### December 15, 2021

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U.S. Department of Transportation 1200 New Jersey Ave. NE Washington, DC 20003

U.S. Department of Justice 950 Pennsylvania Avenue NW Washington DC, 20530

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Re:

- (1) Notice to FAA That Pilots Are Operating Commercial Aircraft in Contravention of Do-Not-Fly Regulations Title 14 Code of Federal Regulations §61.53 (also known as Federal Aviation Regulation 61.53) and Associated Guidance Which Disallow Medical Clearance of Pilots Who Have Injected Non-FDA Approved Medical Products, such as COVID-19 Vaccinations;
- (2) Notice to FAA That Pilots Have Suffered Death and Serious Injury Post-COVID-Vaccinations;
- (3) Notice to FAA that Signors Are Aware That Complaints Were Made to FAA Concerning this Issue;
- (4) Notice That Pilots Flying with Abnormal D-Dimer Values, Which Indicate Active Blood Clotting, Are at Elevated Risk for Pulmonary Embolism, Stroke, Arrhythmias, Cardiac Arrest & Death While In-Flight;
- (5) Notice That Pilots Flying with Abnormal Troponin Values and/or New ECG Changes/Cardiac MRI Changes Which Indicate Active Heart Damage and Possible Acute Myocarditis Are at Elevated Risk for Arrhythmias, Cardiac Arrest, and Death While In-Flight;
- (6) Given That Both the FAA & Commercial Airline Industry Appear to Have Violated Long-Standing CFR Regulations Which Disallow Medical Clearance of Pilots Who Have Received Non-FDA Approved Products Lest "Aeromedically Significant Adverse Effects Manifest" and Further Given the Wholesale Disregard of Evidence Indicating That Such Aeromedically Significant Effects Are In Fact Currently Occurring In Pilot Populations, Signors Hereto Request that the FAA Immediately Adopt a Proactive Screening Program Requiring All Vaccinated Pilots to Undergo Medical Re-Certification Within Four Weeks of the Date of this Letter to Include D-Dimer, Troponin and ECG Tests, as well as Cardiac MRIs, and Medically Clear ONLY Vaccinated Pilots Who Can Show a Clean Bill of Health on ALL Tests;
- (7) Notice to the FAA, All Commercial Airline Companies, and All Carriers Insuring Commercial Airlines That a Failure to Immediately Investigate this Issue, Correctly Apply Federal Do-Not-Fly Regulations and Ground All Vaccinated Pilots Who Cannot Show Clean D-Dimer, Troponin, ECG and Cardiac MRI Tests Could Lead to a Catastrophic Event Involving Mass Fatalities, Causing At-Fault Parties to Suffer Monetary Liability Potentially Extending to USD Hundreds of Millions.

### VIA HAND DELIVERY, U.S. MAIL (RETURN RECEIPT REQUESTED), FACSIMILE & E-MAIL

### Gentlepersons:

The attorneys, medical doctors, and other experts who authored this letter have become aware of the fact that the commercial airline industry, pilots, and Federal Aviation Administration ("FAA") appear to be putting both pilots and the general public at risk of death and/or serious injury by

operating in contravention of Title 14 of the Code of Federal Regulations §61.53 (also known as Federal Aviation Regulation 61.53) and Related Guidance which together operate to disallow medical clearance of pilots who have injected or ingested non-FDA approved products — like the COVID-19 inoculation — which federal framework quite clearly states to Aviation Medical Examiners (AMEs) under the heading "Do Not Issue — Do Not Fly" the following prohibition: "Do Not Issue. AME's should not issue airmen medical certificates to applicants who are using these classes of medications: FDA (Food and Drug Administration) approved less than 12 months ago .... This observation period allows time for uncommon, but aeromedically significant adverse effects to manifest themselves." We lead with our conclusion, and ask that the FAA immediately take action to remedy this problem by:

- 1) Medically flagging all vaccinated pilots.
- 2) Within four weeks of this letter, having these pilots undergo thorough medical re-examinations to include D-Dimer tests (to check for blood clotting problems), Troponin tests (to check for Troponin in the blood, which is a protein that is released when the heart muscle has been damaged), post-vaccination ECG analysis (also known as EKG, which checks the electrical signals that determine cardiac health), and cardiac MRI and PULS Test (to determine heart health). Inclusion of the cardiac MRI as a screening test for pilots is critical, as a recent study showed that using only ECG results and symptoms to screen patients resulted in a 7.4 under-diagnosing of actual myocarditis, while the PULS Test is also critical as a study published last month showed that "Mrna COVID Vaccines dramatically increase ... inflammatory markers" and that the risk of Acute Coronary Syndrome more than doubled in those vaccinated, leading the authors to conclude that "the mRNA COVID-19 vaccines dramatically increase inflammation ... on the endothelium and T cell infiltration of cardiac muscle, and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination."<sup>2</sup>
- 3) Medically de-certifying and grounding all pilots who fail any one of the above tests or who otherwise show symptoms indicative of possible blood-clotting issues or myocarditis (such as chest pain, shortness of breath, decreased exercise tolerance, or new heart palpitations) and re-testing said pilots at six week intervals until all subjective and objective findings return to levels that are aeromedically acceptable (including D-dimer, Troponin, ECG and cardiac MRI findings in aeromedically acceptable ranges) and until clean bills of health issue.
- 4) From this point forward, only allowing commercial aircraft to be operated by pilots who can show D-Dimer and Troponin tests as well as cardiac MRIs, ECGs and PULS tests at aeromedically acceptable levels, and a clean medical examination undertaken a minimum of five (5) days *after* each COVID-19 vaccine and after each COVID "booster" shot, as a review of reporting systems such as the Vaccine Adverse Event Reporting System ("VAERS") indicates that the current FAA wait time of two (2) days is insufficient to detect a significant number of blood clotting and myocarditis cases (which are manifesting more than 48 hours post-inoculation).

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Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2 InfectionResults From the Big Ten COVID-19 Cardiac Registry, (May 27, 2021) https://jamanetwork.com/journals/jamacardiology/fullarticle/2780548.
mRNA COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS

Cardiac Test: a Warning, Steven R Gundry, originally published 8 Nov 2021Circulation. 2021;144:A10712. https://www.ahajournals.org/doi/10.1161/circ.144.suppl 1.10712.

Note that in an affidavit authored earlier this year by a Lieutenant Colonel in the U.S. Army by the name of Theresa Long, who is a Flight Surgeon, Aerospace Medicine Specialist, and an Aviation Officer Course & Mishap Training Specialist with a Master's Degree in Public Health – who collaborated in turn with "renowned cardiologist Dr. Peter McCullough and a Senior Medical Examiner-Federal Air Surgeon's Cardiology Consultant to the Federal Aviation Administration" – all concluded that:

- > the risk of "post-vaccination myocarditis was not trivial,"
- ➤ that the "aviation population is comprised of individuals with demographics that the CDC and FDA established (on June 25, 2021) was at greatest risk for developing post-vaccination induced myocarditis,"
- > that the "unpredictable and potential serious complications thereof present an ... unacceptable level of aeromedical risk,"
- that "risk-stratification, screening and diagnostic testing is necessary for continued safety of flight," and
- ➤ that "immunizations with COVID vaccinations should be immediately suspended until further aviation specific studies can be conducted."

Federal Aviation Regulatory Guidance Disallows Medical Clearance of Pilots Who Have Consumed Non-FDA Approved Products Like COVID Vaccines – Precisely To Ensure That Aeromedically Significant Adverse Events Do Not Manifest – As They Have Here

As context for this discussion, it is clear that the "FAA has the responsibility for investigating possible violations of Federal regulations, orders, or standards relating to aviation safety." An AIR21 Whistleblower Complaint may be filed by anyone, confidentially. We are aware that complaints have been filed on this topic, and that FAA is now required, under applicable regulations, to thoroughly investigate all such complaints.

Title 14 of the Code of Federal Regulations §61.53 states that "no person who holds a medical certificate issued under part 67 of this chapter may act as pilot in command, or in any other capacity as a required pilot flight crewmember, while that person... [is] receiving treatment for a medical condition that results in the person being unable to meet the requirements for the medical certificate necessary for the pilot operation." In interpreting this provision, the Guide for Aviation Medical Examiners states:

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<sup>&</sup>lt;sup>3</sup> Federal Aviation Administration, "How to File an AIR21 Whistleblower Complaint." https://www.faa.gov/about/initiatives/whistleblower/complaint#:~:text=The%20FAA%20has%20the%20responsibility,likelihood%20that%20a%20violation%20occurred.

### Pharmaceuticals (Therapeutic Medications)

### Do Not Issue - Do Not Fly

The information in this section is provided to advise Aviation Medical Examiners (AMEs) about two medication issues:

Medications for which they should not issue (DNI) applicants without clearance from the Federal Aviation Administration (FAA), AND

Medications for which they should advise airmen to not fly (DNF) and provide additional safety information to the applicant. The lists of medications in this section are not meant to be all-inclusive or comprehensive, but rather address the most common concerns.

**Do Not Issue. AMEs should not issue airmen medical certificates to applicants** who are using these classes of medications or medications.

- Angina medications
  - o nitrates (nitroglycerin, isosorbide dinitrate, imdur), nolazine (Ranexa)....
- Cancer treatments including chemotherapeutics, biologics, radiation therapy, etc., whether used for induction, "maintenance," or suppressive therapy.
- Controlled Substances (Schedules I V). An open prescription for chronic or intermittent use of any drug or substance....
- FDA (Food and Drug Administration) approved less than 12 months ago. The FAA generally requires at least one-year of post-marketing experience with a new drug before consideration for aeromedical certification purposes. This observation period allows time for uncommon, but aeromedically significant, adverse effects to manifest themselves....

Guide for Aviation Medical Examiners (emphasis added) ("Guide for AMEs").4

As the recipients are likely aware, the FDA has not approved any of the COVID-19 shots currently available in the United States. On August 23, the FDA granted BioNTech Manufacturing GmbH's Biologics Licensing Application to distribute the Comirnaty vaccine in the United States once certain conditions are met; however, the Comirnaty vaccine is not currently available in the United States – and will not be until the supply of the Pfizer-BioNTech vaccine is first exhausted. See https://www.fda.gov/media/151710/download. The Pfizer-BioNTech vaccine is currently available only under an EUA, which the FDA extended on August 23, 2021. See https://www.fda.gov/media/150386/download. It is also important to note that the approved vaccine, Comirnaty, cannot be said to be interchangeable with unapproved inoculations.<sup>5</sup>

<sup>4</sup> https://www.faa.gov/about/office org/headquarters offices/avs/offices/aam/ame/guide/pharm/dni dnf/ (emphasis added).

<sup>&</sup>lt;sup>5</sup> The concept that unapproved COVID inoculations should be considered "interchangeable" was recently adjudged to be incorrect by a federal court examining the argument. See <u>Doe et al v. Austin et al</u>, (USDC Northern Dist. Florida) (October 6, 2021). In this decision relating to the DOD and vaccine mandates for military members, a federal judge began by noting that,

Put simply, any pilot flying right now who has been vaccinated in the United States has almost certainly NOT received an FDA-approved vaccine, as the available J&J, Pfizer and Moderna shots are not yet FDA-approved. And even were such pilots to have received an FDA-approved vaccine, under relevant federal regulations, the pilots should still not be flying for 12 more months – until such time as at "least one year of post-marketing experience" has occurred *after* the FDA's initial approval. Guide for AMEs.

The reason for this cannot be overstated: history and common sense evince that significant time must elapse post-FDA approval to ensure that new medical products do not end up causing adverse effects (as did Thalidomide and Glyphosate). This is particularly true when the individuals who are receiving such new, experimental medical products are spending significant amounts of time at high altitude, and are in control of large vehicles carrying hundreds of other passengers, who could all die or be severely injured should the operator suffer an adverse health event.

Currently, not only have all pilots flying commercial airplanes *not* had at least one year of post-marketing time elapse post-FDA approval of the agent injected into their bodies, these pilots are flying with an entirely UNAPPROVED product in their systems, that is now unfortunately proving to cause all manner of clotting, embolic and thrombosis-related side effects (which side effects are known to occur with greater frequency and severity when at altitude). Additionally, across all populations, the inoculations are resulting in significant increases in myocarditis and subsequent heart failure, arrhythmias, cardiac arrests, and deaths. This is especially true in the younger male cohort, to which many pilots belong.

Indeed, we are aware of pilots who have died post vaccination. We are also aware of other pilots who are suffering side effects, many of whom have been afraid to report them for fear of being grounded, but some of whom have been forced to seek medical care and report them due to the significance of the vaccine-related adverse event, like pilot Cody Flint:

I am a 33 year old husband and father of two young boys. I am an agricultural pilot by profession, with over 10,000 flight hours. I have been very healthy my whole life, with no underlying conditions. I received my first dose of the Pfizer Covid Vaccine on February 1. Within thirty minutes, I developed a **severe stabbing headache**, **which later became a burning sensation in the back of my neck**. Two days after vaccination, I got in my airplane to do a job that would only take a few hours.

Immediately after taking off, I knew that something was not right with me. I was starting to **develop tunnel vision, and my headache was getting worse**. Approximately two hours into flying, I pulled my airplane up to turn around and felt an extreme burst of pressure in my ears.

under the relevant EUA statute, recipients of EUA drugs must be "informed ... of the option to accept or refuse administration of the product." The court went on to explain that "DOD's guidance documents explicitly say only FDA-licensed COVID-19 vaccines are mandated" and that while such a mandate would be applicable to the Comirnaty vaccine since it was FDA-approved, the "plaintiffs have shown that the DOD is requiring injections from vials <u>not</u> labeled 'Comirnaty' and that "defense counsel could not even say whether vaccines labeled 'Comirnaty' exist at all." In considering the DOD's argument that it was okay to interchange vaccine vials because allegedly "the contents of EUA-labeled vials are chemically identical to the contents of vials labeled 'Comirnaty'" the judge noted that such argument was entirely "unconvincing" and went on to further state that "FDA licensure does not retroactively apply to vials shipped before BLA approval" and that EUA provisions suggest "drugs mandated for military personnel be actually BLA-approved, not merely chemically similar to a BLA-approved drug." Id.

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Instantly, I was nearly blacked out, dizzy, disoriented, nauseous and shaking uncontrollably. By the grace of God, I was able to land my plane without incident – although I do not remember doing this.

My initial diagnosis of vertigo and severe panic attacks – although I've never had a history of either of these – was later replaced with **left and right peri-lymphatic fistulas, Eustachian tube dysfunction, and elevated intra-cranial pressure due to brain swelling.** My condition continued to decline, and my doctors told me that only an adverse reaction to the vaccine or a major head trauma could have caused this much spontaneous damage.

I've had six spinal taps over eight months to monitor my intra-cranial pressure, and two surgeries, eight weeks apart, to repair the fistulas. I have missed nearly an entire year of my life — and my children's lives. Days of baseball games, playing in the backyard, and just picking up my kids to hug them have been replaced with living in a sick body, doctor's visits, and more questions than answers. I don't know if I'll ever be able to fly again.

