA's Center for Biologics and Evaluation and Research, sent an email response which contained no explanation for the agency's over four-month-long delay in responding and, instead, incredibly suggested that the de Garays file a VAERS report. The de Garays had already done so.[12] The FDA seemingly left the determination as to whether Maddie's injuries were caused by the vaccine or not to the principal investigator, paid by Pfizer. Maddie – injured over 2 years ago – remains unhealed and uncompensated.

[8] https://www.nejm.org/doi/full/10.1056/NEJMoa2107456.

[9] https://www.sirillp.com/wp-content/uploads/2022/03/nr_EUA-27034.132-Review-Memo-Pfizer-BioNTech-COVID-19-Vaccine_RE-4dc738480420dad83663dbb169bd3fd3.pdf.

[10] https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-1-Oct.-22-2022-Ltr-to-Fed.-Health-Agencies-a4c120ce47dcfe008aa6d9ee38b682e4.pdf; https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-2-10-25-2021-VRBPAC-Letter_FINAL-3ba813862ca35aaea42a9c5dcf2480a0.pdf; https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-3-Jan-3-2022-Dr.-Peter-Mark-Letter_2022_01_03-41fe80ff1853909f2e9b5e329a55934e.pdf; https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-3-Jan-3-2022-Dr.-Peter-Mark-Letter_2022_01_03-41fe80ff1853909f2e9b5e329a55934e.pdf.

[11] https://www.sirillp.com/wp-content/uploads/2022/03/Paul-Richards-email-response_2022_02_26_Redacted-33b881e4534f7fc2af8e5872c01984ea.pdf.

[12] https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-6-VAERS-Report-45f531e089effee94bec01a9a9b4a0f9.pdf

Significantly, one of Maddie's early diagnoses was Functional Neurological Disorder ("**FND**").[13] While the principal investigator of Maddie's trial declined to report even this diagnosis as research related, a recent study acknowledged that a diagnosis of FND post-Covid-19 vaccination is "increasingly recognized, but likely under-reported or misdiagnosed as Long-COVID," and typically has an acute onset as it did in Maddie's case.[14] We urge you to carefully look at all claimed adverse events, including those of a functional nature.

IV. V-Safe Data

In its effort to understand more about the rate of claimed adverse events following Covid-19 vaccination, ICAN, after over a year of litigation, obtained data from v-safe, the CDC's new smartphone-based program designed to track side effects of Covid-19 vaccines. V-safe collects data by having users periodically provide health check-ins after vaccination.[15] Among numerous alarming results that the data revealed, more than 7.7% of v-safe users reported a health event requiring medical attention, emergency room intervention, and/or hospitalization following Covid-19 vaccination.[16] An additional more than 25% had an event that required them to miss school or work and/or prevented normal activities.[17] Assuming this data can be generalized to the American public, which ICAN believes it can be (or is, if anything, underreporting), this sheds bright light on the true rate of Americans who have suffered after receiving a Covid-19 vaccine.

V. VAERS Data

In addition to speaking on the 2012 IOM report at your January meeting, Dr. Tom Shimabukuro also gave a presentation in which he represented the following with respect to Vaccine Adverse Event Reporting System ("**VAERS**") data:

> I think one difference for Covid compared to the data that were available back in 2012, is during Covid we had very accurate and timely information on doses administered. So, we had good denominator data that was reported from the states to CDC. And it contained quite a bit of detail, age, sex, things like that. So, we were able to, in our system, the Vaccine Adverse Event Reporting System, able to calculate reporting rates and able to do things like compare

[13] This is something our firm commonly with the HPV vaccines; many adolescents are told they have FND or conversion disorder. Due to the VICP turning a blind eye to these injuries, these HPV vaccines are now being litigated through a multi-district litigation in civil court.

[14] Alonso-Canovas et al., *Functional neurological disorders after COVID-19 and SARS-CoV-2 vaccines: a national multicentre observational study*, J. Neurology & Psychiatry (Mar. 8, 2023), https://jnnp.bmj.com/content/early/2023/03/07/jnnp-2022-330885; *see also* George, Judy, *Functional Neurological Disorder Emerges After COVID Infection, Vaccines — Long COVID functional manifestations differ from post-vaccine effects*, MedPage Today (Mar. 24, 2023), https://www.medpagetoday.com/neurology/longcovid/103708?utm_source=substack&utm_medium=email.

[15] https://icandecide.org/press-release/breaking-news-ican-obtains-cdc-v-safe-data/.

[16] https://icandecide.org/article/v-safe/.