This vaccine has taken my career from me, and the future I have worked so hard to build. I've used all of my savings just to pay my medical bills: my family and I are on the verge of losing everything we have. I was and still am pro-science and pro-vaccine. The main issue rests squarely on the fact that the FDA, CDC and NIH refuse to acknowledge that real lives are being absolutely destroyed by this vaccine....

U.S. Senate Press Briefing on COVID-19 Vaccine Injuries, November 2021, Testimony of Cody Flint, https://rumble.com/voz514-cody-flint-i-have-missed-an-entire-year-of-my-life-trapped-in-vaccine-injur.html.

The Intent of Federal Aviation Regulations Requires – Given the Adverse Events That Have Now Manifested Post-COVID Vaccinations – That the FAA Medically Re-Test Vaccinated Pilots to Ensure Cardiovascular & Circulatory Health and Prevent Catastrophic Fatalities

While we understand the hesitancy to do what morality and the law requires given the current situation, here's the upshot: should the FAA fail to ground and medically de-certify all pilots who have received experimental and non-FDA approved COVID-19 vaccines in accordance with CFR §65.13 and related Guidance that require this result – and bar reinstatement of such pilots until such time as they can show aeromedically acceptable D-Dimer, Troponin, ECGs, cardiac MRIs, PULS tests and clean bills of health – the FAA will be putting many innocent airline passengers' lives in harm's way in the event a pilot loses control of his aircraft after suffering a major blood-clotting event (pulmonary embolism, stroke, etc.) or a myocarditis-related event, either of which can result in incapacitation, cardiac arrest, and death.

In the case of a major seizure, which is apparently what affected American Airline pilot Wil Wolfe post-COVID-vaccination and prior to his death (albeit not while in an airplane), the adverse event may cause untold devastation: a seizure that creates massive muscle stiffening and jerking of large muscle groups could be catastrophic if the pilot were on approach for landing, and actively flying the plane only a few hundred feet above the runway. A vaccinated pilot who suffers such a full-blown tonic-clonic seizure while on approach – such that the pilot could not maintain level control of the plane a few hundred feet above the tarmac, and uncontrollably and inadvertently dipped a wing thus causing the plane to cartwheel down the runway at landing – would likely cause not just massive injury and death to innocent passengers, but also create shocking monetary liability for the airline

company and insurance carriers, potentially extending into the hundreds of millions USD. Indeed, as noted in a recent article in an insurance publication concerning a 2019 plane crash:

Calculations by Reuters based on the Montreal convention [estimated]... initial compensation costs for all 157 passengers who died on the flight [at] ... around \$25 million...

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[But] legal compensation payments for crash victims could run around \$2 million to \$3 million per person in the US.

See article entitled "Insurers Face Tens of Millions in Claims after Ethiopian Airlines Crash," published in Insurance Business America (Alicja Grzadkowska, March 12, 2019). Using the above math, if a large plane carrying between 250 and 450 Americans crashes because a pilot suffered a major vaccine-related health event one week after, *e.g.*, his second Pfizer jab, which event then results in the death of every American on board, the liability could easily run – given that the airlines and FAA were on notice as to the issue herein – an astounding \$750 million at the low end to \$1.35 billion+ USD at the high end.

Many of the undersigned are trial attorneys, and we believe the potential liability from this issue would be truly staggering, given the following: (1) nearly all players in the aviation industry appear to be acting in concert to ignore the Code of Federal Regulations/Federal Aviation Regulations §61.53 and associated Guidance which disallow pilots from being cleared to fly if they have non-FDA approved products in their systems; (2) said aviation players appear to further be in lockstep agreement to turn a blind eye to airlines like United, Alaska and Jet Blue which have mandated the COVID vaccine in defiance of black-letter federal law (the Emergency Use Authorization Act) that prohibits the mandate of any medical product while it is still in the experimental phase; and (3) the industry has not course-corrected, despite receiving reports of pilots suffering adverse events post-vaccination, both in-air and at-home (see data involving death of pilot Wil Wolfe; see also Calgary Herald article from last week involving Canadian pilot (all Canadian pilots are vaccinated) stating "West Jet Flight Diverted Back to Calgary after Pilot Passes Out" and noting that a "plane flying from Calgary to Atlanta Monday was forced to turn around due to a medical emergency involving the pilot....").

It bears mention that decisions to "conceal[] material information" or "engage[] in an effort to cover up deception" by aviation giants are not taken lightly, and indeed were primary factors in the \$2.5 billion assessment against Boeing reported earlier this year over its 737 Max:

Boeing will pay a total criminal monetary amount of over \$2.5 billion, composed of a criminal monetary penalty of \$243.6 million, compensation payments to Boeing's 737 MAX airline customers of \$1.77 billion, and the establishment of a \$500 million crash-victim beneficiaries fund to compensate the heirs, relatives, and legal beneficiaries of the 346

<sup>6</sup> https://calgaryherald.com/news/local-news/westjet-flight-diverted-back-to-calgary-after-pilot-passes-out

<sup>&</sup>lt;sup>7</sup> The FAA and all airlines should also be on notice regarding any pilot who may avail himself of the Americans with Disabilities Act and later amendments of the following: Each of the EUA Covid Injectables ("vaccines") are designed to genetically program (modify) the user's cardiovascular cells to produce unnatural synthetic spike proteins (prions), which is prospectively prohibited where the user is or may become availed to the Rehabilitation Act of 1973 and/or the Americans with Disabilities Act, 2008 amendment per 42 U.S.C. § 12102(a)(2)(B) because it interferes in the Major Bodily Function of "normal cell growth."

passengers who died in the Boeing 737 MAX crashes of Lion Air Flight 610 and Ethiopian Airlines Flight 302.

See "Boeing Charged with 737 Max Fraud Conspiracy and Agrees to Pay Over \$2.5 Billion" (January 7, 2021), https://www.justice.gov/opa/pr/boeing-charged-737-max-fraud-conspiracy-andagrees-pay-over-25-billion.

In arriving at this multi-billion dollar penalty, Department of Justice personnel, investigators and attorneys cited the "misleading statements, half-truths, and omissions" on the part of Boeing as the linchpins in the above damages calculation, and further noted that while colluding to hide facts should never be countenanced, such is especially true "in industries where the stakes are this high." The attorneys concluded by holding that Boeing's "lack of candor" was untenable - and that the multi-billion dollar hit against Boeing was designed to deter such conduct on the part of aviation players in future, whilst restoring public confidence:

The substantial penalties and compensation Boeing will pay demonstrate the consequences of failing to be fully transparent.... The public should be confident that government regulators are effectively doing their job, and those they regulate are being truthful and transparent.... This landmark [] agreement will forever serve as a stark reminder of the paramount importance of safety in the commercial aviation industry, and that integrity and transparency may never be sacrificed....

Note that we have confined our focus for the time being, among many known adverse effects of the vaccines, to only those that would result in immediate incapacitation of the pilot. That said, we urge the FAA to create a database to track pilot adverse events in a manner similar to VAERS, as we fear that medical adverse events post-vaccination in pilot populations are occurring at greater rates than have been tracked or monitored in either civilian or military populations, based on, inter alia, the following Senate Testimony of U.S. Army Lieutenant Colonel Theresa Long, M.D., Master's Degree in Public Health, Army Aerospace Medicine Specialist and Aviation Officer Course & Mishap Training Specialist:<sup>8</sup>

Last May, I attended the Senior Preventative Leadership Program for the Army. When we were given an opportunity to ask the senior leaders questions, I simply asked:

<sup>8</sup> We are aware of a memo which sought to end-run the rather strict prohibitions under Title 14 CFR §65.13 (aka FAR 61.53) and its associated DNF Guidance which prohibit pilots from flying with medical products that are NOT FDA approved in their systems, by stating that pilots should simply not fly for 48 hours post-vaccination, based on the fact that the Agency believes the vaccine to be "safe." Given that multiple years of Phase 2 and Phase 3 clinical trials were skipped, and that no significant human testing was done in connection with this vaccine, the undersigned authors of this letter would like to know on exactly what scientific studies or other basis the designation of "safe" was predicated? Put simply, how did the FAA determine safety - given the wholesale absence of any significant studies on humans - including the absence of any studies on pilots, who often undertake long-haul flights which put their cardiac and vascular systems under significant stress and can thus magnify the cardiac and vascular side-effects from experimental medical products? It appears to the undersigned that the determination of "safe" was not issued in good faith nor after actual due diligence, and that the only relevant clinical trial of note is the one being conducted on the pilots as we speak - which is to say: the pilots are the lab rats from which safety data or lack thereof will be generated. On a related note, in that same memo, the agency indicated it would "monitor the patient response to each vaccine." Please provide the undersigned with all reporting protocols, testing and other evidentiary measures the FAA or its sub-agencies have adopted to "monitor the patient response to EACH vaccine" – because per this statement – it appears that the FAA represented it would be actively collecting data on pre- and post-objective tests and subjective symptoms that pilots are reporting before and after each COVID vaccine, and each booster.

"So we skipped two years of Phase 2 trials, and three years of Phase 3 trials? We only lost 12 active duty soldiers to COVID – yet we're going to risk the health of the entire fighting force, on a vaccine we only had two months of safety data on?"

The response was:

"You're damn right Colonel. And you're going to get every soldier you can to take the vaccine so I can get enough data points to determine if the vaccine is safe."

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Numerous soldiers told me of threats and intimidation to get the vaccines that were still under the EUA. This violated medical ethics, specifically the Nuremberg Code. When I emailed Army Public Health Command... they told me they were <u>not</u> tracking, tracing or monitoring adverse events.

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I saw five patients in clinic, two of which presented with chest pain, days to weeks after vaccination, and were subsequently diagnosed with pericarditis, and then worked up to rule out myocarditis. The third pilot had been vaccinated and felt like he was drunk, chronically fatigued within 24 hours after vaccination. The pilot told me he did not know what to do, so he drank a lot of coffee to "try and wake himself up," and continued to fly, until he realized the problem wasn't going away. After I reported to my command my concerns that — in one morning — I'd had to ground 3 out of 3 pilots due to vaccine injuries, the next day my patients were cancelled, my charts were pulled for review, and I was told that I would not be seeing acute patients anymore, just healthy pilots there for their flight physical."

US Senate Press Briefing on COVID-19 Vaccine Injuries (Nov 2021), Testimony of Dr. Theresa Long, MD, MPH, https://rumble.com/voz7ik-theresa-long-md-mph-the-vaccine-is-a-greater-threat-to-soldiers-and-defense.html.

Attached to this letter is a list of pilots in VAERS who have suffered adverse events. It is by no means an exhaustive list. Rather, it represents a sampling of ten individuals, aged 30 to 70, fairly evenly split between Moderna and Pfizer inoculations (with one Janssen), who were otherwise healthy – many were athletic and the list boasts one triathlete. But within a short period of time after their vaccinations, these pilots suffered vaccine-related adverse health events that were nothing short of bone-chilling:

- Myocardial Infarction (heart attack)
- > Atrial Fibrillation
- Pericarditis
- ➤ Brain Swelling
- > Elevated Intra-Cranial Pressure affecting Spinal Cord and Brain Stem
- ➤ Sub-Arachnoid Hemorrhages (brain bleed)
- Blindness

Half had cardiac issues, the other half had brain issues, and in a majority of the ten cases, VAERS listed their injures as "life threatening," "permanently disabling" or both. The upshot? Not only were the large majority of these individuals suffering life-ruining injuries, they were not the specimens of pilot health required by aviation industry regulators in order to ensure passenger safety.

### Conclusion

In sum, neither the law nor common sense countenances that federal agencies charged with ensuring public safety ignore concerning data and thereby jeopardize public safety. Nor do law and common sense countenance ignoring information that evinces that both pilots and the passengers they serve are at risk of severe injury and possibly death. Finally, neither precept countenances killing a plane full of hundreds of Americans because a commercial pilot loses control of his or her aircraft after suffering a major blood clot, seizure, or myocarditis-related event, which in turn causes his jet to be involved in a fatal catastrophic crash... before regulators decide to finally act.

Quite the opposite: both federal regulations and good sense require that all commercial pilots who have received a COVID-19 vaccine, and are thus flying with a non-FDA approved medical product in their bodies, be immediately flagged and medically re-certified only after showing aeromedically acceptable D-Dimer, Troponin, ECGs, cardiac MRIs and PULS tests, and otherwise clean bills of health.

Sincerely,

Leigh Taylor Dundas

Leigh Taylor Dundas, Esq. Advocates for Citizens' Rights

Mary Holland Mary Holland, Esq.

Children's Health Defense

Reiner Fuellmich Reiner Fuellmich, Esq.

Tom Renx Tom Renz, Esq.

Cody Flint Pilot Cody Flint Robert F. Kennedy, Jr.

Robert F. Kennedy, Jr., Esq. Children's Health Defense

Peter Mc Cullough

Dr. Peter McCullough, M.D. (CV attached)

Ryan Cole

Dr. Ryan Cole, M.D. (CV attached)

Theresa Long

LTC Colonel Theresa Long, M.D., MPH Aerospace Occupational Medicine Specialist (CV attached)

Peter Chambers

LTC, D.O.,

Special Forces Flight Surgeon - Green Beret Purple Heart, Meritorious Service Medal Bronze Star (CV attached)

**FAQs** 

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### VAERS Event Details

Details for VAERS ID: 1026783-1

Event Information			
Patient Age	33.00	Sex	Male
State / Territory	Mississippi	Date Report Completed	2021-02-12
Date Vaccinated	2021-02-01	Date Report Received	2021-02-12
Date of Onset	2021-02-01	Date Died	
Days to onset	0		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only \*\* VAERS-1 Report Form Only

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

\*\* VAERS-1 Report Form Only

"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	UNK	SYR	LA

Symptom	
ACOUSTIC STIMULATION TES	STS
BALANCE TEST	
BURNING SENSATION	
COMPUTERISED TOMOGRAM	
CONFUSIONAL STATE	
CSF PRESSURE INCREASED	
DISORIENTATION	
DIZZINESS	
HEAD DISCOMFORT	
HEADACHE	
HYPERSENSITIVITY	
INNER EAR DISORDER	
MAGNETIC RESONANCE IMAG	GING
NAUSEA	
PARAESTHESIA	
PRESYNCOPE	
TREMOR	
VERTIGO	
VISION BLURRED	
VISUAL FIELD TESTS	

**Adverse Event Description** 

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

I noticed a headache in the very top of my head within an hour of getting the vaccine. I thought it was normal because everyone I know said they got a headache from it. Over the next few hours, the pain moved down the back of my neck and became a burning sensation at the bottom of my skull. The pain was not excruciating but was constant. I thought it would eventually go away. I'm a pilot and fly for a living. Two days after receiving the vaccine I flew my plane and immediately noticed something was wrong with me. I was having a very hard time focusing. Approximately 2 hours into my flying I felt sudden and extreme pressure in my head and nearly blacked out. I immediately landed and stopped flying. Two days later I tried flying again and the exact same thing happened again after 20 minutes. The burning in my neck intensified and was now accompanied by dizziness, nausea, disorientation, confusion, uncontrollable shaking, and tinkling in my toes and fingers. I immediately went to my hometown doctor and he diagnosed me with vertigo. He prescribed me meclizine on Friday 02/05/2021. I took the medicine as prescribed all weekend with no relief. Monday 02/08/2021 I made an appointment for that Wednesday at the Institute. During Wednesday 02/10/2021-02/11/2021 I had roughly 10-15 test performed on me including balance, eye and hearing test, CT scan, MRI, and measured my spinal fluid pressure. The physician determined on 02/11/2021 that I had an allergic reaction to the Pfizer COVID vaccine the severely increased the pressure in my spinal cord and brain stem. That pressure causes my vision problems and ultimately ruptured my left inner ear breaking off several crystals in the process. I cannot fly with this condition. I'm currently taking Diamox to reduce the pressure in my spinal cord and brain stem.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Over a dozen test including balance, vision, hearing, spinal cord pressure, ct scan, and mri. All performed on 02/10/2021 and 02/11/2021.	None	

Medications At Time Of Vaccination	History/Allergies
None	None,None

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### VAERS Event Details

Details for VAERS ID: 1651301-1

Event Information			
Patient Age	69.00	Sex	Male
State / Territory	New Hampshire	Date Report Completed	2021-08-28
Date Vaccinated	2021-01-12	Date Report Received	2021-08-28
Date of Onset	2021-03-15	Date Died	
Days to onset	62		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
<b>Existing Hospitalization Prolonged</b>	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	011L20A	1	IM	LA
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	012M20A	2	IM	LA

Symptom		
BLINDNESS UNILATERAL		
MACULAR OEDEMA		
RETINAL VEIN OCCLUSION		

### **Adverse Event Description**

On the morning of March 15, 2021 I got up and noted that I had no vision in my right eye. As a commercial pilot I considered this an emergency and sought specialist care from a retina specialist near our winter home in. That specialist diagnosed an episode of macular edema, caused by an occlusion of a vein behind my right eye. I was treated with injections of Avastin, an off label drug that has been effective in patients with this problem. I received one injection on March 15, 2021 and a second by the same doctor on April 12, 2021, before returning to my home. My course of treatment has continued at Medical Center also with injections of Avastin. My vision is now 20/50 in my right eye. After

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None.	

Medications At Time Of Vaccination	History/Allergies
"1. An ""over 50"" multi vitamin 2. A pro-biotic"	None.,None.

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

<sup>\*\*</sup> VAERS-1 Report Form Only

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### **VAERS** Event Details

Details for VAERS ID: 1743012-1

Event Information			4 - 17
Patient Age	30.00	Sex	Male
State / Territory	Arizona	Date Report Completed	2021-09-29
Date Vaccinated	2021-06-18	Date Report Received	2021-09-29
Date of Onset	2021-06-22	Date Died	
Days to onset	4		
Vaccine Administered By	Military	Vaccine Purchased By	Not Applicable
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	3
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	UNK		

Symptom	155
AORTITIS	
ASTHENIA	
BLOOD TEST	
CHEST PAIN	
COMPUTERISED TOMOGRAM	
DIZZINESS	
DYSPNOEA	
ELECTROCARDIOGRAM ABNORMAL	
ELECTROENCEPHALOGRAM	
GASTROOESOPHAGEAL REFLUX DIS	EASE
PAIN	
PERICARDITIS	
PULMONARY VASCULITIS	

### **Adverse Event Description**

Symptoms began almost immediately as constant dizziness, body aches, overall weakness. Two months later I woke up with severe chest pain and difficulty breathing. As a military pilot, my flight doctor took an EKG (abnormal results) and instructed me to visit the ER. I was diagnosed with inflammation of the heart cavity and pulmonary arteries. Upon being admitted to a local Medical Center, I was later diagnosed with vasculitis, specifically aortitis. During this timeframe I was also diagnosed with gastroesophageal reflux disease. I was completely healthy prior to the vaccination and there is not a single member of my family with any of the listed conditions. Presently, I am on a high dosage of prednisone and methotrexate to deal with the inflammation. I am also awaiting a medical evaluation board with the military group to determine if I'm allowed to remain on flying status and in the military.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Lab Data	Current Inness	Adverse Events Arter Titor Vacantations

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>\*\*</sup> VAERS-1 Report Form Only

Blood tests, CT Scans, EKGs, aEEG, etc. None

Medications At Time Of Vaccination	History/Allergies
None	None,None

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### VAERS Event Details

Details for VAERS ID: 1245452-1

<b>Event Information</b>			
Patient Age	37.00	Sex	Male
State / Territory	California	Date Report Completed	2021-04-21
Date Vaccinated	2021-03-19	Date Report Received	2021-04-23
Date of Onset	2021-03-21	Date Died	
Days to onset	2		
Vaccine Administered By	Unknown	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	USMODERNATX, INC.MOD20210	Report Form Version	2
Recovered	Unknown	Serious	No

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	045A21A	1	ОТ	

Symptom
ATRIAL FIBRILLATION
BLOOD THYROID STIMULATING HORMONE
ELECTROCARDIOGRAM
STRESS ECHOCARDIOGRAM
THYROID HORMONES DECREASED

### **Adverse Event Description**

Atrial fibrillation; Thyroid hormone (TSH) goes down; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ATRIAL FIBRILLATION (Atrial fibrillation) in a 37-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion medically significant) and THYROID HORMONES DECREASED (Thyroid hormone (TSH) goes down). At the time of the report, ATRIAL FIBRILLATION (Atrial fibrillation) and THYROID HORMONES DECREASED (Thyroid hormone (TSH) goes down) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Mar-2021, Blood thyroid stimulating hormone: low (Low) Low. On 21-Mar-2021, Electrocardiogram: atrial fibrillation (abnormal) Atrial fibrillation. On 21-Mar-2021, Stress echocardiogram: atrial fibrillation (abnormal) Atrial fibrillation. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. The patient was in emergency room for few hours and was given 3 doses of apixaban (Eliquis) for treatment for the events. The patient was on holter monitor for 3 days. The patient reported, his thyroid level comes near normal after one and half weeks. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. He is pilot and kept off the duty for Atrial fibrillation.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Lab Data	Current Iilness	Adverse Events After Prior Vaccinations
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<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>\*\*</sup> VAERS-1 Report Form Only

Test Date: 20210321; Test Name: TSH; Result Unstructured Data: Low; Test Date:	
20210321; Test Name: EKG; Result Unstructured Data: Atrial fibrillation; Test Date:	
20210321; Test Name: Echo stress test; Result Unstructured Data: Atrial fibrillation	

Medications At Time Of Vaccination	History/Allergies
	Medical History/Concurrent Conditions: No adverse event (No reported medical history),

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### VAERS Event Details

Details for VAERS ID: 1358033-1

Event Information	A11 1000 000 000 000 000		
Patient Age	70.00	Sex	Male
State / Territory	Utah	Date Report Completed	2021-05-28
Date Vaccinated	2021-04-22	Date Report Received	2021-05-28
Date of Onset	2021-04-24	Date Died	
Days to onset	2		
Vaccine Administered By	Pharmacy *	Vaccine Purchased By	Not Applicable
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	Unknown	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	2
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	007C21A	2	SYR	LA

Symptom	
JOINT RANGE OF M	OTION DECREASED
MYOCARDIAL INFA	RCTION
THROMBOSIS	

### **Adverse Event Description**

2 days after second shot blood clot in left arm. Hit while walking in my home. Could not lift my arm. 5 days later heart attack. Pilot with EKG yearly. Last EKG less than one month from my heart attack on April 29, 2021

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
On going	None	

<b>Medications At Time Of Vaccination</b>	History/Allergies
None	None,None

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>\*\*</sup> VAERS-1 Report Form Only

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VAERS Event Details

Details for VAERS ID: 1702509-1

Event Information			
Patient Age		Sex	Male
State / Territory	Foreign	Date Report Completed	2021-09-13
Date Vaccinated	2021-06-14	Date Report Received	2021-09-16
Date of Onset	2021-06-22	Date Died	
Days to onset	8		
Vaccine Administered By	Other	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NLPFIZER INC202101120866	Report Form Version	2
Recovered	Yes	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only \*\* VAERS-1 Report Form Only

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	Unknowr
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>\*\*</sup> VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FC3143	1		

Symp	tom a
ALANI	NE AMINOTRANSFERASE
ANGIC	GRAM
ASPAR	TATE AMINOTRANSFERASE
BLOOD	CHOLESTEROL
BLOOD	CREATINE PHOSPHOKINASE
BLOOD	CREATININE
BLOO	GLUCOSE
BLOO	LACTATE DEHYDROGENASE
BLOOD	POTASSIUM
BLOO	PRESSURE MEASUREMENT
BLOOK	SODIUM
BLOO	TRIGLYCERIDES
C-REA	CTIVE PROTEIN
CARD	IAC FUNCTION TEST
COMP	UTERISED TOMOGRAM
ECHO	CARDIOGRAM
ELECT	ROCARDIOGRAM
GLOM	ERULAR FILTRATION RATE
HAEM.	ATOCRIT
HAEM	OGLOBIN
HIGH	DENSITY LIPOPROTEIN
LDL/H	DL RATIO

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

LIPOPROTEIN (A)	
LOW DENSITY LIPOPROTEIN	
MEAN CELL HAEMOGLOBIN	
MEAN CELL VOLUME	
PERICARDITIS	
PHYSICAL EXAMINATION	
PLATELET COUNT	
RED BLOOD CELL COUNT	
TOTAL CHOLESTEROL/HDL RAT	Ю
TROPONIN	
WHITE BLOOD CELL COUNT	

### **Adverse Event Description**

Pericarditis/chest pressure and irregular heartbeat; This is a spontaneous report from a contactable consumer downloaded from the regulatory authority, regulatory authority number NL-LRB-00665454. A 38-year-old male patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on 14Jun2021 (Lot Number: FC3143) as DOSE, 1 SINGLE for COVID-19 immunization. Medical history included not smoking, alcohol and drugs, hypertension, hypercholesterolaemia, diabetes and vascular disease from an unknown date. Family history of cardiovascular disease (father had a myocardial infarction at age 36). The patient's concomitant medications were not reported. The patient experienced pericarditis on 22Jun2021and recovered from pericarditis two weeks after onset on 14Jul2021. The patient experienced pericarditis following administration of COMIRNATY treated with in ambulance: nitrospray, ascal; rest and 3 days ibuprofen 3dd400mg. The patient is a pilot and an athlete (triathlons). During a training week, patient after the patient woke up, he experienced chest pain with radiating pain to his neck and jaw. Ambulance came and gave him nitrospray and Ascal, which reduced his pain. The patient underwent tests: CTa: no coronary stenosis, ECG: showed diffuse ST elevation compared to his ECG in 2020. Echo cor showed observations fitting with an athlete's heart. The patient had no previous COVID-19 infection. The event occurred on the sixth day after a hard week of training (cycling). Woke up with chest pressure and irregular heartbeat. Finally picked up by ambulance and presented to cardiologist. The patient had diagnostic procedures: EKGs, CT, blood. The patient was admitted on 22Jun2021 to - in the Cardiology department in connection with thoracic pain. As conclusion: VG familial burden for cardiovascular disease: Observation of thoracic pain, coronary artery disease was excluded by CTa coronaries; Slightly dilated heart with slight eccentric left ventricular hypertrophy consistent with sports heart in tall athlete; and Diffuse ST elevation increase compared to EKG 2020. Diagnosis: pericarditis based on sports heart. The patient takes ibuprofen 3dd400mg for 3 days and Poli for 3 weeks + EKG. The patient was instructed to return earlier in case of fever, dyspnea, dizziness, increase in pain. The patient had referral to sports cardiologist. Check-up appointment: 3 weeks, outpatient clinic after admission. The patient woke up around 5:30 this morning to go to the toilet. No trouble getting up yet. When lying back in bed, a feeling of pressure in the chest. Couldn't walk anymore, vas 6/7. Radiated to jaw and neck. Is a pilot and has never noticed any heart problems during major inspections. No palpitation complaints, dyspnea or dyspnea of effort. No edema or nocturia. No vegetative phenomena. In the ambulance nitro spray and charged with ascal. After the spray complaints dropped to VAS 1. Per physical examination: BP: 121/76 mmHg, HR 55/min, cor: s1 s2 grade 1/6 ejection promptle, no pericardial rub, pulm: VAG; EKG: 22Jun2021: Sinus bradycardia 44/min, intermediate cardiac axis PQ 0.17 QRS 0.10 QT 0.45, diffuse ST elevation in all leads. Echo sound. Per quality and rhythm: the image quality of the examination is good. Sinus bradycardia around 46 bpm. LV: The left ventricle is slightly dilated. Eccentric LVH, RWT 0.37 at a mass of 130 gr/m2. Left ventricular systolic function is good. The left ventricular EF measured 65%. Combination of findings is consistent with normal LV diastolic function. RV: The right ventricle is moderately dilated. The systolic function of the RV is normal. Atria: The left atrium is slightly dilated (15-41 ml/m2). The right atrium is severely dilated. Floppy atrial septum. AoV: The aortic valve is tricuspid and opens well. Edges of the aortic valve thickened. Track ADI. MV: The mitral valve is normal. MINOR mitral insufficiency, TV: The tricuspid valve is normal. Minor tricuspid valve insufficiency. PV: The pulmonary valve is normal. Physiological pulmonary valve insufficiency. Great vessels: undilated ascending aorta. VCI is dilated, collapses 29% on sniff. CTA Coronaries 22Jun2021, 12:16, Calcium score 0, heart rate 52/min. Prospective scan protocol. No coronary stenoses. No mass or lymphadenopathy in the mediastinum. Depicted lung fields clear. No indication of current pathology in the scanned trajectory. Conclusion: no coronary stenoses. Lab Collection date: 22Jun2021. Hemoglobin 8.9 mmol/L Hematocrit 0.42 L/L Erythrocytes: 4.7 x10^12/L Leukocytes: 4.0x10^9/L MCV 90 fL MCH: 1.88 fmol Thrombytes 212 x10^9/L Sodium: 138 mmol/l Potassium: 3.5 mmol/l Creatinine 84 u¦mol/L eGFR CKD epi >90 ml/min AST: 41 U/L (H) ALT 36 U/L LD: 327 U/I (H) CK: 712 U/I (H) Cholesterol 4.1 mmol/I HDL cholesterol 1.4 mmol/I Cholesterol-HDL ratio: 3.0 LDL cholesterol: 2.4 mmol/l Triglycerides 0.7 mmol/l (L) Glucose 6.6 mmol/l HS troponin I: <10 mg/l Lipoprotein a follows CRP <5 mg/l. The patient was seen on 15Jul2021 at the Cardiology Outpatient Clinic for check-up after a recent visit to first heart aid. As conclusion, VG familial burden for cardiovascular disease. On 1. 22Jun2021, the patient visit emergency room for pericarditis. Now completely complaint-free; Slightly dilated heart with slight eccentric left ventricular hypertrophy consistent with sports heart in endurance athlete. No further outpatient monitoring indicated. The patient is referred back to the general practitioner. Anamnesis, Had no more complaints. Per her physical examination; BP 142/75 mmHg, cor: s1s2 no prompt; ECG: SR 44/min, intermediate heart axis, PQ 0.17 QRS 0.10 QTc 0.41, decrease ST elevation compared to 22-6-21 0.5 mm ST elevation I, aVL, V5, V6 and 2 mm ST elevation V3-V4. The patient had no medication in use. The outcome of pericarditis was recovered on 14Jul2021. No follow-up attempts are possible. No further information is expected.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
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Test Date: 20210622; Test Name: alt; Result Unstructured Data: Test Result:36 IU/I; Test Date: 20210622; Test Name: CT coronary; Result Unstructured Data: Test Result: No coronary stenoses; Test Date: 20210622; Test Name: ASAT; Result Unstructured Data: Test Result:41 IU/I; Test Date: 20210622; Test Name: choletserol; Result Unstructured Data: Test Result:4.1 mmol/L; Test Date: 20210622; Test Name: CK; Result Unstructured Data: Test Result:712 IU/I; Comments: high; Test Date: 20210622; Test Name: creatinine; Result Unstructured Data: Test Result:84 umol/l; Test Date: 20210622; Test Name: glucose; Result Unstructured Data: Test Result:6.6 mmol/L; Test Date: 20210622; Test Name: LD; Result Unstructured Data: Test Result:327 IU/I; Test Date: 20210622; Test Name: potassium; Result Unstructured Data: Test Result:3.5 mmol/L; Test Date: 20210622; Test Name: BP; Result Unstructured Data: Test Result:123/76 mmHg; Test Date: 20210715; Test Name: BP; Result Unstructured Data: Test Result:142/75 mmHg; Test Date: 20210622; Test Name: HR; Result Unstructured Data: Test Result:55; Comments: Units: {beats}/min; Test Date: 20210622; Test Name: sodium; Result Unstructured Data: Test Result:138 mmol/L; Test Date: 20210622; Test Name: triglycerides; Result Unstructured Data: Test Result:0.7 mmol/L; Comments: low; Test Name: heart examination; Result Unstructured Data: Test Result: Slightly dilated heart; Test Date: 20210622; Test Name: CT coronary; Result Unstructured Data: Test Result: Observation of thoracic pain, coronary artery dise; Comments: Observation of thoracic pain, coronary artery disease was excluded. No coronary stenoses. No mass or lymphadenopathy in the mediastinum. Depicted lung fields clear. No indication of current pathology in the scanned trajectory.; Test Date: 20210622; Test Name: CRP; Result Unstructured Data: Test Result:less than 5 mg/l; Test Date: 20210622; Test Name: echocardiogram; Result Unstructured Data: Test Result: Measurement values appropriate to sports heart in; Comments: Measurement values appropriate to sports heart in endurance athlete. Does entire triathlons!; Test Name: ECG; Result Unstructured Data: Test Result: Diffuse ST elevation increase compared to EKG 2020; Test Date: 20210622; Test Name: ECG; Result Unstructured Data: Test Result: Sinus bradycardia 44/min, intermediate cardiac axi; Comments: Sinus bradycardia 44/min, intermediate cardiac axis PQ 0.17 QRS 0.10 QT 0.45, diffuse ST elevation in all leads; Test Date: 20210715; Test Name: ECG; Result Unstructured Data: Test Result:SR 44/min, intermediate heart axis PQ 0.17 QRS 0.1; Comments: SR 44/min, intermediate heart axis PQ 0.17 QRS 0.10 QTc 0.43, decrease ST elevation from 22Jun2021. 0.5 mm ST elevation I, aVL, V5, V6 and 2 mm ST elevation V3-V4; Test Date: 20210622; Test Name: eGFR CKD epi; Result Unstructured Data: Test Result:greater than 90; Comments: units: ml/min; Test Date: 20210622; Test Name: hematocrit; Result Unstructured Data: Test Result:0.42; Comments: units: I/I; Test Date: 20210622; Test Name: hemoglobin; Result Unstructured Data: Test Result:8.9 mmol/L; Test Date: 20210622; Test Name: HDL; Result Unstructured Data: Test Result:1.4 mmol/L; Test Date: 20210622; Test Name: LD; Result Unstructured Data: Test Result: 327 IU/I; Comments: high; Test Date: 20210622; Test Name: lipoprotein a; Result Unstructured Data: Test Result:less than 5 mg/l; Test Date: 20210622; Test Name: LDL cholesterol; Result Unstructured Data: Test Result: 2.4 mmol/L; Test Date: 20210622; Test Name: MCH; Result Unstructured Data: Test Result:1.88 fmol; Test Date: 20210622; Test Name: MCV; Result Unstructured Data: Test Result:90; Comments: units: fL; Test Name: physical examination; Result Unstructured Data: Test Result:BP 121/76 mmHg, HR 55/min, cor: s1 s2 grade 1/6 ej; Comments: BP 121/76 mmHg, HR 55/min, cor: s1 s2 grade 1/6 ejection promptle, no pericardial rub, pulm: VAG; Test Name: physical examination; Result Unstructured Data: Test Result:BP 142/75 mmHg, cor: s1s2 no prompt; Comments: RR 142/75 mmHg, cor: s1s2 no prompt; Test Date: 20210622; Test Name: thrombocyte; Result Unstructured Data: Test Result:212 ng/L; Test Date: 20210622; Test Name: erythrocytes; Result Unstructured Data: Test Result:4.7 x10 12/l; Test Date: 20210622; Test Name: cholesterol- HDL ratio; Result Unstructured Data: Test Result:3; Test Date: 20210622; Test Name: HS troponin; Result Unstructured Data: Test Result:less than 10 mg/l; Test Date: 20210622; Test Name: Leukocyte; Result Unstructured Data: Test Result:4 ng/L