[17] *Id.*

> reporting rates to expected background rates – so observed versus expected. So, I think for Covid, the data from our passive surveillance are unique and different to data than may have been available earlier. We really did not have that type of quality information for the denominator.[18]

Unfortunately, Dr. Shimabukuro expresses far more confidence than the data merits. His sentiments imply that VAERS captures all adverse events to vaccination, but this is demonstratively incorrect. In fact, a flagship HHS-funded review of vaccine adverse events over a three-year period by Harvard Medical School involving 715,000 patients reported that "fewer than 1% of vaccine adverse events are reported."[19] A U.S. House Report reflected this as well: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."[20] Even if that historical 1% reporting rate were to have increased fivefold during the pandemic, it nonetheless means that fewer than 5% of adverse events are being reported. So even if Dr. Shimabukuro were correct about a denominator for Covid-19 vaccines, the numerator is far from accurate real-world data. There are numerous serious additional issues with VAERS (likely one of the core reasons that CDC developed v-safe for the Covid-19 vaccine rollout) that the committee should consider before ruling out causation for any alleged injury based on VAERS data.

VI. Many People Do Not Get Second Dose of Covid-19 Vaccine or Booster

Since the Covid vaccine's rollout, it became clear that an extraordinary number of Americans were forgoing their second dose of mRNA Covid vaccines. At present, according to CDC data, approximately 39,552,907 Americans have skipped their second dose.[21] Given the rate of reactions to mRNA vaccines reported to v-safe, VAERS, and other vaccine safety monitoring platforms, reactions to mRNA vaccines is the most reasonable explanation for why such a significant percentage of those received the first dose have not returned for their second. Notably, peer-reviewed studies have indicated that some patients do not complete a multi-dose vaccine series due to an adverse reaction after one of the doses in the series.[22] Much higher numbers of

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[18] https://www.nationalacademies.org/event/01-25-2023/review-of-relevant-literature-regarding-adverse-events-associated-with-vaccines-meeting-1 starting at 1:08:20.

[19] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.

[20] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf#page=19. By way of example, the CDC reports that "[a]naphylaxis after COVID-19 vaccination is rare and has occurred at a rate of approximately 5 cases per one million vaccine doses administered." *Selected Adverse Events Reported After COVID-19 Vaccination*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (updated Mar. 7, 2023). However, a study at Mass General Brigham that assessed anaphylaxis in a clinical setting after administration of Covid-19 vaccines found "severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations" – a rate almost 50 times higher than the CDC reports. Blumenthal et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, JAMA (Mar. 8, 2021), https://jamanetwork.com/journals/jama/fullarticle/2777417.

[21] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-total (subtracting individuals who have completed a primary series verses individuals receiving at least one dose).

[22] *See, e.g.*, Pittman, et al., *Anthrax vaccine: Immunogenicity and Safety of a Dose-Reduction, Route-Change Comparison Study in Humans*, Vaccine (Jan. 31 2002), https://www.sciencedirect.com/science/

individuals have not received any booster doses. Unfortunately, the CDC's silence on this glaring issue only leads to greater concerns about vaccine safety.

* * *

In conclusion, we respectfully urge you to take the above into account as you work on what will likely determine the fate of numerous Americans injured by these vaccines. We would welcome the opportunity to further discuss any of these issues, or related issues and/or to provide you more information in your review of relevant literature regarding adverse events to vaccines.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Jessica Wallace, Esq.
Catherine Cline, Esq.

Encl: Appendix with a sample of studies concerning adverse events following Covid-19 vaccination.

article/pii/S0264410X01004625?casa_token=KnXjiCJiK8kAAAAA:pvZHey50ifWQZFfcllrffyQN63U01kmPQrMW5wJN7Uj7p4Bdsu.

APPENDIX

The following are only a sample of studies concerning adverse events following Covid-19 vaccination.

Blistering

- Bullous pemphigoid after inactivated Covid-19 vaccination: Case report
- Subepidermal blistering eruptions, including bullous pemphigoid, following COVID-19 vaccination – Letter to the editor
- The first dose of COVID-19 vaccine may trigger pemphigus and bullous pemphigoid flares: is the second dose therefore contraindicated?
- Bullous Pemphigoid Associated With COVID-19 Vaccines: An Italian Multicentre Study
- Can Covid-19 vaccines cause or exacerbate bullous pemphigoid? A report of seven cases from one center
- Association between vaccination and autoimmune bullous diseases: A systematic review