Medications At Time Of Vaccination	History/Allergies
5	Medical History/Concurrent Conditions: Abstains from alcohol; Abstains from recreational drugs; Diabetes; Hypercholesterolaemia; Hypertension; Myocardial infarction (father); Non-smoker; Vascular disorder,

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### **VAERS** Event Details

Details for VAERS ID: 1768479-1

Event Information			
Patient Age	32.00	Sex	Male
State / Territory	California	Date Report Completed	2021-10-07
Date Vaccinated	2021-06-01	Date Report Received	2021-10-07
Date of Onset	2021-06-01	Date Died	
Days to onset	0		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (JANSSEN))	JANSSEN	201A21A	1	SYR	LA

Symp	tom
AMNE	SIA
ARRH'	YTHMIA
COGN	ITIVE LINGUISTIC DEFICIT
DIZZI	NESS
FATIG	UE
FEELI	NG ABNORMAL
GAIT	DISTURBANCE
HEAD	DISCOMFORT
IMPAI	RED WORK ABILITY
MENT	AL IMPAIRMENT
MOTIC	ON SICKNESS
MUSC	LE TWITCHING
STRES	SS
VERTI	GO

### **Adverse Event Description**

Morning following injection, I experienced extreme dizziness and brain discomfort. Dizziness was bad enough to make walking difficult and even created motion sickness. 5 months later the dizziness has eased but still present, flying, driving, elevators, anything seems to trigger some form of dizziness. Hights of about 10 feet give bad vertigo, I am a pilot and aircraft mechanic and this creates an issue working on jets and I do not want to possibly loose my pilots medical. Brain fog is also long lasting still and makes mental clarity difficult which was never an issue until the day after the shot. My heart has created irregular heart rhythms, I have physical stress and tire easily and my muscles will shake and twitch after minimal effort. Biggest concern is dizziness and clarity and loss of short term memory, talking in front of large audiences for work has become difficult since my cognitive skills seem to have diminished from the lasting brain fog.

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

<sup>\*\*</sup> VAERS-1 Report Form Only

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
None yet	None	

Me	edications At Time Of Vaccination	History/Allergies
ı	None	None,None

2 of 3

### FAQs

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### **WONDER Search**

### **VAERS** Event Details

Details for VAERS ID: 1144388-1

Event Information			
Patient Age	71.00	Sex	Male
State / Territory	Maine	Date Report Completed	2021-03-29
Date Vaccinated	2021-02-22	Date Report Received	2021-03-29
Date of Onset	2021-03-08	Date Died	
Days to onset	14		
Vaccine Administered By	Other	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	No

<sup>\*</sup> VAERS 2.0 Report Form Only

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
<b>Existing Hospitalization Prolonged</b>	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information Is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EN5313	1	IM	LA

Symptom
BALANCE DISORDER
DIZZINESS
FATIGUE

### **Adverse Event Description**

Dizziness, balance issues began @ weeks after1st shot. most pronounced when first getting up in the morning. continued fatigue throughout the period. I healthy and have never had balance issue. (retired military and airline pilot. Meclizine of on help.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
none	none	

Medications At Time Of Vaccination	History/Allergies	
NONE	none,NONE	

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

<sup>\*\*</sup> VAERS-1 Report Form Only

FAQs Help Co

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**WONDER Search** 

### **VAERS** Event Details

Details for VAERS ID: 1376453-1

Event Information			· · · · · · · · · · · · · · · · · · ·
Patient Age	45.00	Sex	Male
State / Territory	Colorado	Date Report Completed	2021-06-06
Date Vaccinated	2021-06-03	Date Report Received	2021-06-06
Date of Onset	2021-06-04	Date Died	
Days to onset	1		
Vaccine Administered By	Pharmacy *	Vaccine Purchased By	Not Applicable
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	No

<sup>\*</sup> VAERS 2.0 Report Form Only

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EW0178	2	SYR	RA

### Symptom VERTIGO

### **Adverse Event Description**

Severe vertigo experienced for four days and counting. Early morning symptoms are the worst, but symptoms continue throughout the day and evening. As a professional helicopter pilot, I cannot perform my job with these symptoms.

Lab Data	Current Illness	Adverse Events After Prior Vaccination		
No tests performed yet	None			

<b>Medications At Time Of Vaccination</b>	History/Allergies
None	None,Penicilin

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

<sup>\*\*</sup> VAERS-1 Report Form Only

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**WONDER Search** 

### VAERS Event Details

Details for VAERS ID: 1388581-1

Event Information			
Patient Age	47.00	Sex	Male
State / Territory	Ohio	Date Report Completed	2021-06-10
Date Vaccinated	2021-04-27	Date Report Received	2021-06-10
Date of Onset	2021-04-28	Date Died	
Days to onset	1		
Vaccine Administered By	Pharmacy *	Vaccine Purchased By	Not Applicable
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	Yes	Serious	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	10
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

<sup>\*</sup> VAERS 2.0 Report Form Only

<sup>&</sup>quot;N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	046B21A	1	IM	AR

Symptom	
ANGIOGRAM CERE	BRAL NORMAL
ARACHNOID CYST	
COMPUTERISED TO	MOGRAM HEAD ABNORMAL
HEADACHE	
IMPAIRED WORK A	BILITY
NAUSEA	
РНОТОРНОВІА	
SUBARACHNOID HA	AEMORRHAGE
ULTRASOUND DOP	PLER
VOMITING	

### **Adverse Event Description**

Vaccine information (brand name, dosage, lot number) Date, time, and location administered: Date: 4/27/2021; Time: ? m; Location: Pharmacy Date and time when adverse event(s) started: Date: 4/28/2021; Time: afternoon Description of the adverse event, including medical treatment and diagnosis: Description: Symptoms include: Worst headache of life Exam Findings include: No focal neurologic findings but given history, CT head ordered.

Lab Data	Current Iliness	Adverse Events After Prior Vaccinations
----------	--------------------	--

<sup>\*\*</sup> VAERS-1 Report Form Only

<sup>\*\*</sup> VAERS-1 Report Form Only

Results of medical tests and laboratory tests: CT head showed subarachnoid hemorrhage with full information below. Outcome of the adverse event (for example: doctor office visit, emergency room visit, hospitalization, etc.) Hospital Course: 47 y/o Male with Hx of HTN who presented 4/28/21 with worst headache of life while doing pushups with associated nausea, vomiting, and photophobia. Pt states he has had this type of headache a few times in the past several weeks but it usually went away. CT head showed prepontine subarachnoid hemorrhage; Incidental cerebellar arachnoid cyst. 4/29/21 Cerebral angio negative for aneurysm; Daily TCD's monitored. 5/7/21 Repeat Cerebral angio negative for aneurysm. PT/OT eval with no needs. Patient was discharged to home in satisfactory condition with scheduled follow up. Whether the patient has recovered from the adverse event:
Patient seems to be normal neurologically but remains off work pending FAA evaluation as he is a commercial airline passenger pilot.

Medications At Time Of Vaccination	History/Allergies
None	Patient Active Problem List: Essential hypertension [I10] Need for prophylactic vaccination and inoculation against influenza [Z23] Hyperlipidemia with target LDL less than 130 [E78.5] Overwelght [E66.3] Routine general medical examination at a health care facility [Z00.00] Chronic or long-standing health conditions Past Medical History: Diagnosis Date ? BMI 27.0-27.9, adult 10/15/2016 ? Elevated cholesterol ? Lower urinary tract symptoms (LUTS) 11/29/2011 ? Overweight 3/3/2019 Diagnosed and Discussed with patient. Complications include htn and high cholesterol. On personal lifestyle changes only . ? Rhabdomyolysis 1992 in college and resolved ? Routine general medical examination at a health care facility ? Seborrhea 10/22/2002 ? Unspecified essential hypertension 2007 diet controlled, None

ARTERIOSCLEROSIS, THROMBOSIS, VASCULAR BIOLOGY SESSION TITLE: DAMPS, INFECTION AND CARDIOVASCULAR METABOLISM

**O**Details

A Related P References

Tools < Share</p>

Jump to

Steven R Gundry

Test: a Warning

Abstract

Originally published 8 Nov 2021 | Circulation 2021;144:A10712

Footnotes

This article has an expression of concern  $\vee$ 

Circulation

### **Abstract**

Our group has been using the PLUS Cardiac Test (GD Biosciences, Inc., Irvine, CA) a clinically validated measurement of multiple protein biomarkers which generates a score predicting the 5 yr risk (percentage chance) of a new Acute Coronary Syndrome (ACS). The score is based on changes from the norm of multiple protein biomarkers including IL-16, a proinflammatory cytokine, soluble Fas, an inducer of apoptosis, and Hepatocyte Growth Factor (HGF)which serves as a marker for chemotaxis of T-cells into epithelium and cardiac tissue, among other markers. Elevation above the norm increases the PULS score, while decreases below the norm lowers the PULS score. The score has been measured every 3-6 months in our patient population for 8 years. Recently, with the advent of the mRNA COVID 19 vaccines (vac) by Moderna and Pfizer, dramatic changes in the PULS score became apparent in most patients. This report summarizes those results. A total of 566 pts, aged 28 to 97, M:F ratio 1:1 seen in a preventive cardiology practice had a new PULS test drawn from 2 to 10 weeks following the 2<sup>nd</sup> COVID shot and was compared to the previous PULS score drawn 3 to 5 months previously pre- shot. Baseline IL-16 increased from 35=/-20 above the norm to 82 =/-75 above the norm post-vac; sFas increased from 22+/- 15 above the norm to 46=/-24 above the norm post-vac; HGF increased from 42+/-12 above the norm to 86+/-31 above the norm post-vac. These changes resulted in an increase of the PULS score from 11% 5 yr ACS risk to 25% 5 yr ACS risk. At the time of this report, these changes persist for at least 2.5 months post second dose of vac. We conclude that the mRNA vacs dramatically increase inflammation on the endothellum and T cell infiltration of cardiac muscle and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination.

Abstract 10712: Mrna COVID Vaccines Dramatically Increase Endothelial

Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac



November 16, 2021 Vol 144, Issue Suppi\_1

### **Article Information**

### Metrics



See more details

Picked up by 18 news outlets
Blogged by 8
Tweeted by 63294
On 17 Facebook pages
Referenced in 2 Wikipedia pages
Reddied by 61
On 4 uideos
Download: 0

### **Footnotes**

Author Disclosures: For author disclosure information, please visit the AHA Scientific Sessions 2021 Online Program Planner and search for the abstract title.

### VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports, @

All VARAS COVID Reports On US/Tetritor HA/Unknown

946,461 Reports
Through December 3, 2021 •













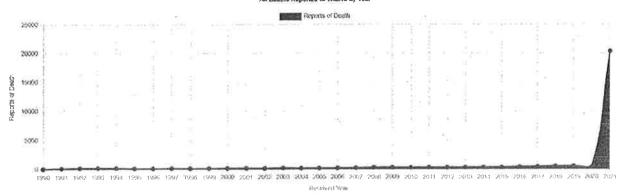
3,230 Miscarriages 9,977 Heart Attacks 16,918
Myocarditis/Pericarditis

32,644 Permanently Disabled

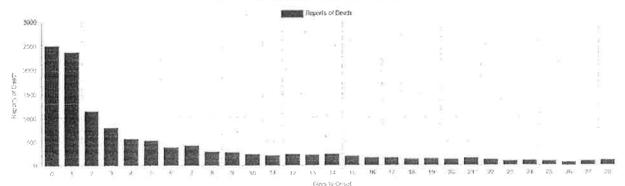
4,717
Thrombocytopenia/
Low Platelet

22,422 Life Threatening 35,009 Severe Allergic Reaction 10,946 Shingles

### AR Courts Deposited to VAPUS for Year



VAER'S COVID Voccine Reports of Deaths by Days to Driskt-All Ages



### THERESA MARIE LONG, MD, MPH, FS LTC, MEDICAL CORPS, U.S. Army

### **Medical Education**

United States Army School of Aviation Medicine Aerospace/Occupational Medicine Residency University of West Florida
Graduate Student -MPH

06/2019-6/2021

Carl R. Darnall Army Medical Center, Fort Hood, Texas Family Medicine Internship 06/2008-11/2010
Unrestricted Medical License, IN

09/2003 - 06/2008 University of Texas Medical School at Houston, Houston, Texas 06/2008 M.D.

08/2001 - 08/2004 Undergraduate - University of Texas at Austin, Austin, TX 05/2004 B.S. Neurobiology

### Research Experience

08/2018 – 5/2020
School of Aviation Medicine
University of West Florida MPH program
https://tml526.wixsite.com/website
Performed a cross-sectional study on Intervertebral Disc Disease Among Army Aviators and Air Crew

### 08/2002 - 05/2003

University of Texas at Austin, Texas
Research Assistant, Dr. Dee Silverthorn
Performed academic research in effort to update medical facts and the latest research information for the publication of the fourth edition of Human Physiology

### 09/2000 - 11/2000

Neuropharmacology Research, Texas

Lab Tech, Dr. Silverthorn

Acquisition of rat cerebellums for research in gene sequencing. The focus of the project was to determine the DNA sequence of the receptor in the developing fetal brain that binds to ethanol and induces apoptosis leading to fetal alcohol syndrome.

### **Publications/Presentations/Poster Sessions Presentations/Posters**

Poster: Intervertebral Disc Disease Among Army Aviators and Air Crew, presented during the 2021 American Occupational Healthcare Conference.

Long, Theresa M., Sorensen, Christian, Victoria Zumberge. (2003, May). Sodium dependent transport of Chlorophenol red uptake by Malpighian tubules of acheta domesticus. Poster presented at: University of Texas at Houston; Austin, TX.

### **Volunteer Experience**

08/ 2005 - 09/2005 University of Texas - Houston, Health Science Ctr, Texas Medical Student -Provided medical aid and support for Acute Care and triage of Hurricane Katrina evacuees.

### **Work Experience**

### 06/2021- Present

### 1st Aviation Brigade TOMS Surgeon

Serve as the Medical Advisor to the 1st Aviation Brigade Commander regarding health and fitness of over 3600 officers, warrant officers and Soldiers. The Brigade is comprised of three aviation training battalions, responsible for initial entry rotary wing/ fixed wing flight training, advanced aircraft training, as well as Specific duties include ensuring safety of flight in Army Aviation operations by functioning as Flight Surgeon, while ensuring the health and fitness of military police, firefighters and military working dogs that support Ft. Rucker. Tasked with conducting epidemiological and biostatistical analysis of injuries and illnesses (SARs CoV-2) and medical trends that occur during training and identify and implement strategies to mitigate delays or lost training time.

### 05/2018-06/2021

### **Aerospace and Occupational Medicine Resident**

Graduate Medical Education training in Aerospace and Occupational Medicine while obtaining a Master's in Public Health. Specialty training included the Flight surgeon course, The Instructor/Trainer course, Space Cadre Course, Medical Effects of Ionizing Radiation, Medical Management of Chemical and Biological Casualties course at USAMIIRD, Ft. Detrick, NASA, 7th Special Forces, Aviation Safety Officer Course, Global Medicine Symposium, OSHA, Dept of Transportation, Textron Bell Helicopters, Brigade Healthcare Course, Preventative Medicine Senior Leaders Course, Joint Enroute Critical Care Course, Army Aeromedical Activity, research on Intervertebral Disc Disease.

05/2015-05/2018

### Department of Rehabilitation Services General Medical Officer

Assigned to Carl R. Darnall Army Medical Center Physical Medicine clinic with special duties Function as General Medical Officer, to mitigate the number of high risk patients get referred off-post to Pain management and PM&R clinics. Functioned as the Performance Improvement officer for PM&R, the Chiropractic Clinic OIC, and the MEB/IDES Subject Matter Expert to IPMC multi-disciplinary team. Significantly increased access to care to the Physical Medicine clinic. Was instrumental in leading the hospital transition for the Chiropractic clinic, contributing to the subsequent successful Joint Commission inspection. Increased access to care in the Chiropractic clinic by 500%.

9/2013- 5/2015

### Department of Pediatrics/ Department of Deployment & Operational Medicine General Medical Officer

Assigned to the Carl R. Darnall Army Medical center Pediatric Clinic with special duties within the Department of Deployment & Operational Medicine. Provided acute and routine medical care for newborn to age 18 and collaborated with Lactation Team Leader to develop research matrix to ensure effective use of resources to meet Perinatal Core Measures PC-05 for Joint Commission Accreditation. Demonstrated initiative by providing emergency medical care to one of the victims of the April 2, 2014 FT Hood shooting.

10/2012-9/2013

### Department of Deployment Medicine/ Emergency Medicine General Medical Officer

Assigned to the Department of Deployment & Operational Medicine at Carl R Darnall Army Medical Center (CRDAMC) with specific duties directed by the CRDAMC DCCS. Supported soldier deployment/redeployment from combat, while also performing clinical rotations within the Emergency and Internal Medicine Departments to increase access to care for acutely ill patients. Improved productivity of the SMRC by conducting ETS, Chapter, Special Forces, Airborne, Ranger, SERE, and OCS/WOCS physicals. Ensured DODM success with 90% CRDAMC staff compliance of their annual PHA's. Selected to become an ACLS instructor.

06/2012-10/01/2012

**Department of the Army Inspector General Agency** 

Disability Medicine Subject Matter Expert (SME) - Temporary Dept of the Army Inspector General

Assistant Inspector General on Medical Disability (Subject Matter Expert)
Selected above my peers, from across the Army AMEDD as one of three medical NARSUM Subject Matter Experts to function as a temporary assistant Inspector General, in a SECARMY directed inspection of the MEB/IDES system. Planed, coordinated, and conducted inspections of agencies/commands and to gather required data and

perspectives relevant to the inspection topic. Developed inspection concepts, objectives, methodologies while coordinating inspection site requirements with major Army Commands ASCC, DRUs, Installations and Components. Identified trends, analyzed root causes to systemic problems and proposed solutions to the IG, Army Chief of Staff and Secretary of the Army for service-wide implementation.

06/2011-06/2012

### Carl R. Darnall Army Medical Center Integrated Disability Evaluation System

Increased patient access to care by conducting 203 acute care appointments in four months. Increased productivity by 25% by completing 202 NARSUMs, 12 TDRLs, 42 Psychiatric addendums in nine months with only a single case returned from the PEB. Performed duties of MEB chief and QA physician in their absence by performing QA on seven NARSUMS, and reviewing 13 cases for initial intake. Functioned as IDES Physician Training officer, applying PDA training to develop a comprehensive training program for new MEB/IDES NARSUM physicians.

11/2010-05/2011

### Carl R. Darnall Army Medical Center, Hospital Operations, Clinical Plans and Medical Operations Officer

Served as Clinical Plans and Medical Operations Officer for Hospital Operation (HOD), responsible for the synchronization of external and internal MEDCEN operations supporting over 3,000 MEDCEN employee as well as the DoD's largest military installation and surrounding civilian population; assisted in development and execution of medical plans supporting Installation, Garrison, MEDCEN and Civilian AT/FP and MASCAL events

06/2005 - 07/2005

### United States Army, Texas, Officer Basic Course - Class 1st Sergeant

Supervised 306 medical, dental, and veterinarian HPSP scholarship recipients for Officer Basic training. 10/2002 - 08/2003

United States Army - Texas National Guard, Texas Flight Medic -EMT/BCLS Instructor Training

10/2001 - 10/2002

United States Army Reserve, Texas, Instructor/Trainer

# Surriculum Vitae

# Peter Constantine Chambers

Physician / Flight Surgeon / Green Beret / Civilian LE (Reserve) EMSLLC2017@Gmail.com / peter.c.chambers.mil@mail.mil PO Box 670 Madill, OK 73446 / 580-677-0792

November 1997 - May 2000 \* Residency Family Practice Medicine \* Oklahoma State University

June 1995 - June 1996 \* Rotating Internship - Columbia July 1996 – October 1997 \* Rotation – Cosmetic Surgery

**University General Hospital** 

September 1990 - August 1995 \* Doctorate of Osteopathic Medicine \* University of New England

## LICENSURE

Oklahoma State Medical License / License Number: 3712 /

Expires: 30 June 2022

DEA / Reg. No: BC 6554251 / Expires: September 2021

## LANGUAGES

Persian Farsi

Greek

Dari

## WORK EXPERIENCE

- Operations February 2016 - Present \* Sole Proprietor EMS LLC \* Worldwide
- July 2015 February 2016 \* Physician Convenient Care Clinic \* Ardmore, OK
- Bragg, NC March 2013 - May 2015 \* Battalion Surgeon - 2nd BN, 3nd SFG(A) \* FT
- Medical Center \* Madill, OK July 2012 - March 2013 \* ER Physician / Integris Marshall County
- June 2004 October 2010 \* ER Physician / Integris Marshall County
- December 2006 December 2007 \* FP Physician Family Practice Clinic Medical Center \* Madill, OK
- May 2003 January 2004 \* Emergency Medicine \* (Purcell, Ada, Paul's Valley, Holdenville) OK

of Atoka, Inc. \* Atoka, OK

- August 2000 May 2003 \* Integris Marshall Memorial Hospital \* Family Practice Clinic \* Madill, OK
- County, OK April 2001 - February 2004 \* Director - Marshall County EMS \* Marshall
- Marshall County, OK February 2000 - Present \* Reserve LE / SWAT / Crisis Negotiator \*
- June 1995 May 2000 \* Internship / Residency \* Noted Above
- September 1983 June 1990 \* United States Army / Army Reserve \* Honorable Discharge

# DEPLOYMENTS / ASSIGNMENTS

- Flintlock '20 January '20 (SOD-A) \* West Africa
- Operation Enduring Freedom '19 (Joint Task Force GTMO)
   \* Guantanamo Bay, Cuba
- Flintlock '19 January '19 (SOD-A) \* West Africa
- OIR \* May October '16 (XO AOB 9530) \* Jordan
- JCET June '15 (C Co. 5/19th SFG) \* Greece
- OEF XXI '14 (SOTF-NE, 2/3 SFG) \* Afghanistan
- Foal Eagle '10 (1/19 SFG) \* S. Korea
- Operation Enduring Freedom '08 (TF PHX ETT 2/2/207)
- \* Afghanistan
- Balance Nail '08 (19th SFG) \* Nepal
- Balanced Nail '07 (19th SFG) \* Nepal
- Earthquake Relief '05 (NGO) \* Pakistan / NWFP
- Hurricane Katrina Relief / Hurricane Rita Relief '05
- \* Gulf Coast
- Talisman Sabre '05 (19th SFG) \* Australia
- Operation Iraqi Freedom '04 (2/5 SFG) \* Iraq
- Balanced Nail '03(19th SFG) \* Nepal
- Unified Endeavor '03 (19th SFG) \* Puerto Rico
- First Responder to Twin Towers 09/11/01 \* New York City
- Team Spirit '85 (25th Infantry Division) \* S. Korea

### MILITARY

- December 2018 Present \* Special Operations Detachment -Africa \* SURG \* Austin, TX
- January 2018 December 2018 \* 176th ENG BDE (TX-ARNG) \* BDE SURG \* Camp Mabry, TX
- May 2015 January 2018 \* C/5/19 SFG(A) \* TRNG DET CDR \* Camp Bullis, TX
- May 2014 May 2015 \* 2nd BN 3rd SFG(A) \* Battalion Surgeon,
- October 2013 May 2014 \* SOTF-NE SURGEON \* Afghanistan
- March 2013 October 2013 \* 2nd BN 3<sup>rd</sup> SFG(A) \* Battalion Surgeon, FT Bragg, North Carolina
- 2012 2013 \* 1st BN 19th SFG(A) \* National Guard, Camp Williams, Utah
- 2012 \* Special Forces Qualification Course \* Fort Bragg, NC
- 2009 2012 \* 1st BN 19th SFG(A) \* National Guard, Camp
   Williams, Utah
- 2008 \* Embedded Training Team (ETT) Executive Officer \*
- Afghanistan
- 2003 2004 \* Task Force 161 Surgeon \* Iraq
- 2002 2003 \* Deputy Group Surgeon, 19th SFG(A) \* Draper, Utah
- 1995 2003 \* General Medical Officer \* Reserves
- Discharge 1983 - 1990 \* U.S. Army Infantry \* Enlisted Soldier \* Honorable

# EXPERIENCE / COURSES

- Combat Tactical Medical Care Course
- \* Fort Sam Houston, San Antonio, TX
- SWAT Operational Team Physician (Commissioned CIV LE)
- Tactical Medicine Instructor
- \* DEA Counter-Narcotics and Interdiction Course
- Certified Peace Officer \* CLEET Certified
- Hyperbaric Medicine \* University of Texas Medical Branch
- FBI Crisis Negotiator Course
- Combat Tracker Course (FLETTC)
- Special Forces Qualification Course (18A) \* Ft Bragg, NC
- Survival Evasion Resistance and Escape (SERE) Course
- Concealed Weapons Training (w/ yearly Quals)
- Driving Training OTC (Urban and Off Road)
- Source Operations / Real World Operations
- Surveillance OTC / Real World Operations
- HTM Course Instructor / Real World Operations
- Flight Surgeon Course