Cancer

- Case Report: Acquired Haemophilia A Following mRNA-1273 Booster Vaccination Against SARS-CoV-2 With Concurrent Diagnosis of Pleomorphic Dermal Sarcoma

Clotting Thrombosis

- Association of Cerebral Venous Thrombosis with mRNA COVID-19 Vaccines: A Disproportionality Analysis of the World Health Organization Pharmacovigilance Database

Death/Excess Deaths/All-cause Mortality

- Risk of death following COVID-19 vaccination or positive SARS-CoV-2 test in young people in England
- Exploring the relationship between all-cause and cardiac-related mortality following COVID-19 vaccination or infection in Florida residents: a self-controlled case series study
- High viral loads: what drives fatal cases of COVID-19 in vaccinees? – an autopsy study
- The Rollout of COVID-19 Booster Vaccines is Associated With Rising Excess Mortality in New Zealand

Diabetes

- Supplementary Appendix to Evaluation of mRNA-1273 Vaccine in Children 6 Months to 5 Years of Age

Fertility Issues, Infertility and Newborn Deaths

- Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors
- Temporal trends in sperm count: a systematic review and meta-regression analysis
- Addressing anti-syncytin antibody levels, and fertility and breastfeeding concerns, following BNT162B2 COVID-19 mRNA vaccination
- COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function
- Safety of COVID-19 vaccines in pregnancy: a Canadian National Vaccine Safety (CANVAS) network cohort study
- Letter to Editor – Comment on "mRNA Covid-19 Vaccine Safety in Pregnant Persons", Shimabukuro et al. (NEJM Apr 2021) (regarding Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons)

General Adverse Reactions

- Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults

Hepatitis

- Autoimmune hepatitis after COVID-19 vaccine – more than a coincidence
- Autoimmune hepatitis triggered by SARS-CoV-2 vaccination
- Auto-immune hepatitis following COVID vaccination
- COVID-19 vaccine triggered autoimmune hepatitis: case report
- Autoimmune hepatitis after SARS-CoV-2 vaccine: New-onset or flare-up?
- SARS-CoV-2 vaccination can elicit a CD8 T-cell dominant hepatitis
- Investigation into cases of hepatitis of unknown aetiology among young children, Scotland, 1 January 2022 to 12 April 2022

Herpes

- A Case Report of Herpes Zoster Ophthalmicus and Meningitis After COVID-19 Vaccination

Immune Activation or Suppression

- Circulatory Exosomes from COVID-19 Patients Trigger NLRP3 Inflammasome in Endothelial Cells

- Cutting Edge: Circulating Exosomes with COVID Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines

- Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs

- Adverse effects of COVID-19 vaccines and measures to prevent them

Lymph Nodes

- Kikuchi-Fujimoto disease can present as delayed lymphadenopathy after COVID-19 vaccination

Myopericarditis/Cardiac Events

- Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents

- Changes of ECG parameters after BNT162b2 vaccine in the senior high school students

- SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents

- COVID-19 Vaccination-Induced Cardiomyopathy Requiring Permanent Left Ventricular Assist Device

- Fulminant Myocarditis 24 Days after Coronavirus Disease Messenger Ribonucleic Acid Vaccination

- Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave

- Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases

- The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients-A Large Population-Based Study

- Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings

Neurological

- COVID-19 vaccination and Guillain-Barré syndrome: analyses using the National Immunoglobulin Database

- Ramsay Hunt syndrome following COVID-19 vaccination

Neuropathies

- Chronic Inflammatory Demyelinating Polyneuropathy Post-mRNA-1273 Vaccination

- Neurological side effects of SARS-CoV-2 vaccinations

- Neuropathic symptoms with SARS-CoV-2 vaccination

Postural Orthostatic Tachycardia Syndrome

- Apparent risks of postural orthostatic tachycardia syndrome diagnoses after COVID-19 vaccination and SARS-Cov-2 Infection

Prion Disease

- Towards the emergence of a new form of the neurodegenerative Creutzfeldt-Jakob disease: Twenty six cases of CJD declared a few days after a COVID-19 "vaccine" Jab

Skin, Rash and Cutaneous Reactions

- Pityriasis lichenoides et varioliformis acuta following COVID-19 mRNA vaccination

- Abrupt onset of Sweet syndrome, pityriasis rubra pilaris, pityriasis lichenoides et varioliformis acuta and erythema multiforme: unravelling a possible common trigger, the COVID-19 vaccine

- Skin ulcer at the injection site of BNT162b2 mRNA COVID-19 vaccine

- COVID-19 vaccine-induced Stevens–Johnson syndrome