## AWARDS / BADGES

Purple Heart \* Meritorious Service Medal \* Bronze Star \* Army Commendation Medal (6) \* Army Achievement Medal (2) \* GWOT Expeditionary Medal \* Good Conduct Medal \* Iraq Service Medal \* Afghan Service Medal \* NATO Ribbon \* Overseas Service Ribbon \* Combat Medical Badge \*

## **DUTY STATIONS**

- December 2018 Present \* Special Operations Detachment -Africa \* SURG \* Austin, TX
- January 2018 December 2018 \* 176th ENG BDE (TX-ARNG) \* BDE SURG \* Camp Mabry, TX
- May 2015 January 2018 \* C/5/19 SFG(A) \* TRNG DET CDR \* Camp Bullis, TX
- May 2014 May 2015 \* 2nd BN 3rd SFG(A) \* Battalion Surgeon, FT Bragg, North Carolina
- October 2013 May 2014 \* SOTF-NE SURGEON \* Camp Montrond, Afghanistan
- March 2013 October 2013 \* 2nd BN 3rd SFG(A) \* Battalion Surgeon, FT Bragg, North Carolina
- 2012 2013 \* 1st BN 19th SFG(A) \* National Guard, Camp Williams, Utah
- 2012 \* Special Forces Qualification Course \* Fort Bragg, NC
- 2009 2012 \* 1st BN 19th SFG(A) \* National Guard, Camp Williams, Utah
- 2008 \* Task Force Phoenix Surgeon / Embedded Training Team
   (ETT) Executive Officer \* Afghanistan
- 2003 2004 \* Task Force 161 Surgeon \* Iraq
- 2002 2003 \* Deputy Group Surgeon, 19th SFG(A) \* Draper, Utah
- 1995 2003 \* General Medical Officer \* Reserves
- 1983 1990 \* U.S. Army Infantry \* Honorable Discharge

### UNITS/ AGENCIES TRAINED

EMS LLC and MIL OPS)

- · USASOC / USSF
- US ARMY INFANTRY
- USMC RAIDER FORCE
- · FBI HRT
- BRITISH 22 SAS
- OHP TAC TEAM
- DEA FAST TEAMS
- DALLAS SWAT
- OGA TIER ONE
- AUSSIE 4<sup>TH</sup> RAR (RGR)
- CAPITOL POLICE (D.C.) and USSS
- OKLAHOMA and TEXAS National Guard
- · USMC GTMO
- USCG GTMO

- OTHER PARTNER NATIONS (FID)
- · ANA CDO'S
- NEPALESE RANGERS
- · THAI SF
- · IRAQI CDO'S
- BURKINA FASO CT FORCES
- POLISH GROM (SF)
- · ROMANIAN SF
- GREEK CT FORCES
- MALI CT FORCES
- NIGER RANGER FORCES
- JORDANIAN CT and SF
- FRENCH COMMANDOS

# Tuesday, October 6, 2021 CURRICULUM VITAE

## PETER A. McCULLOUGH, MD, MPH, FACC, FCCP, FAHA, FNKF, FNLA, FCRSA

Business

HeartPlace

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Dallas TX 75246 Desk: 214-841-2000 Cell: 248-444-6905

e-mail: PeterAMcCullough@gmail.com

Home

5231 Richard Avenue

Dallas, TX 75206

Birth date

December 29, 1962

Birthplace

Buffalo, NY, USA

#### **EDUCATION**

- 1) <u>Certificate of Graduate Liberal Arts Studies</u>: <u>Southern Methodist University</u>, December 17, 2016, principal faculty Dr. Anthony Picchioni, PhD, Adjunct Professor in Human Development, P.O. Box 750181, Dallas, TX 75275, 214-768-3417, <u>www.smu.edu</u>
  - Graduated with Honor
- 2) <u>Master of Public Health</u>: <u>University of Michigan School of Public Health</u>, August 19, 1994, Dean Noreen M. Clark, PhD, 109 Observatory Street, Ann Arbor, MI 48109-2029, phone 734-764-5454, <u>www.sph.umich.edu</u>
  - Major: General Epidemiology
- 3) <u>Doctor of Medicine</u>: <u>University of Texas Southwestern Medical School</u>, June 4, 1988, Dean Bryan M. Williams, MD, 5323 Harry Hines Boulevard, Dallas, TX 75235-9070, 214-648-3111, http://www.utsouthwestern.edu/education/medical-school/
  - Clinical year rank of 1 in 199, overall rank in class of 12 in 199
  - Alpha Omega Alpha Texas Gamma Chapter, installed March 17, 1988
- 4) <u>Bachelor of Science</u>: <u>Baylor University</u>, May 18, 1984, Chancellor Abner McCall, PhD, Office of the Registrar, Waco, TX 76798-7056, 254-710-1181, http://www.baylor.edu/
  - Double-major: Biology and Psychology
  - Graduated with Honor, degree rank of 29 in 131, university rank of 127 in 1,152

Alpha Lambda Delta Freshman Honorary, installed March 19, 1981

#### **POSTGRADUATE TRAINING**

- 1) <u>Cardiovascular Diseases Fellowship</u>: William Beaumont Hospital (WBH) (presently Oakland University William Beaumont School of Medicine), Division of Cardiology, 3601 W. Thirteen Mile Rd, Royal Oak, MI 48073, 248-551-4198, 7-1-94 to 6-30-97, Chief Cardiovascular Fellow for 1996-97, William W. O'Neill, MD, Program Director and Division Chief
- 2) <u>Internal Medicine Residency</u>: University of Washington School of Medicine, Department of Internal Medicine, 1959 NE Pacific, Seattle, WA 98195, (206) 543-3239, 3-year traditional track, 7-1-88 to 6-30-91, James F. Wallace, MD, Program Director, Paul G. Ramsey, MD, Chairman of Medicine

#### PROFESSIONAL EXPERIENCE

HeartPlace , 3409 Worth Street, Suite 500, Dallas TX 75246, March 1, 2021.

Positions Held: 1) Attending Physician

Baylor Scott and White Health, Baylor Health Care System, Baylor University Medical Center (BUMC), Baylor Heart and Vascular Institute, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, Dallas TX, Texas A & M University College of Medicine, Department of Medicine, Division of Cardiology, Baylor Heart and Vascular Institute, 621 N. Hall St., #H030, Dallas, TX 75226, February 3, 2014 to February 25, 2021. Cardiovascular Governance Council, Kevin Wheelan, MD, Cardiology Division Chief and Chief Medical Officer, Heart Institute Office (214) 820-7500

Positions Previously Held:

- 1) Professor in the Principal Faculty, Non-Tenure Track in the Department of Internal Medicine, Texas A & M University Health Sciences Center (2016-2021)
- 2) Chief of Cardiovascular Research (2014-2021)
- 3) Program Director, BUMC Cardiovascular Diseases Fellowship Program (2014-2021)
- 4) Vice Chief, BUMC Internal Medicine (2016-2021)

St. John Providence Health System, Providence Park Heart Institute, Department of Medicine, Cardiology Section, 47601 Grand River Avenue, Suite B-125, Novi, MI 48374, September 1, 2010 to July 19, 2013. Department of Medicine Chair, Anibal Drelichman, MD: 248-849-3152, Cardiology Section Chief: Shukri David, MD, 248-465-5955

Positions Previously Held:

- 1) Chief Academic and Scientific Officer (Academic Dean Equivalent), St. John Providence Health System, (2010 to 2013)
- 2) Medical Director, Clinical Lipidology, Department of Medicine, Cardiology Section (2010 to 2013)

<u>William Beaumont Hospital</u>, Department of Internal Medicine, Divisions of Nutrition and Preventive Medicine, Department of Cardiology, 3601 West Thirteen Mile Road, Royal Oak, MI 48073, October 1, 2002 to 2010. Department of Medicine Chair: Michael A. Maddens, M.D., 248-551-0622, Department of Cardiology Chair: David E. Haines, M.D., 248-858-0404

Oakland University William Beaumont School of Medicine, 472 O'Dowd Hall 2200 N. Squirrel, Rochester, MI 48309, Robert Folberg, MD, Medical School Dean, Kenneth Hightower, PhD, Dean of Allied Health Sciences, 248-370-3562. Clinical Professor of Health Sciences and Medicine (2007 to 2010)

# Positions Previously Held:

- 1) Consultant Cardiologist and Chief, Division of Nutrition and Preventive Medicine (2002 to 2010), Department of Internal Medicine
- 2) Medical Director, Preventive Cardiology (2002 to 2010)
- 3) Medical Director, Lipid Apheresis Program (2007 to 2010)
- 4) Medical Director, Weight Control Center (2002-2005)

<u>University of Missouri-Kansas City (UMKC) School of Medicine, Truman Medical Center,</u>
Department of Medicine, Cardiology Section, 2301 Holmes St., Kansas City, MO 64108. August 18, 2000-September 30, 2002. Department of Medicine Chair: George R. Reisz, M.D, 816-556-3450

## Positions Previously Held:

1) Associate Professor of Medicine (Tenure Track) and Cardiology Section Chief (2000-2002)

Henry Ford Health System (HFHS), Henry Ford Heart and Vascular Institute, 2799 W. Grand Blvd., K-14, Detroit, MI 48202, July 1, 1997 to August 16, 2000. Cardiovascular Division Head: W. Douglas Weaver, M.D, 800-653-6568

## Positions Previously Held:

- 1) Assistant Professor of Medicine (Tenure Track), Case Western Reserve University School of Medicine, and HFHVI Senior Staff Cardiologist Medical Director, Preventive Cardiology, 1999-2000
- 2) Program Director, Cardiovascular Diseases Fellowship Training Program, 1999-2000
- 3) Director of Cardiovascular Informatics Section, 1997-2000
- 4) Associate Director of the Center for Clinical Effectiveness, 1997-99

5) Associate Director of the Cardiovascular Diseases Fellowship Program, 1998-99

Emergency Physicians Medical Group, PC, 2000 Green Road, Suite 300, Ann Arbor, MI 48105, 800-466-3764. Emergency medicine attending at Mission Health McPherson Hospital, Howell, 1991-1997; Oakwood Beyer Hospital Center, Ypsilanti 1991-1997, and Mercy Hospital, Grayling 1991-1992

# Positions Previously Held:

- 1) Associate Member
- 2) Washtenaw County Human Services Deputy Medical Examiner, 1995-1996

Mercy Internal Medicine Associates, 308 Michigan Avenue, Grayling, MI 49738, Mercy Hospital-Grayling, 1100 Michigan Avenue, Grayling, MI 49738, 517-348-5461. Internal medicine attending at Mercy Hospital, Grayling, MI, 1991-1992

# Positions Previously Held:

- 1) Coronary Care Unit Director
- 2) Physician Director of Cardiopulmonary Services

#### **SPECIAL TRAINING**

- 1) The Healthcare Forum Cardiovascular Health Fellowship, 1998-99
- 2) American Heart Association (AHA), 23<sup>rd</sup> 10-Day U.S. Seminar on the Epidemiology and Prevention of Cardiovascular Disease, July-August, 1997
- 3) University of Michigan Summer Session in Epidemiology, 1997-99
- 4) Stanford University Course on Medical Informatics, Palo Alto, CA, June, 1997
- 5) Current Practice of Vascular Ultrasound 3-Day Course, Chicago, IL, April, 1997
- 6) Advanced Pacemaker Concepts Course, CPI, Inc., Lansing, MI, 1995
- 7) Pacesetter Comprehensive Pacemaker 4-Day Course, Santa Fe, NM, 1997
- 8) Medtronic Bakken Education Tutorial and Medtronic Applied Physiological Research Laboratory Lead Implantation Training and Biventricular Implantation Training (2 sessions), Minneapolis, MN, 2001-2002
- 9) 2004 ASCeXAM Review Course, American Society of Echocardiography, San Francisco, CA, April 22-24, 2004
- 10) National Lipid Association Masters Course in Clinical Lipidology, Hilton Head, SC, August 21-23, 2008

## **CERTIFICATION AND LICENSURE**

1) Licensed in the State of Washington 1988-1997 (#MD00027562), Michigan expires January 31, 2022 (#4301058147), and New York 1992 to present (#189283 inactive status), Missouri 2000-2002 (#2000165365 inactive status) and Texas expires May 31, 2022 (#P9222)

- 2) FLEX passed April 4, 1990, State of Washington, Department of Health, Board of Medical Examiners
- 3) Diplomate, American Board of Internal Medicine, Candidate #136084, September, 25, 1991, recertified May 1, 2001, recertified June 10, 2011, recertified April 6, 2021, valid through 2031, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
- 4) Diplomate, American Board of Internal Medicine, Cardiovascular Diseases Subspecialty, Candidate #136084, November, 1997, valid through 2007, recertified October 1, 2007, valid through 2017, recertified September 28, 2017, valid through 2027, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
- 5) Diplomate, American Board of Clinical Lipidology, September 27, 2008, 6816 Southpoint Parkway, Suite 1000, Jacksonville, FL 32216. Fellow, National Lipid Association
- 6) National Board of Echocardiography (NBE), Examination of Special Competence in Adult Echocardiography, 2004-2014 expired
- 7) Diplomate, American Board of Forensic Examiners, July 16, 1996, no expiration date

#### **RECOGNITION**

## Teaching:

1. Henry Ford Hospital, 1999 Chief Medical Resident's Best Teacher Award

#### Research:

- 1. Chest Foundation Young Investigator Award 2001, Philadelphia, PA, November 7, 2001, President's International Awards Ceremony
- 2. National Kidney Foundation (NKF) of Michigan, Innovations in Health Care Award Finalist 2008, East Lansing, Ml, April 17, 2008
- 3. American College of Cardiology (ACC) Simon Dack Award for Scholarly Excellence by the Journal of the American College of Cardiology, March 5, 2009
- 4. 11<sup>th</sup> International Vicenza Award in Critical Care Nephrology, International Renal Research Institute, Vicenza, Italy, June 11, 2013

## Postgraduate:

- 1. Founding Fellow, Cardiorenal Society of America, March 2016
- 2. Fellow, National Lipid Association, January, 2013
- 3. Fellow, National Kidney Foundation, January, 2012
- 4. Fellow, American College of Chest Physicians, February, 2001
- 5. Fellow, American College of Physicians, January, 2001 to September, 2021
- 6. Fellow, American College of Cardiology, February, 1999

## **AFFILIATIONS**

1) Alpha Omega Alpha, National Honor Medical Society, 1988 to present

- 2) American College of Emergency Physicians, Member, 1992-1994
- 3) American College of Forensic Examiners, Member 1996 to present
- 4) AHA, Council on Epidemiology and Prevention, 1995 to present
- 5) AHA, Grassroots Network, 1998-2000.
- 6) Central Society for Clinical Research, Member, 1999-2000
- 7) Council on Geriatric Cardiology, Member 1996-1997
- 8) Michigan Chapter of the ACC, Chair, Annual Cardiology Board Review, 1999-2000
- 9) Michigan State Medical Society, Member, 1997-2000, 2004 to 2009
- 10) The American Medical Informatics Association, 1997-2000
- 11) The Health Forum, Charter Cardiovascular Health Charter Alumni Representative, 1998 to 2002
- 12) Cardiorenal Society of America, Founding Executive Board Member, 2013 to present, Vice President 2014-2016, President 2016 to present
- 13) Dallas County Medical Society, 2014 to present
- 14) Texas Medical Association, 2014 to present
- 15) Baylor Alumni Association, 2015 to present
- 16) New York Academy of Sciences, 2016 to present
- 17) Truth for Health Foundation, Founding Executive Board Member, Chief Medical Advisor, 2021 to present

# **EDITORIAL RESPONSIBILITIES**

- 1) Advances in Chronic Kidney Disease, Editorial Board Member, 2003-present. [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE]
- 2) American Journal of Cardiology, Associate Editor, 2014 to present
- 3) American Journal of Kidney Disease, [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE] Associate Editor, 2006 to 2019, Guest Editor, 2011, 2012
- 4) Arquivos Brasileiros de Cardiologia, International Editorial Board, 2006 to present
- 5) Biocritique, Editorial Board, 2001 to 2013, www.biocritique.com
- 6) Blood Purification, Editorial Board 2018 to present
- 7) Cardiovascular Clinician, Editorial Board, 2011 to 2013, internet site, CARDIOVASCULARClinician.com™
- 8) Cardiovascular Diagnosis and Therapy (CDT), Editorial Board (Print ISSN: 2223-3652; Online ISSN: 2223-3660, 2012 to present
- 9) Cardiovascular Innovations and Applications (CVIA), Editorial Board 2015 to present
- 10) Cardiorenal Medicine, Associate Editor, 2016-2017, Editor-in-Chief 2018 to 2021
- 11) Circulation, Editorial Board, 2016 to present
- 12) Circulation Heart Failure, Editorial Board, 2008 to present, Associate Editor, 2008 to 2016, Guest Editor 2010, 2011, 2012
- 13) Clinical Exercise Physiology, Clinical Consultant to the Editorial Board, 1998-2002.
- 14) Cochrane Renal Group Module, 2008, Editorial Contributor, Centre for Kidney Research, The Children's Hospital at Westmead, Westmead NSW, Australia

- 15) Expert Review of Cardiovascular Therapy, Editorial Advisory Panel, 2002 to present, www.future-drugs.com
- 16) Journal of the American College of Cardiology, Editorial Consultant, 2003-present. "Elite Reviewer" Recognition, 2004, 2005, 2006, 2007, 2008, 2011, 2014, 2016 (DeMaria AN. The elite reviewer. J Am Coll Cardiol 2003;41(1):157-8.)
- 17) Journal of Geriatric Cardiology, Editorial Board Member, 2003-present. The Institute of Geriatric Cardiology, Chinese PLA Hospital, Beijing. [Joint China-U.S.A. publication]
- 18) Journal of Biorepository Science for Applied Medicine, Honorary Editorial Board, 2012 to 2018
- 19) Journal of Clinical & Experimental Cardiology, OMICS Publishing Group, Open Access, CrossRef, PubMed, DOAJ, Index Copernicus, Scientific Commons, EBSCO, 2010 to 2017
- 20) Journal of Diabetes & Metabolism, OMICS Publishing Group, Open Access, 2010 to 2017
- 21) *Journal of Interventional Cardiology,* "News and Views", Section Editor, 2000-2003. Editorial Board Member, 2003 to present
- 22) Journal of Nephrology and Therapeutics, Editorial Board, OMICS Publishing Group, Editorial Board, 2010 to 2017
- 23) Reviews in Cardiovascular Medicine, MedReviews, LLC, <a href="www.medreviews.com">www.medreviews.com</a> "Cardiorenal Function," Section Editor, 2001-2002, Associate Editor, 2003-2009, Co-Editor, 2009 to present
- 24) The American College of Cardiology Foundation ACCEL Audio Journal, Editorial Board 2008 to present
- 25) The Open Atherosclerosis & Thrombosis Journal, [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2012
- 26) The Open Heart Failure Journal, [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2010
- 27) Therapy, [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE], Editorial Board, 2008 to 2010

# **Manuscript Reviewer**

- 1) Advances in Chronic Kidney Disease, 2004 to present (18)
- 2) Advances in Medical Sciences, 2012 to present (2)
- 3) Advances in Therapy, 2008 to present (1).
- 4) American Family Physician, 2004 to present (2)
- 5) American Journal of Cardiovascular Drugs, 2002 to present. (2)
- 6) American Heart Journal (AHJ), 1998 to present (22)
- 7) American Journal of Cardiology (AJC), 1999 to present (60)
- 8) American Journal of Human Biology, 2014 to present (1)
- 9) American Journal of Hypertension, 2011 to present (1)
- 10) American Journal of Kidney Diseases (AJKD), 2002 to present (30)
- 11) American Journal of Medicine (AJM), 1997 to present (7)
- 12) American Journal of the Medical Sciences (AJMS), 2006 to present (3)
- 13) American Journal of Nephrology, 2004 to present (24)
- 14) American Journal of Physiology: Renal Physiology, 2006 to present (2)

- 15) American Journal of Transplantation, 2004 to present (1)
- 16) Annals of Epidemiology, 2004 to present (1)
- 17) Annals of Internal Medicine, 2008 to present (3)
- 18) Annals of Noninvasive Electrocardiology, 2009 to present (1)
- 19) Antimicrobial Agents and Chemotherapy, 2020 to present (1)
- 20) Archives of Internal Medicine, 2004 to present (2)
- 21) Archives of Pathology and Laboratory Medicine, 2007 to present (1)
- 22) Arteriosclerosis, Thrombosis, and Vascular Biology, 2010 to present (2)
- 23) Autonomic Neuroscience: Basic and Clinical, 2007 to present (1)
- 24) BUMC Proceedings, 2012 to present (3)
- 25) Biochemia Medica, 2012 to present (1)
- 26) Biomed Central (BMC) Medical Imaging, 2010 to present (1)
- 27) Blood Purification, 2010 to present (2)
- 28) BMC Medicine, 2007 to present (1)
- 29) BMC Nephrology, 2011 to present (1)
- 30) BMJ Clinical Evidence, 2008 to present (1)
- 31) British Medical Journal (BMJ), 2009 to present (1)
- 32) Canadian Medical Association Journal (CMAJ), 2006 to present (3)
- 33) Cardiac Failure Review, 2015 to present (1)
- 34) Cardiology, 2007 to present (1)
- 35) Cardiorenal Medicine; 2013 to present (10)
- 36) Cardiovascular Innovations and Applications, 2016 to present (1)
- 37) Cardiovascular Therapeutics, 2010 to present (1)
- 38) Catheterization and Cardiovascular Interventions, 2000 to present (6)
- 39) Chest, 2000 to present (6)
- 40) Circulation, 1998 to present (100)
- 41) Circulation Cardiovascular Interventions, 2012 to present (1)
- 42) Circulation Cardiovascular Quality and Outcomes, 2010 to present (1)
- 43) Circulation Heart Failure, 2009 to present (4)
- 44) Circulation Imaging, 2012 to present (1)
- 45) Cleveland Clinic Journal of Medicine, 2008 to present (1)
- 46) Clinica Chimica Acta, 2013 (1)
- 47) Clinical Cardiology, 2001 (3)
- 48) Clinical Chemistry and Laboratory Medicine, 2010 to present (2)
- 49) Clinical Exercise Physiology, 2000-2002 (4)
- 50) Clinical Journal of the American Society of Nephrology 2008 to present (3)
- 51) Clinical Kidney Journal, 2012 to present (1)
- 52) Clinical Medicine and Research, 2008 to present (1)
- 53) Clinical Nephrology, 2008 to present (2)
- 54) Clinical Physiology and Functional Imaging, 2010 to present (1)
- 55) Clinical Researcher, 2002 to present (1)
- 56) Clinics, 2010 to present (1)
- 57) Cochrane Collaboration, 2009 to present (2)
- 58) Congestive Heart Failure, 2005 to present (4)

- 59) Coronary Artery Disease, 2005 to present (1)
- 60) Critical Care Medicine, 2008 to present (2)
- 61) Current Medical Research and Opinion, 2005 to present (1)
- 62) Diabetes Care, 2011 to present (2)
- 63) Diabetes and Vascular Disease Research, 2011 to present (1)
- 64) Diabetes, Obesity, and Metabolism, 2019 to present (1)
- 65) Diabetic Medicine, 2008 to present (1)
- 66) Drug Benefit Trends, 1999 (1)
- 67) Drugs, 2000 (2)
- 68) European Heart Journal, 1995 (12)
- 69) European Journal of Cardiovascular Prevention and Rehabilitation, 2006 (1)
- 70) European Journal of Heart Failure, 2012 (4)
- 71) Expert Opinion on Pharmacotherapy, 2003 to present (3)
- 72) Expert Opinion Therapeutic Patents, 2004 to present (1)
- 73) Expert Review of Cardiovascular Therapy, 2008 to present (2)
- 74) Global Heart, 2012 (1)
- 75) Heart, 2004 (2)
- 76) Heart and Vessels, 2007 (2)
- 77) Hemodialysis International 2013 (2)
- 78) Internal Medicine Journal (Australasia), 2009 to present (1)
- 79) International Journal of Infectious Diseases 2020 to present (2)
- 80) International Journal of Nephrology, 2010 to present (2)
- 81) Journal of Biomarkers, 2013 (1)
- 82) Journal of Geriatric Cardiology, 2017 (1)
- 83) International Journal of Infectious Diseases, 2021 to present (3)
- 84) Journal of Internal Medicine, 2009 to present (1)
- 85) Journal of Interventional Cardiology (JIC), 1996 to present (9)
- 86) Journal of the American College of Cardiology (JACC), 1998 to present (228)
- 87) Journal of the American College of Cardiology: Heart Failure (JACC Heart Fail), 2014 to present (12)
- 88) Journal of the American College of Cardiology: Imaging (JACC Imag), 2014 to present (6)
- 89) Journal of the American College of Cardiology: Interventions (JACC Interv), 2010 to present (10)
- 90) Journal of the American Medical Association (JAMA), 2002 to present (60)
- 91) Journal of the American Medical Association Cardiology (JAMA Cardiology), 2016 to present (20)
- 92) Journal of the American Society of Echocardiography (JASE), 2009 to present (1)
- 93) Journal of the American Society of Nephrology (JASN) 2005 to present (14)
- 94) Journal of Cardiac Failure, 2003 to present (10)
- 95) Journal of Clinical Outcomes Management, 2011 to present (1)
- 96) Journal of Critical Care, 2011, to present (1)
- 97) Journal of General Internal Medicine, 2008 to present (1)
- 98) Journal of Human Hypertension, 2010 to present (1)

99) Journal of Inherited Metabolic Disease, 2014 to present (2) 100) Journal of Lipid Research, 2010 to present (1) 101) Journal of Managed Care, 2004 to present (1) 102) Journal of Physiology and Pathophysiology, 2009 to present (1) 103) Kidney and High Blood Pressure Research, 2008 to present (1) 104) Kidney International, 2004 to present (8) 105) Medical Science Monitor, 2008 to present (1) 106) Medicine & Science in Sports and Exercise, 2005 to present (3) Nature Clinical Practice Cardiovascular Medicine, 2004 to present (4) 107) Nature Clinical Practice Nephrology, 2008 to present (1) 108) 109) Nature Reviews Nephrology, 2009 to present (3) Nephron, 2005 to present (1) 110) 111) Nephrology, 2009 to present (1) Nephrology, Dialysis, and Transplantation, 2005 to present (7) 112) New England Journal of Medicine, 2006 to present (8) 113) 114) Pharmacological Research (Italy), 1999 (1) 115) Pharmaceutical Sciences, 2011 (1) 116) PLoS Medicine, 2005 (1) 117) PLOS ONE, 2013 (1) Prehospital Emergency Care, 2015 (1) 118) Preventive Medicine, 2008 (1) 119) 120) Rejuvenation Research, 2007 (1) Renal Failure, 2011 (2) 121) The Lancet, 1999 to present (11) 122) 123) The Lancet Diabetes, 2013 to present (5) 124) The Lancet Global Health, 2015 to present (2)

## **Major Meeting Abstract Grader**

- 1) ACC Scientific Sessions 2001 to present (10)
- 2) ACC I2 Summit, 2006 to present (2)
- 3) American Diabetes Association, 2008 to present (13)
- 4) AHA Scientific Sessions, 1997 to present (8)
- 5) American Medical Informatics Association, Annual Symposium, 1998-2001 (3)
- 6) International Academy of Cardiology World Congress on Heart Disease, Academy of Cardiology Annual Scientific Sessions—Mechanisms and Management, 2002-present (3)
- 7) Transcatheter Therapeutics (TCT), 2004 (1)

#### **Grant Reviewer**

- 1. National Medical Research Council, Singapore, 2003-2004
- 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Panel/Initial Review Group 2006/01 ZDK1 GRB-9, 2005

- 3. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Review Group, 1 R01 DK070033-01A2, 2006
- 4. National Institutes of Health, National Heart Lung and Blood Institute, Study Section, ZHL1 CSR-H (M1), March 6-7, 2006, Heart Failure Network
- 5. Diabetes UK, The British Diabetic Association, Macleod House, 10 Parkway, London NW1 7AA. December 24, 2008
- 6. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, Chronic Renal Insufficiency Cohort Study (CRIC) and A Prospective Cohort Study of Kidney Disease in Children (CKiD) Study, February 23-25, 2012, March 6, 2013
- 7. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, ZDK1 GRB-7 (O3)S in response to PAR-DK-09-247: Ancillary Studies to Major Ongoing Clinical Research Studies to Advance Areas of Scientific Interest within the Mission of the NIDDK (R01), July 11, 2012
- 8. Alberta Innovates Health Solutions Collaborative Research & Innovation Opportunities (CRIO) Grant Review, September, 2012
- 9. Health Research Board of Ireland, Health Research Awards, 2013
- 10. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases 2017/01 ZRG1 DKUS-R (55) Study Section 2016

## **Guidelines Reviewer**

- 1. Kidney Disease Improving Global Outcome (KDIGO) Guidelines Review
  - a. Prevention, Diagnosis, Evaluation and Treatment of Hepatitis C in Chronic Kidney Disease, Published April, 2008
  - b. Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease related Mineral and Bone Disorders (CKD-MBD), Published August, 2009
  - c. Acute Kidney Injury (AKI), published March, 2012

#### CLINICAL TRIAL AND STUDY RESPONSIBILITIES

# **Overall Study Responsibilities: Steering and Executive Committees**

- 1) <u>Study Principal Investigator</u>, <u>Medicine vs Angiography for Thrombolytic Exclusion Patients</u> (M.A.T.E.), 1994-1997, (multicenter, U.S., randomized controlled trial [RCT]). Status: closed.
- 2) <u>Study Principal Investigator</u>, The <u>Re</u>source Utilization <u>A</u>mong <u>C</u>ongestive <u>H</u>eart <u>F</u>ailure Study (R.E.A.C.H.), 1998-2000, (single-center, prospective cohort study). Status: closed.
- 3) <u>Study Principal Investigator</u>, The <u>Asthma</u>, <u>Beta-Agonists</u>, and <u>Congestive Heart Failure Study</u>, (A.B.C.H.F.), 1998-1999, (single-center, case-control study). Status: closed.

- 4) <u>Study Co-Principal Investigator</u>, The <u>Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation (P.R.I.N.C.E.) Study, 1995-1998, (single-center, RCT). Status: closed.</u>
- 5) <u>Study Co-Principal Investigator</u>, BNP Multinational Study, Principal Investigator, Alan Maisel, MD, Biosite Diagnostics, Inc., 2000-2006, (multicenter, international, prospective cohort study). Status: closed.
- 6) <u>Study Co-Investigator</u>, <u>Prophylactic Oral Amiodarone Compared to Placebo for Prevention of Atrial Fibrillation Following Coronary Artery Bypass Graft Surgery (P.A.P.A.C.A.B.G.), 1996-1998, (single-center, RCT). Status: closed.</u>
- 7) <u>Study Co-Investigator</u>, Rapid Early Bedside Markers of Myocardial Injury, 1998-1999, HFHS and Biosite Diagnostics, Inc. (prospective cohort study). Status: closed.
- 8) Member, Steering Committee, Clinical Study Protocol No. 2000-025: A Phase IIIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety, Efficacy, and Tolerability of Fenoldopam Mesylate in Subjects Undergoing Interventional Cardiology Procedures (CONTRAST), William W. O'Neill, MD and Gregg Stone, MD, Co-Principal Investigators, Abbott Laboratories, Inc., 2000-2003 (multicenter, US, RCT). Status: closed.
- 9) <u>Chair, National Steering Committee</u>, Kidney Early Evaluation Program (KEEP) NKF, Member 2000-2005, Co-Chair 2005-2010, Chair 2010-present (multicenter, U.S., prospective cohort study). Annual budget ~ 1,325,198 (2009), ~ 1,233,832 (2010), ~ 1,614,953.00 (2011), ~ 989,500 (2012), ~ 1,217,000 (2013). Status: inactive.
- 10) Member, Steering Committee, Protocol No. 704.351 Evaluation of Synergy between Natrecor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003-2005 (multicenter, U.S., randomized cross-over trial). Status: closed.
- 11) Member, Steering Committee, Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Pharmaceuticals, Inc., 2003-2006. Status: closed.
- 12) <u>Rotating Executive Committee Principal Investigator Member</u>, NIH HF-ACTION Trial (Exercise Training Program to Improve Clinical Outcomes in Individuals With Congestive Heart Failure), HL63747 01A2, 2006-2009. Principal Investigator, David Whellan, MD, status: closed.

- 13) <u>Overall Study Principal Investigator</u>, Neutrophil Gelatinase-Associated Lipocalin: A Novel Blood Marker for Risk of Developing Contrast Induced Nephropathy (ENCINO), multicenter, prospective, blinded cohort study, 2006-2009, status: closed.
- 14) <u>Member, Steering Committee</u>, VA NEPHRON-D: Diabetes iN Nephropathy Study, 2008 to 2013, trial stopped early for safety cardiovascular and acute kidney safety concerns in angiotensin converting enzyme inhibitor plus losartan arm, status: closed.
- 15) <u>Member, External Expert Panel</u>, National Institutes of Health, National Institute of Digestive and Diabetes and Kidney Diseases, Chronic Renal Insufficiency Cohort Study, status open, 2010 to present.
- 16) Member, Optimal Medical Management Subcommittee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA), status: open, 2011 to present.
- 17) Member, Steering Committee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) in patients with Chronic Kidney Disease (ISCHEMIA-CKD), status: open, 2012 to present.
- 18) Member, Steering Committee, Thrasos Innovation, Inc, A Phase II Multi-Center, Parallel-Group, Randomized, Double Blind, Proof-of-Concept, Adaptive Study Investigating the Safety and Efficacy of THR-184 Administered via Intravenous Infusion in Patients at Increased Risk of Developing Cardiac Surgery Associated-Acute Kidney Injury (CSA-AKI), status: closed, 2012 to 2015.
- 19) Overall Principal Investigator, AbbVie, Inc, Clinical Study Protocol M13-796, A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Cardiac Surgery, status: closed, 2013 to 2014.
- 20) Overall Principal Investigator, Bioporto, Inc, The NGAL Test™ As An Aid in the risk assessment for AKI stage II and III in an Intensive Care Population, status: open 2017 to present.
- 21) <u>Member, Global Expert Panel</u>, Novo Nordisk, Inc, A Research Study to See How Semaglutide Works Compared to Placebo in People With Type 2 Diabetes and Chronic Kidney Disease (FLOW), status: open.

**Overall Study Responsibilities: Endpoint Committees** 

- Member, Critical Endpoints Committee, Treat Angina with Aggrastat and Determine Cost of Therapy with an Invasive or Conservative Strategy, TACTICS-TIMI 18 (Protocol 019-00), 1998-2000, (multicenter, international, RCT). Status: closed
- 2) <u>Member, Study Endpoints Committee</u>, A Phase II, Escalation Trial of Vasoflux<sup>™</sup> in Patients Undergoing Thrombolysis with Streptokinase for Acute Myocardial Infarction, Protocol CLN-P-V18-07001, Parexel International Corporation,1998, (multicenter, international, RCT). Status: closed
- 3) Member, Safety Endpoint Evaluation Committee, A Phase III, Single-Blind Controlled Study to Evaluate the Clinical Effects of a Hemoglobin-based Oxygen Carrier (HBOC-210) Given as a Transfusion Alternative in Patients Undergoing Orthopedic Surgery. (Protocol HEM-0115), Biopure Corporation with Quintiles, Inc., Clinical Event and Adjudication Services, 2000-2001. (multicenter, international, RCT). Status: closed
- 4) <u>Member, Critical Endpoints Committee</u>, Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (multicenter, international, RCT). Status: study terminated early due to drug withdrawal from market
- 5) <u>Member, Clinical Events Classification Committee</u>, Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR), Ajay Singh, MD, Donal Reddan, MBBS, Principal Investigators, Ortho Biotech Inc., 2001-2004 (multicenter, international, RCT). Status: closed
- 6) Member, Critical Endpoint Committee, A Randomised, Double-blind, Parallel Group, Phase 3, Efficacy and Safety Study of AZD6140 (Ticagrelor) Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST Elevation Acute Coronary Syndromes (ACS) [PLATO A Study of PLATelet inhibition and Patient Outcomes.], AstraZeneca, Inc., Duke Clinical Research Institute, 2008, status: closed
- Chair, Clinical Endpoints Committee, Alere San Diego, Inc, Alere Prospective Blinded Study of a Novel Troponin Assay (PEARL), status: closed 2015
- 8) <u>Chair, Adjudication Committee</u>, Myeloperoxidase In the Diagnosis of Acute coronary Syndromes (MIDAS) study, Alere, Inc., status: closed 2012
- 9) <u>Independent Endpoint Adjudicator</u>, BioPorto Diagnostics, The NGAL test as an aid for the Diagnosis of AKI in an Intensive Care Population, Code of the Study: KLIN 12-005, status closed, 2015
- 10) Independent Endpoint Adjudicator, Ischemix, Inc., Safety and Efficacy of CMX-2043 for Protection of the Heart and Kidneys in Subjects Undergoing Coronary Angiography (CARIN), status: closed 2016

11) <u>Chair, Data Adjudication Committee</u>, Estimating versus Measuring Plasma Volume and Kidney Function in Acute Decompensated Congestive Heart Failure, Eudra-CT Number 2018-002638-18, Sponsor: Charite-Universitatsmedizin Berlin, FAST Biomedical, Inc., 2018-present

## Overall Study Responsibilities: Data Safety Monitoring Committees

- Member, External Advisory Committee/Data Safety Monitoring Board, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Polycystic Kidney Disease (PKD) Clinical Trials Network HALT-PKD Trial, Robert Schrier, MD, Principal Investigator, Committee Chair: William Henrich, MD, 2004-2008, Data Safety Monitoring Board, status: closed 2014
- 2) Chairman, Data Safety Monitoring Committee, Clinical Trials Program CS0011-A-U301, Daiichi Sankyo Pharma Development (DSPD) CS-011, Seven Core Trials of Rivoglitazone in Type 2 Diabetes: 1) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U301); 2) A 26-week placebo-controlled trial of 0.5, 1.0 and 1.5 mg rivoglitazone vs. 15, 30 and 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U302); 3) A 26-week placebocontrolled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, in type 2 diabetics on metformin therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U303); 4) A 26-week placebo-controlled trial of 0.5 and 1.0 rivoglitazone vs. 30 mg pioglitazone, in type 2 diabetics on sulfonylureas therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U304); 5) A 26-week placebocontrolled trial of 0.5 and 1.0 mg rivoglitazone vs. 15 mg pioglitazone in type 2 diabetics on insulin therapy (CS0011-A-U305); 6) A long-term (12-24 months) randomized, general efficacy and safety study of rivoglitazone vs. pioglitazone, as monotherapy or add-on therapy, in type 2 diabetics (CS0011-A-U306); 7) A 26-week placebo-controlled trial of rivoglitazone and metformin, in type 2 diabetics (CS0011-A-U307), USFDA Special Protocol Assessment Agreement granted, status: closed, 2009 trials program terminated
- 3) Member, Data Safety Monitoring Committee, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment with Alogliptin in Addition to Standard of Care in Subjects with Type 2 Diabetes and Acute Coronary Syndrome SYR322\_402, EXAMINE Trial Takeda Global Research and Development Center, Inc. (US) Takeda Global Research and Development Centre, Ltd. (Europe), status: 2009 trial stopped early for non-inferiority but futility on superiority outcome
- 4) Chair, Data Safety Monitoring Committee, Protocol D9120C00019, A randomised, double-blind, placebo controlled, multi-centre phase IIb dose finding study to assess the effect on GERD symptoms, safety and tolerability during four weeks treatment with AZD3355 in doses 60 mg, 120 mg, 180 mg and 240 mg bid as add-on treatment to a PPI in patients with GERD that are partial responders to PPI treatment, AstraZeneca, status: closed 2009, trials program terminated for safety

- 5) Member, Data Safety Monitoring Committee, Protocols: AMAG-FER-IDA-301, A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Ferumoxytol for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-302, A Phase III, Randomized, Open-Label, Active Controlled Trial Comparing Ferumoxytol with Iron Sucrose for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-303, A Phase III, Open-Label Extension, Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of Iron Deficiency Anemia, AMAG Pharmaceuticals, Inc., status: closed 2010, trial completed in 2013 without safety concerns
- 6) <u>Chair, Independent Data Monitoring Committee</u>, Protocol 402-C-0903 Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease and Type 2 Diabetes: the Occurrence of Renal Events (BEACON), Reata Pharmaceuticals, Inc., status: trial stopped in 2012 early for cardiovascular and mortality safety concerns
- 7) Member, Independent Safety Council, Affymax Inc and Takeda Pharmaceutical Co., Omontys (peginesatide), status: closed, post-marketing surveillance led to voluntary drug withdrawal from market in 2013 for serious and fatal allergic reactions
- 8) <u>Chair, Independent Data Monitoring Committee</u>, AbbVie, Inc, Clinical Study Protocol M11-352 A Randomized, Multicountry, Multicenter, Double Blind, Parallel, Placebo-Controlled Study of the Effects of Atrasentan on Renal Outcomes in Subjects with Type 2 Diabetes and Nephropathy SONAR: Study Of Diabetic Nephropathy with Atrasentan, status closed 2018
- 9) <u>Chair, Independent Data Monitoring Committee</u>, AbbVie, Inc., Clinical Study Protocol M13-958 A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Major Surgery, status: closed 2015
- 10) Member, Data Monitoring Committee, Akebia Therapeutics, Inc., AKB-6548-CI-0007, Phase 2b Randomized, Double-Blind, Placebo-Controlled Study to Assess the Pharmacodynamic Response, Safety, and Tolerability to 20 Weeks of Oral Dosing of AKB-6548 in Subjects with Anemia Secondary to Chronic Kidney Disease (CKD), GFR Categories G3a-G5 (Stages 3, 4, and 5) (Pre-Dialysis), status: closed 2015
- 11) Member, Study Monitoring Team, Akebia Therapeutics, Inc., AKB-6548-CI-0011, Phase 2a Open-Label Study to Assess the Efficacy, Safety, and Tolerability of AKB-6548 in Subjects with Anemia Secondary to End Stage Renal Disease (ESRD), Undergoing Chronic Hemodialysis, status: closed 2016
- 12) Member, Data Monitoring Committee, Merck, Inc., Pfizer, Inc, Clinical Trials Program, Ertugliflozin (MK-8835/PF-04971729) Phase 2 and Phase 3 Development Program, status closed, 2012 to 2020

- 13) Member, Steering Committee, Medtronic, Inc., Monitoring in Dialysis, status: closed 2016
- 14) <u>Member, Data Safety and Monitoring Board</u>, St. Jude Medical, EnligHTN IV Multi-center, randomized, single-blind, sham controlled clinical investigation of renal denervation for uncontrolled hypertension, status: 2013 trial terminated before recruitment started
- 15) <u>Chair, Data Safety Monitoring Board</u>, Neumedicines, Inc., A Phase 2, Single-Dose, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HemaMax™ (rHulL-12) in Healthy Subjects, status: closed 2016
- 16) <u>Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc.</u>, A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Friedreich's Ataxia, 2014 to 2019, status: closed
- 17) <u>Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc.</u>, A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Mitochondrial Myopathy, 2015 to 2019, status: closed
- 18) Member, Patient Safety Review Committee, Reata Pharmaceuticals, Inc, A dose-ranging study of the efficacy and safety of Bardoxolone Methyl in patients with pulmonary arterial hypertension (402-C-1302), 2014 to 2018, status: closed
- 19) <u>Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc.</u>, A Study of the Efficacy and Safety of Bardoxolone Methyl in Patients with Connective Tissue Disease-Associated Pulmonary Arterial Hypertension (CATALYST), 2016 to present, status: closed
- 20) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2/3 of Efficacy and Safety of Bardoxolone Methyl in Patients with Alport Syndrome (CARDINAL), 2017 to present, status: closed
- 21) Chair, Data Safety Monitoring Board, Sanfit, Inc., A double-blind, randomised, placebo-controlled study to assess the effect of SNF472 on progression of cardiovascular calcification on top of standard of care in end-stage-renal-disease (ESRD) patients on haemodialysis (HD) SNFCT2015-05, 2017 to 2019, status: closed
- 22) <u>Chair, Data Monitoring Committee, Renew Research, KAI Research</u>, A Randomized Pivotal Study of RenewTM NCP-5 for the Treatment of Mild Cognitive Impairment due to Alzheimer's Disease or Mild Dementia of the Alzheimer's Type, 2018 to present, status: closed
- 23) <u>Chair, Data Safety Monitoring Committee, Sanofi, Inc.</u>, Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal