UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, United States Navy, NAVY SEAL 2, United States Navy, EOD OFFICER, United States Navy, SENIOR CHIEF PETTY OFFICER, United States Navy, CHAPLAIN, United States Navy, LIEUTENANT COLONEL 1, United States Marine Corps, LIEUTENANT COLONEL 2, United States Marine Corps, MAJOR, United States Marine Corps, SECOND LIEUTENANT, United States Marine Corps, CAPTAIN, United States Marine Corps, ARMY RANGER, United States Army, LANCE CORPORAL 1, United States Marine Corps, LANCE CORPORAL 2, United States Marine Corps, MAJOR, United States Air Force, NATIONAL GUARDSMAN, Virginia Army National Guard, COAST GUARD LIEUTENANT, United States Coast Guard, COLONEL, United States Army, TECHNICAL SERGEANT, United States Air Force, DEFENSE DEPARTMENT CONTRACTOR, United States Department of Defense, FEDERAL CIVILIAN ENGINEER CONTRACTOR, FEDERAL CIVILIAN CONTRACTOR EMPLOYER, FEDERAL NUCLEAR CONTRACTOR EMPLOYEE, DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH, for themselves and all others similarly situated, Plaintiffs, v. JOSEPH R. BIDEN, in his official capacity as President of the United States, LLOYD AUSTIN, in his official capacity as Secretary of the United States Department of Defense, and ALEJANDRO MAYORKAS, in his official capacity as Secretary of the Department of Homeland Security, Defendants.	Case No. _____

VERIFIED CLASS ACTION COMPLAINT FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF AND DECLARATORY RELIEF

"Our citizens in uniform may not be stripped of basic rights simply because they doffed their civilian clothes."[1]

For their VERIFIED CLASS ACTION COMPLAINT against Defendants, JOSEPH R. BIDEN, in his official capacity as President of the United States, LLOYD AUSTIN, in his official capacity as Secretary of the United States Department of Defense, and ALEJANDRO MAYORKAS, in his official capacity as Secretary of the Department of Homeland Security, Plaintiffs, NAVY SEAL 1, United States Navy, NAVY SEAL 2, United States Navy, NAVY EOD OFFICER, United States Navy, CHIEF PETTY OFFICER, United States Navy, CHAPLAIN, United States Navy, LIEUTENANT COLONEL 1, United States Marine Corps, LIEUTENANT COLONEL 2, United States Marine Corps, SECOND LIEUTENANT, United States Marine Corps, MAJOR, United States Marine Corps, CAPTAIN, United States Marine Corps, ARMY RANGER, United States Army, LANCE CORPORAL 1, United States Marine Corps, LANCE CORPORAL 2, United States Marine Corps, MAJOR, UNITED STATES AIR FORCE, NATIONAL GUARDSMAN, Virginia Army National Guard, LIEUTENANT, United States Coast Guard, COLONEL, United States Army, TECHNICAL SERGEANT, United States Air Force, DEFENSE DEPARTMENT CONTRACTOR, United States Department of

[1] *Chappell v. Wallace*, 462 U.S. 296, 304 (1983) (citing E. Warren, *The Bill of Rights and the Military*, 37 N.Y.U. L. Rev. 181, 188 (1962)).

Defense, FEDERAL CIVILIAN ENGINEER CONTRACTOR, FEDERAL CIVILIAN CONTRACTOR EMPLOYER, FEDERAL NUCLEAR CONTRACTOR EMPLOYEE, DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH, for themselves and all others similarly situated, (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, allege and aver as follows:

URGENCIES JUSTIFYING EMERGENCY RELIEF

"The Executive Order mandating vaccinations for all federal employees has provided clear direction. . . . Frankly, if you are not vaccinated, you will not work for the U.S. Navy."[2]

1. Plaintiffs are United States Armed Forces servicemembers, federal employees, and federal civilian contractors who face a deadline under the Federal COVID-19 Vaccine Mandate to receive a COVID-19 vaccine that violates their sincerely held religious beliefs, and have been refused any religious exemption or accommodation. United States Navy and United States Marine Corps servicemembers have until November 28 to become fully vaccinated. United States Army and United States Air Force servicemembers have until December 15. United States Coast Guard servicemembers have until November 22. And civilian federal employees and contractors have until November 22. **These are the terminal dates after which**

[2] Vice Admiral William Galinis, Commander, Naval Sea Systems Command (NAVSEA), *ALL HANDS NOTE (10/14/2021) COMNAVSEA Vaccination Message* (Oct. 14, 2021) (warning entire command, comprising more than 85,000 civilian and military personnel).

discipline will unquestionably be imposed, but the effective due date for the one-dose Johnson and Johnson (J&J) shot is earlier, and earlier still for the first of two Pfizer or Moderna shots. Missing the earlier due dates will necessarily result in discipline at the terminal dates. Moreover, the pressure and abuse are intense, and disciplinary actions have already commenced for some. Relief is needed now to prevent these military heroes, federal employees, and federal contractors from facing punishments including dishonorable discharge, court martial, other life-altering disciplinary procedures, and termination.

2. "Greater love hath no man than this, that a man lay down his life for his friends." *John* 15:13 (KJV). Servicemember Plaintiffs have all agreed, voluntarily and sacrificially, to devote their entire lives by this axiomatic truth, regardless of the cost to them personally or to their families who likewise sacrifice in defense of this Nation. They all have sworn an oath to protect and defend the Constitution of the United States, to sacrificially lay down their lives for their fellow citizens against enemies both foreign and domestic, and to preserve for our progeny the heritage and treasure passed down to them by Veterans of old. And, for that ultimate sacrifice in defense of the Constitution and our freedoms, **Defendants are threatening these military heroes with dishonorable discharge for even requesting a religious exemption from the COVID-19 shots. Dishonorable discharge is worse than criminal conviction for these servicemembers because it is a badge of disgrace that follows them for the rest of their lives**. *Having sacrificed everything to defend America and its citizenry—and while*

carrying the images and sounds of war with them throughout their lives—America, the "land of the free and the home of the brave," would betray them with the worst punishment of dishonorable discharge. And for what cause? Simply because they seek an accommodation from the COVID-19 shots on account of their sincerely held religious beliefs.

3. **The deadlines for servicemember Plaintiffs to receive the COVID-19 shots are fast approaching in October and November**. *No servicemembers should be forced to choose between dishonorable discharge by the Nation they love or sinning against God by violating their sincere religious beliefs (which, by the way, can be easily accommodated)*. **This Court must protect the rights of these military heroes and remove from the Republic the stain of government coercion of conscience**.

4. As the Supreme Court has long affirmed, **the heroes of the United States Armed Forces do not shed their constitutional rights at the moment of their sacrificial oath**. Indeed, "[t]his Court has never held, nor do we now hold, that military personnel are barred from all redress in civilian courts for constitutional wrongs suffered in the course of military service." *Chappell v. Wallace*, 462 U.S. 296, 304 (1983).

5. Moreover, while servicemembers certainly have duties and responsibilities "without counterpart in civilian life," *Schlesinger v. Councilman*, 420 U.S. 738, 757 (1975), **the Constitution still provides them with the same blanket of constitutional protection that their dedicated service and sacrifice provide to the average civilian**. For to turn the same Constitution that United States Armed Forces

members protect and defend into a weapon against them would be a travesty unknown to the Nation's founding charter and eclipse any dereliction of duty heretofore seen in the great experiment of America. Indeed, as Justice Brennan noted,

> Military (or national) security is a weighty interest, not least of all because national survival is an indispensable condition of national liberties. But the concept of military necessity is seductively broad, and has a dangerous plasticity. **Because they invariably have the visage of overriding importance, there is always a temptation to invoke security "necessities" to justify an encroachment upon civil liberties. For that reason, the military-security argument must be approached with a healthy skepticism: its very gravity counsels that courts be cautious when military necessity is invoked by the Government to justify a trespass on First Amendment rights.**

Brown v. Glines, 444 U.S. 348, 369 (1980) (Brennan, J., dissenting) (emphasis added) (citation omitted).

6. As he continued,

> To be sure, generals and admirals, not federal judges, are expert about military needs. **But it is equally true that judges, not military officers, possess the competence and authority to interpret and apply the First Amendment.** Moreover, in the context of this case, the expertise of military officials is, to a great degree, tainted by the natural self-interest that inevitably influences their exercise of the power to control expression. Partiality must be expected when government authorities censor the views of subordinates, especially if those views are critical of the censors. **Larger, but vaguely defined, interests in discipline or military efficiency may all too easily become identified with officials' personal or bureaucratic preferences. This Court abdicates its responsibility to safeguard free expression when it reflexively bows before the shibboleth of military necessity.**

Id. at 370.

7. Servicemembers who protect the constitutional freedoms cherished in this Nation can also invoke those same constitutional protections for breaches of their own liberties, despite military service. Here, Defendants have made it clear that they think servicemember Plaintiffs' sacrificial act of swearing an oath to protect the Nation and support and defend the Constitution is accompanied by the sacrificial surrender of those same constitutional protections they defend. The Constitution opposes such callous indifference to sacrificial service, and so, too, should this Court. Indeed, "military life do[es] not, of course, render entirely nugatory in the military context the guarantees of the First Amendment." *Goldman v. Weinberger*, 475 U.S. 503, 507 (1986). *See also Crawford v. Cushman*, 531 F.2d 1114, 1120 (2d Cir. 1976) (**"[T]he military is subject to the Bill of Rights and its constitutional implications**." (emphasis added)). Put simply, "although First Amendment rights . . . may be 'less' for a soldier than a civilian, they are by no means lost to him." *Anderson v. Laird*, 466 F.2d 283, 295 (D.C. Cir. 1972). "**Individual freedom may not be sacrificed to military interests to the point that constitutional rights are abolished**." *Id.* (emphasis added).

8. Servicemember Plaintiffs and all those dedicated members of the United States Armed Forces voluntarily and sacrificially answered their Nation's call to defend the freedoms we enjoy. Yet, Defendants are demanding that these brave military members sacrifice their constitutional rights which they risk their lives to defend. Indeed, "**[i]t is a basic tenet of our legal system that a government agency is**

not at liberty to ignore its own laws and that agency action in contravention of applicable statutes and regulations is unlawful. The military departments enjoy no immunity from this proscription." *Dilley v. Alexander*, 603 F.2d 914, 920 (D.C. Cir. 1979) (emphasis added) (citation omitted). For without question, when critical constitutional rights are at issue, "the Supreme Court [has] heard numerous constitutional challenges to military policies." *Singh v. Carter*, 168 F. Supp. 3d 216, 225 (D.D.C. 2016) (cleaned up).

9. As the Supreme Court held just last year, "**even in a pandemic, the Constitution cannot be put away and forgotten**." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 68 (2021) (emphasis added). When we have demanded so much of our Soldiers, Sailors, Airmen, and Marines, we owe them nothing less than the full measure of our own devotion and commitment to constitutional principles. Anything less would be desecrating the sacrifices these heroes have made for untold numbers of people when the call of duty demanded it, and would trample upon the graves of so many who made the ultimate sacrifice before them.

10. When the great American experiment was commenced, our Founders ordained and established the Constitution—including all of the rights it recognized and enshrined—"in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defence, promote the general Welfare, and **secure the Blessings of Liberty to ourselves and our Posterity**." U.S. Const. Pmbl. (emphasis added). To this very day, "we continue to strive toward '[that] more

perfect union.'" *Smith v. City of New Smyrna Beach*, No. 6:11–cv–1110–Orl–37KRS, 2013 WL 5230659, at *1 (M.D. Fla. Sept. 16, 2013). That work is not easy, and sometimes it requires the intervention of the judiciary to set the guardrails for the protection of the Republic's liberties.

11. Recognizing that times of crisis would arise, that such times might lead governments to seek to repress precious freedoms, and that the Republic's survival depended upon defeating such repressive instincts, the genius of our founding document is that it placed explicit protections into the text of the Bill of Rights. And, importantly, "[o]ur Bill of Rights placed our survival on firmer ground—that of freedom, not repression." *Konigsberg v. State Bar of California*, 366 U.S. 36, 79 (1961) (Black, J., dissenting).

12. During times of national crisis, the very times when we call upon the United States Armed Forces heroes most, "the fog of public excitement obscures the ancient landmarks set up in our Bill of Rights." *American Communist Ass'n, C.I.O. v. Douds*, 339 U.S. 382, 453 (1950) (Black, J., dissenting). But, where the fog of public excitement is at its apex, "the more imperative is the need to preserve inviolate the constitutional rights of [the First Amendment]." *De Jonge v. Oregon*, 299 U.S. 353, 365 (1937). Without doubt, "[t]herein lies the security of the Republic, the very foundation of constitutional government." *Id.*

13. Indeed, "[t]imes of crisis take the truest measure of our commitment to constitutional values. **Constitutional values are only as strong as our willingness to**

reaffirm them when they seem most costly to bear." *Hartness v. Bush*, 919 F.2d 170, 181 (D.C. Cir. 1990) (Edwards, J., dissenting) (emphasis added). Our willingness to reaffirm our staunch commitment to our fundamental freedoms is imperative to the very survival of the American experiment. **Servicemember Plaintiffs have demonstrated their staunch commitment, and it is time that we honor ours.** "History reveals that the initial steps in the erosion of individual rights are usually excused on the basis of an 'emergency' or threat to the public. **But the ultimate strength of our constitutional guarantees lies in the unhesitating application in times of crisis and tranquility alike**." *United States v. Bell*, 464 F.2d 667, 676 (2d Cir. 1972) (Mansfield, J., concurring) (emphasis added). For, "**[i]f the provisions of the Constitution be not upheld when they pinch as well as when they comfort, they may as well be discarded**." *Home Bldg. & Loan Ass'n v. Blaisdell*, 290 U.S. 398, 483 (1934) (Sutherland, J., dissenting) (emphasis added).

14. Plaintiffs have demonstrated their commitments to the United States Constitution and the Nation's future comfort, security, and prosperity. **This Court should demand that the Nation return the favor**. Telling Plaintiffs they must accept or receive a shot they oppose according to their sincerely held religious beliefs, or face court martial, dishonorable discharge, and other life altering disciplinary measures, disgraces the sacrifices these heroes have made.

15. Defendants' vaccine mandate, ostensibly responding to a public health crisis, has created a national emergency of much greater magnitude. The mandate

attacks the military from *within* by removing brave servicemembers from defending the Nation by land, air, and sea, and from *without* by eliminating the dedicated civilian defense contractors and employees providing everything from boots and uniforms, to cyber security, to the world's most advanced stealth fighter jet—the F-35 Raptor—solely because these protectors of our constitutional freedoms requested accommodation of their sincerely held religious beliefs under the same Constitution. The crisis created by Defendants' mandates, applied to two million federal employees, is unnecessary and completely avoidable, but nonetheless imminent and real.

16. A TRO is needed now to prevent the immediate and irreparable injury to Plaintiffs imposed by these unlawful COVID-19 mandates.

PARTIES

17. Plaintiff NAVY SEAL 1, United States Navy, is a citizen of the State of California currently stationed at a United States Naval facility in California. NAVY SEAL 1 has requested an exemption and accommodation of his sincerely held religious objections to the Secretary's mandate that all United States Armed Forces personnel accept and receive one of the COVID-19 vaccines as a condition of remaining in their sworn posts. NAVY SEAL 1's request for a religious exemption and accommodation was denied, and he was immediately removed from his position in the United States Navy. Special Operations Chief NAVY SEAL 1 enlisted in the Navy in 2009 and wanted to serve his country to the best of his ability. NAVY SEAL 1 sought to and became a Navy SEAL. He received training from 2009 starting and finishing BUD/S (Basic Underwater Demolition/SEAL) and SQT (SEAL

Qualification Training) with class 278. He deployed to Afghanistan from December 2011 to September 2012, and received a Navy and Marine Corps Commendation Medal with a combat "V" (valor) for his actions during deployment, along with a combat action ribbon. NAVY SEAL 1's second tour was to the Philippines in support of Operation Enduring Freedom, working under Joint Special Operations Task Force (JSOTF), and receiving an Army Commendation medal. For his third tour, which was outside of his usual deployment cycle and thus 100% voluntary, NAVY SEAL 1 volunteered to augment SEAL Team Seven during the height of the Mosul, Iraq clearance from February to April 2017. During NAVY SEAL 1's fourth tour, in Iraq from August 2017 to March 2018, NAVY SEAL 1 was the acting assault lead, putting him in charge of a platoon level force to execute the tactical direction of the platoon chief, and he earned a Navy and Marine Corps Achievement Medal and a Navy and Marine Corps Commendation Medal with a "C" (Combat). His most recent tour was to the United Arab Emirates (UAE) from March to September 2020. For his leadership setting up, organizing, and executing a large joint close air support (CAS) and combat search and rescue (CSAR) exercise, NAVY SEAL 1 received a Navy and Marine Corps Commendation Medal. This robust exercise included units from 5 different countries and over 15 assets. NAVY SEAL 1 also received awards for his time spent at training commands. His first tour was at TRADET-1 as the SOUC (Special Operations Urban Combat) Lead Petty Officer from December 2014 to June 2016. He received a Navy and Marine Corps Achievement Award for his efforts there. His second training command tour was as the Lead Chief Petty Officer of the Navy's only

Joint Close Air Support school. For his efforts in synchronizing joint assets and providing mission critical qualification training for creating Joint Terminal Attack Controllers (JTAC) he received a Navy and Marine Corps Commendation Award.

18. Plaintiff NAVY SEAL 2, United States Navy, is a citizen of the State of Texas and is stationed in the State of Florida. NAVY SEAL 2 has served his country honorably and sacrificially for 19 years. NAVY SEAL 2 submitted a request for a religious accommodation and exemption from the United States Navy. NAVY SEAL 2's request for a religious exemption and accommodation detailed NAVY SEAL 2's religious beliefs and practices that compel him to abstain receiving any of the currently available COVID-19 vaccines. NAVY SEAL 2's request for a religious accommodation was supported by a letter from a religious leader, which demonstrated the sincerity of NAVY SEAL 2's personal beliefs. NAVY SEAL 2's commander noted that NAVY SEAL 2's religious beliefs were sincere and strongly held, but recommended that his request be disapproved, citing readiness, despite NAVY SEAL 2's currently working in a non-deployable staff position. NAVY SEAL 2's request for an accommodation has been forwarded to the Chief of Naval Personnel who is responsible for making the final determination. NAVY SEAL 2 faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for merely requesting an accommodation for his sincerely held religious beliefs.

19. Plaintiff NAVY EXPLOSIVE ORDNANCE DISPOSAL OFFICER ("NAVY EOD OFFICER"), United States Navy, is a citizen of the State of Florida currently stationed at a United States Naval facility in the State of Hawaii. NAVY

EOD OFFICER has requested an exemption and accommodation of his sincerely held religious objections to the Secretary's mandate that all United States Armed Forces personnel accept and receive one of the COVID-19 vaccines as a condition of remaining in their sworn posts. After NAVY EOD OFFICER's request for a religious exemption and accommodation, he was immediately placed in a "Not Physically Qualified" ("NPQ") status. If his religious exemption and accommodation request is not granted, he will not be allowed to deploy in January, thus removing him from his position at that time. NAVY EOD OFFICER has admirably and honorably served in the United States Navy for over 19 years, initially becoming an enlisted Navy salvage diver, following which he became an officer specializing in Explosive Ordnance Disposal (EOD). NAVY EOD OFFICER submitted a request for a religious accommodation and exemption from the United States Navy. NAVY EOD OFFICER articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. NAVY EOD OFFICER's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for merely requesting an accommodation of his sincerely held religious beliefs.

20. NAVY SENIOR CHIEF PETTY OFFICER is a 17-year Active Duty Senior Chief Petty Officer stationed with the Marines. His career is marked with service primarily within Special Operations Units, with eight (8) deployments, high performance marks, and nine (9) personal awards. He holds a bachelors from George

Washington University in Clinical Health Sciences, and four (4) years of military medical, CBRN and advanced medical training with a focus on operational medicine in the deployed setting. NAVY SENIOR CHIEF PETTY OFFICER obtained his Sub-Investigator Certification in 2017 from the FDA, so he could conduct informed consent of EUA Freeze Dried Plasma (FDP) product, track its use and report back up the chain of command to the FDA. As part of this informed consent, NAVY SENIOR CHIEF PETTY OFFICER was required to conduct an hour long brief to all eligible personnel of the risks, benefits and right to refusal of the EUA product. The program placed heavy emphasis on the impropriety of coercive tactics to obtain "consent." Impeccable documentation was required, all personnel had to be afforded consent, all consents had to be legible, contain addresses, contain witnessed signatures, with formatting and dates matching. Audits were regularly conducted so any improper documentation that failed to meet this stringent standard was returned and required to be immediately resubmitted. In contrast, NAVY SENIOR CHIEF PETTY OFFICER's experience with COVID-19 vaccine has been completely the opposite, having observed coercion, public shaming, improper documentation, vaccine stacking and an overall cavalier attitude towards new technology that does not have any long term data. In Summer 2021, NAVY SENIOR CHIEF PETTY OFFICER was infected with SARS-CoV-2 and recovered within two weeks, and now has serological evidence of natural immunity that many experts believe to be consistent with or even superior to the COVID-19 vaccine, and which is recognized by Navy regulation as a basis for exemption from immunization. NAVY SENIOR CHIEF PETTY OFFICER has

submitted a religious exemption request to the COVID-19 vaccine, on the basis of the leading of the Holy Spirit, and his Christian religious beliefs, including beliefs that the body is the temple of the Holy Spirit, and the COVID-19 vaccine's close connection to abortion.

21. Plaintiff NAVY CHAPLAIN is a Chaplain in the United States Navy, with over 18 years' honorable service. NAVY CHAPLAIN has personally observed the effect the mandatory COVID vaccination orders have had on mental health and readiness of multiple Sailors, in the course of his recent deployment with a Carrier Strike Group.

22. Based on his own sincerely-held Christian religious beliefs, NAVY CHAPLAIN has submitted a religious exemption request for an accommodation from the COVID shot mandates. NAVY CHAPLAIN believes accepting any of the approved COVID vaccines would be an act of irreverence toward God and would be an attempt to alter the embodied image of God within individuals, and therefore a sin contrary to historic Judeo-Christian tradition and his Christian faith.

23. NAVY CHAPLAIN's commander has provided a negative recommendation for NAVY CHAPLAIN's religious accommodation request. If his request is not approved, NAVY CHAPLAIN fears being forced to choose between his career of service to fellow Sailors, which he loves, and his faith in God and God's commands.

24. Plaintiff, LIEUTENANT COLONEL 1, United States Marine Corps, is a citizen of the State of Texas currently stationed at a United States military facility in

the State of Arizona. LIEUTENANT COLONEL 1 has requested an exemption and accommodation for his sincerely held religious objections to the Secretary's mandate that all United States Military personnel accept and receive one of the COVID-19 vaccines as a condition of remaining in their sworn posts. LIEUTENANT COLONEL 1's request for a religious exemption and accommodation is processing and adjudication of his request is pending. LIEUTENANT COLONEL 1 is currently an officer and a pilot in the Marine Corps. He has more than 18 years' exemplary service in the Marine Corps and wishes to continue serving his country for many more. LIEUTENANT COLONEL 1's duties include service as a senior officer and pilot with his unit. LIEUTENANT COLONEL 1 has served the United States on five combat tours and deployments, including one combat deployment in support of Operation Iraqi Freedom (OIF) and two combat deployments in Operation Enduring Freedom (OEF – Afghanistan). LIEUTENANT COLONEL 1 has also served as a TopGun graduate, F/A-18 pilot and instructor, Forward Air Controller (ground-based position calling in air strikes in support of Marine infantry), and in many other billets. Close Air Support and Forward Air Control involves responsibility for dropping ordnance (bombs), firing rockets, and aerial gunnery on enemy targets in close proximity to Marine infantry. An error in judgment or calculation can result in the deaths of Americans and allies in who are in close proximity to the enemy. LIEUTENANT COLONEL 1's skill at both has saved countless American lives and has destroyed America's enemies. LIEUTENANT COLONEL 1, United States Marine Corps, submitted a request for a religious accommodation and exemption from the United

States Marine Corps. LIEUTENANT COLONEL 1 articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. LIEUTENANT COLONEL 1 met with his unit's Chaplain, who reviewed his request for a religious exemption and accommodation and who found that LIEUTENANT COLONEL 1's request was made from a position of "absolute sincerity." LIEUTENANT COLONEL 1's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for merely requesting an accommodation for his sincerely held religious beliefs.

25. Plaintiff LIEUTENANT COLONEL 2 is a FY 22 Command Selected Officer and native of Queens, NY. She enlisted in the Marine Corps in June of 1997 and served as an Administrative Clerk after completing the Unit Diary Clerks Course in the top ten percent of the class. She served in the reserves and volunteered for active duty following the attacks on September 11th. In 2003, LIEUTENANT COLONEL 2 wanted to be a role model for other women and completed Officer Candidate School where she received her commission as a Second Lieutenant in the Marine Corps. As a Company Grade Officer, she served in several leadership roles including duties as a Platoon Commander in garrison and during Operation Iraqi Freedom. She served as a Series Commander at Marine Corps Recruit Training, Parris Island and staff jobs at several O5 level commands. She also deployed as a staff officer in support of Operation Enduring Freedom (Afghanistan). As a Field Grade Officer, she was selected and

served as a Department of Defense Fellow and helped conduct research to integrate women into ground combat arms jobs. Later, she was selected for Command and Staff College where she earned her Master's Degree through the Advanced Studies Program As a field grade officer, she held billets as a Company Commander, Battalion Executive Officer, and Operations Officer She also served as her unit's Diversity and Inclusion Officer. LIEUTENANT COLONEL 2 is currently pending a second modification to her permanent change of station orders to NAVCENT, Bahrain because she submitted a religious accommodation package although she was administratively and medically cleared to execute her orders. LIEUTENANT COLONEL 2 has had an exemplary career. However, like many others, her faith journey has several blemishes that she does not typically discuss unless she is moved by the Holy Spirit to share personal aspects of her life story to help someone in need. One of the concerns that contributes to her decision not to receive the COVID 19 shot is because of her strong opposition to abortion and how God forgave and healed her from her own abortion. Specifically, in 1995, LIEUTENANT COLONEL 2 became pregnant after being raped. The anger and humiliation of the sexual assault led her to have an abortion which made her even more ashamed. In fact, after her abortion, LIEUTENANT COLONEL 2 felt like a murderer, and punished herself because she felt unworthy. This behavior only stopped after her husband caught her punishing herself, and helped her realize that God had truly forgiven her for the abortion. The COVID shot mandate, given the use of aborted fetal cell lines in testing and development, places LIEUTENANT COLONEL 2 in the position of reliving her

rape and subsequent abortion, by being forcibly injected with a product tested on or made with aborted fetal cells, or being dismissed from the service she loves.

26. Plaintiff MAJOR, United States Marine Corps ("USMC MAJOR") is stationed in North Carolina. He is a patriotic American who believes that Jesus Christ is the virgin-born, incarnate Deity: the King over all kings and the LORD of all lords, Whose shed blood is the sole hope for human redemption from sin and eternal judgment, Whose death and resurrection testify to His preeminence over all creation, and at Whose name alone every knee shall bow. Desiring to serve his country, and follow God's leading for his life, USMC MAJOR took the oath of conditional enlistment in 2004 and was commissioned a second lieutenant upon completion of the Officer Candidate Course in August 2005. After graduating from The Basic School, he attended the Military Police Officer Basic Course, and spent his first tour of duty in Okinawa, Japan, where he served as Officer in Charge (OIC) for two districts, including an Air Station, off-base jurisdiction areas, and three military camps. He also performed duties as the Antiterrorism and Force Protection officer for two multinational exercises in Korea. USMC MAJOR then deployed to Iraq, where as a platoon commander and convoy commander he led Marines across Al Anbar and Diyala Provinces. Thereafter, as a Provost Marshal's Office Operations Officer, he directed law enforcement operations at the Marine Corps' largest training base for several years; went to Headquarters United States Marine Corps and worked as a staff officer in the Pentagon for several more. USMC MAJOR received additional specialized training and deployed a second time to Iraq, advising and assisting Iraqi

Security Forces in counterpropaganda efforts to defeat ISIS terrorists. Subsequently, he commanded Headquarters Company in a Law Enforcement Battalion; served as Force Protection Officer for a Marine Logistics Group (Forward) in Norway; and deployed to Afghanistan as an advisor to several military, police, and governmental organizations. USMC MAJORhas submitted a religious exemption request to the COVID shot mandates. He desires to continue serving in the Marine Corps, consistent with his deep personal faith in the Bible as the Word of God, and consistent with his conscience and the personal leading of Jesus Christ regarding what he admits into his body (which is the temple of the Holy Spirit). These require him to reject any involvement with the destruction of innocent human life as exemplified by the use of human fetal cell lines derived from abortions.

27. Plaintiff SECOND LIEUTENANT, United States Marine Corps, is a citizen of the State of Alabama who graduated from the United States Naval Academy (USNA) in 2021 and is now currently at The Basic School (TBS). Prior to the Naval Academy, he attended Marion Military Institute (MMI) for two years. His six years of military college were deliberate, as he has spared no expense in preparing himself to serve as the caliber of leader that United States Marines deserve. He has maintained a flawless conduct record throughout his time in college and in service, as he believes setting such an example is paramount. He has sought out every opportunity for leadership positions requiring ironclad integrity and a dedication to the Profession of Arms, including the MMI Cadet Honor Board and USNA Brigade of Midshipman Honor Investigation System. His professional education and mentorship has focused

extensively on the nuances of military law, good order and discipline, the concept of "immediate obedience to orders," and the invaluable obligation that a commissioned officer holds to honor his or her Oath of Office. He is well known by his peers to be exceptionally disciplined in his conduct and dedicated to his Oath of Office, even in facing the potential loss of his livelihood and lifelong dream of serving and leading Marines. SECOND LIEUTENANT submitted a request for a religious accommodation from the COVID shot mandate, on multiple grounds, including his sincerely-held religious belief "that, first and foremost, a Christian's body is the Temple of the Holy Spirit and should be protected from deliberate or reckless injury or violation," and second, that "deceit pursuant to personnel compliance and/or financial gain, is morally objectionable before God." Upon submitting his religious exemption request, he was immediately removed from his training company, and placed in Mike Company, a non-training company reserved for 2nd Lieutenants who are either injured and unable to complete training, or are pending punitive legal action, while his religious accommodation request is routed up his Chain of Command for a final decision from the Deputy Commandant of the Marine Corps. SECOND LIEUTENANT should have been kept in his training company while his request was pending, as he has not violated any DoD or Marine Corps orders in doing so, and is administratively exempt from all pertinent orders for the duration of time awaiting a final decision. His placement in Mike Company and removal from active training does not protect the force from COVID, as SECOND LIEUTENANT is required to provide administrative and labor assistance to the command, in support of his

colleagues in the field and elsewhere. He is required to physically interact with his peers in all current Basic Officer Course classes in the execution of his support role duties. In other words, he remains active around base, working to help his former colleagues graduate from training, while his own training has been placed on hold indefinitely despite no legal or administrative misconduct. This is punitive and an improper response to a religious exemption request. SECOND LIEUTENANT deeply desires to continue training for service to the Nation in the United States Marine Corps, without the profound conflict between his religious beliefs and the COVID shot directives, and without discrimination.

28. Plaintiff CAPTAIN, United States Marine Corps, is a citizen of the State of South Carolina and a patriotic American whose faith is Islam. Desiring to serve his country, he enlisted in the United States Marine Corps in 2014, graduating from recruit training in March 2015. After serving with a Law Enforcement Battalion and earning his undergraduate degree, he was selected for Officer Candidate School, and commissioned as a second lieutenant in 2016. After graduating from The Basic School, he attended the Military Police Basic Officer Course, with his first duty assignment at a Marine Corps Law Enforcement Battalion as a Platoon Commander. He attended courses in Norway and commanded a Military Police Integrated Company during a NATO Exercise. He has been deployed in several locations, including Africa. CAPTAIN desires to continue serving in the Marine Corps, consistent with his Islamic religious beliefs that require him to abstain from

participation in that which is *haram* – forbidden – including the destruction and commoditization of innocent human life as exemplified by the use of human fetal cell lines derived from abortions. CAPTAIN desires to exercise "complete reliance on God" rather than in what he believes to be morally-tainted COVID shots.

29. Plaintiff ARMY RANGER, United States Army, ARMY RANGER, United States Army, is a citizen of the State of Missouri currently stationed at a United States military facility in the State of Washington. ARMY RANGER has requested an exemption and accommodation for his sincerely held religious objections to the Secretary's mandate that all United States Military personnel accept and receive one of the COVID-19 vaccines as a condition of remaining in their sworn posts. ARMY RANGER has submitted a request for a religious exemption and accommodation, but he has been told by a superior the superior is concerned that the request will "put a target on him" as he is one of two men in the company who have requested a religious exemption from getting the COVID shot. Nonetheless, this superior supports his request for a religious exemption. ARMY RANGER entered active duty in 2015 as an Infantryman (11B). He was selected for Ranger Assessment Selection Program (RASP) in 2015, and graduated Ranger School in 2017, earning his Ranger Tab. He has deployed twice in support of Operation Freedom Sentinel. He is committed to serving the Nation and desires to continue, so long as he is not forced to violate his own religious beliefs and what he believes God requires of him.

30. Plaintiff LANCE CORPORAL 1, United States Marine Corps, is a citizen of the State of California currently stationed at a United States Marine Corps facility in California. LANCE CORPORAL 1 has requested an exemption and accommodation of his sincerely held religious objections to the Secretary's mandate that all United States Armed Forces personnel accept and receive one of the COVID-19 vaccines as a condition of remaining in their sworn posts. LANCE CORPORAL 1's request for a religious exemption and accommodation was **denied**. LANCE CORPORAL 1 is currently serving in the United States Marine Corps in the 1st Radio Battalion, I Marine Expeditionary Force Information Group with the I Marine Expeditionary Force. LANCE CORPORAL 1 was raised in a Christian home where his father always told him that he had the choice of going to college or joining the military. Once he decided to join the military, LANCE CORPORAL 1 instantly chose the Marines because he believed they are the best of the bunch. LANCE CORPORAL 1 started dedicating his life to physical fitness to prepare for the difficult journey he chose. LANCE CORPORAL 1 has discovered a talent and passion for Electrical Maintenance, and intends to pursue it as a civilian career post-military. LANCE CORPORAL 1 signed a 5-year contract, and he plans on serving his country for 5 years. LANCE CORPORAL 1 submitted a religious exemption request from the United States Marine Corps. LANCE CORPORAL 1's request for a religious accommodation and exemption articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. LANCE CORPORAL 1's request for a

religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for merely requesting an accommodation of his sincerely held religious beliefs.

31. Plaintiff LANCE CORPORAL 2 is a citizen of the Commonwealth of Virginia, currently stationed in North Carolina. LANCE CORPORAL 2 joined the Marine Corps in 2018 out of a desire to serve his Country. He graduated Boot Camp, Marine Corps Combat Training, and MOS School, and became a Combat Engineer. LANCE CORPORAL 2 has a strong faith in God and his Son Jesus Christ. He submitted a religious exemption request to the COVID shot orders based on his sincere Christian religious beliefs. He feels the strong conviction of God's Holy Spirit upon his heart that he must not get the COVID shot, and that if he were to get the COVID shot, it would be sin as a violation of the Holy Spirit's leading and direction, and also that it would be sinful complicity in the murder of innocent unborn humans. He believes that all people, born and unborn, are created in God's image, and that life should be respected. He believes it is disrespectful to innocent human life to be associated with or take into his body products derived from abortion. Lance Corporal 2 has been told by several non-commissioned officers that "it is unlikely your religious exemption request will be approved," and that "they're just going to deny them all." If these superiors are correct, he faces involuntary administrative separation at best, and at worst, dishonorable discharge and other life-altering punishment.

32. Plaintiff MAJOR, UNITED STATES AIR FORCE (AIR FORCE MAJOR), is an officer in the U.S. Air Force with over 18 years of honorable active-duty service, and holds a Master of Science degree from an accredited Christian university. As a teenage Christian missionary to Mexico, he developed a strong appreciation for the blessings of his home in America and the legacy of Christian values that sets our nation apart. With this love of God and his Christian American legacy, he answered the call on his life to serve the Nation in the Air Force. He was sworn in as a lieutenant by his grandfather, a retired Colonel. AIR FORCE MAJOR went on to fly many life-saving combat missions in Iraq, Africa, and Afghanistan. The hell of war struck AIR FORCE MAJOR very deeply through the loss of friendly forces' lives, the suicide of fellow airmen, as well as the deaths of innocent civilians. During one tragic mission, while defending forces surrounded by heavy enemy gunfire, AIR FORCE MAJOR suffered a deadly loss in the gunfight. In his profound devastation, AIR FORCE MAJOR called on Jesus' help to carry him through the night of continued danger to the special operations team. In subsequent years, his faith journey out of the depths of that pain and pains from other combat missions has led him to assist in several Christian ministries. He supervised weekly youth church services, Christian summer camp, counseled at a Christian charity relief center, and travelled on leave to Ethiopia to help establish a care point for an international Children's poverty relief center. AIR FORCE MAJOR's life ministry now includes his own children. Having recently learned of the use of human abortion derived fetal cell lines in the development, production, or selection and testing of COVID vaccines, AIR

FORCE MAJOR's religious convictions conflict with DoD orders that he partake of them. AIR FORCE MAJOR follows God's written direction from Scripture, and knows that he must abstain from the use of vaccines derived from aborted fetal cell lines. Per Proverbs 6:16-17, he has a strong conviction that God will judge "hands that shed innocent blood" and he cannot align himself with such deeds. He believes respect for innocent human life is what differentiates America from horrific perpetrators of human rights abuses and genocide.

33. Plaintiff NATIONAL GUARDSMAN, Virginia Army National Guard, a citizen of the Commonwealth of Virginia, entered service with the Virginia Army National Guard in 1987. He graduated Fort Benning Infantry school and became an Infantryman. His unit attended and graduated Jungle Expert school and pulled guard duty in 1988 before the Invasion of Panama. He is an expert rifleman more times than not. He was selected as the Soldier of the Year for his company and went on to win the board for the Battalion Soldier of the year in 1989. He was promoted to SGT in June of 1990. NATIONAL GUARDSMAN was employed by a Textile Mill in Virginia where he quickly rose to Production Supervisor where he served until June 2001 when NAFTA was taking a toll on the economy. He made a career change and enlisted into the Active Guard Reserve (AGR) program 2001. From May 2001-2005, he's served as Readiness/Training NCO and deployed to Guantanamo Bay, Cuba where he performed Force Protection Duties along with being the Sergeant of the Guard of Camp Delta Detainment Center. Upon returning to the United States, he earned another MOS in Logistics. In 2007, NATIONAL GUARDSMAN was

promoted to Sergeant First Class. With his new unit, he served as the Senior Logistics NCO in charge and in May of 2010, NATIONAL GUARDSMAN deployed to the austere Shindand, Afghanistan during the 2010 Surge, and it was there that he earned the Bronze Star (without V Device). He deployed as the Senior BN Logistics NCO with the 1-116th IN to Doha, Qatar for a Force Protection mission. NATIONAL GUARDSMAN served or trained in 7 countries and has over 50 awards / Impact awards. He has served as an Infantryman Squad Leader, Platoon SGT, First SGT and a Logistics NCO, has two additional skill identifiers of Battle Staff NCO and DoD Contracting Specialist. He is currently Number 2 on the State of Virginia Army National Guard. NATIONAL GUARDSMAN submitted a request for a religious accommodation and exemption from the Virginia Army National Guard. NATIONAL GUARDSMAN articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. NATIONAL GUARDSMAN's request for a religious exemption and accommodation has not been approved, and he has been told that he could potentially face court martial, dishonorable discharge, and other life-altering disciplinary measures for merely requesting an accommodation for his sincerely held religious beliefs. NATIONAL GUARDSMAN has also been REMOVED from his scheduled deployment because of his request for an accommodation and exemption.

34. Plaintiff COAST GUARD LIEUTENANT, United States Coast Guard, is a citizen of the State of Florida. She has spent 14 years in service to her country, and

is currently stationed along the Gulf Coast. Following in the footsteps of two generations of her family, she felt the call to serve as a young child. COAST GUARD LIEUTENANT had a desire to serve the people of this nation and steward its natural resources and the Coast Guard's missions had been a perfect fit. During her time in the Coast Guard, COAST GUARD LIEUTENANT has felt privileged to serve alongside a diverse group of people from all around the world, including the Naval and Coast Guard members of other nations. COAST GUARD LIEUTENANT submitted a request for a religious accommodation and exemption from the United States Coast Guard outlining her sincerely held religious objections to receiving one of the COVID-19 vaccines. While breastfeeding her child born earlier this year, she is currently under a temporary medical exemption while undergoing testing for allergies to vaccine components. Though her immediate supervisor supports her requests, COAST GUARD LIEUTENANT has been informed that should these waivers be denied, she may face an other-than-honorable discharge, loss of benefits, and other disciplinary measures if she does not accept the COVID-19 vaccine. COAST GUARD LIEUTENANT has also been informed that even if the medical waivers are approved, she may be determined medically unfit for service and discharged.

35. Plaintiff COLONEL, United States Army, is a citizen of the State of Texas and has served as a health care provider in the United States Army for 22 years. He has been deployed twice to Bosnia for six-months, and to Iraq for one year. COLONEL has treated countless numbers of Soldier patients over his career, and his family has sacrificed, as a military families do, for him to be able to serve Soldiers and

other members of the military. COLONEL hoped to retire with the United States Army, but as a result of the COVID-19 mandate, he faces discipline for the mere exercise of his sincerely held religious beliefs. COLONEL submitted a request for a religious accommodation and exemption from the United States Army. COLONEL articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. COLONEL met with his unit's Chaplain, who reviewed his request for a religious exemption and accommodation and found that COLONEL's request was sincere. COLONEL's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for merely requesting an accommodation of his sincerely held religious beliefs.

36. Plaintiff TECHNICAL SERGEANT, United States Air Force, is a citizen of the State of Oklahoma and has spent 15 years in service to her country in the United States Air Force. She felt the call to serve after high school, after being so emotionally affected by the events that transpired on September 11, 2001. TECHNICAL SERGEANT wanted to become a part of something much bigger than herself, and the Air Force offered her a wonderful opportunity. During her time in the Air Force, TECHNICAL SERGEANT felt privileged to serve with so many selfless and inspirational people all around the world. She spent time in Texas, Mississippi, Illinois, Hawaii, and South Korea. She has been deployed to Kandahar Air Base, Afghanistan, spending six months supporting Operation Enduring Freedom.

TECHNICAL SERGEANT submitted a request for a religious accommodation and exemption from the United States Air Force outlining her sincerely held religious objections to receiving one of the COVID-19 vaccines. Although she is currently under a temporary medical exemption due to being seven months pregnant, TECHNICAL SERGEANT has been informed that once that runs out, she will face court martial, dishonorable discharge, and other disciplinary measures if she does not accept the COVID-19 vaccine.

37. Plaintiff DEFENSE DEPARTMENT CONTRACTOR (and NAVY RESERVE CHIEF WARRANT OFFICER) is a citizen of the State of Florida and a contractor of the United States Department of Defense (DoD). DEFENSE DEPARTMENT CONTRACTOR is on leave of absence from his DoD Contractor employer, where he conducted Intelligence, Surveillance, and Reconnaissance (ISR) quantitative and qualitative assessments and studies in all phases of ISR asset and sensor performance and effectiveness for the DoD. These assessments are briefed to DoD senior leadership to inform decisions on future employment, allocation, and procurement. He holds a Top Secret/Sensitive Compartmented information (TS/SCI) security clearance. As a NAVY RESERVE CHIEF WARRANT OFFICER, he formerly enlisted in the Navy Reserve's Non-Prior Service and Advance Pay Grade (APG) programs in November 2003. After completing basic training in August 2004, DEFENSE DEPARTMENT CONTRACTOR was assigned to NR SECGRU Minneapolis from 2004 to 2010. From January to December 2008, DEFENSE DEPARTMENT CONTRACTOR was mobilized in support of Operation Iraqi

Freedom as part of a Joint Task Force stationed in Balad, Iraq. Following his mobilization, DEFENSE DEPARTMENT CONTRACTOR returned to NR NIOC Texas-Minneapolis and was advanced to Chief Petty Officer in September 2009. DEFENSE DEPARTMENT CONTRACTOR's military leadership assignments include Operations Department Leading Chief Petty Officer at NR NIOC Minneapolis, Senior Enlisted Leader and then Senior Chief Petty Officer in 2015 at NR NIOC Georgia-Orlando, Senior Enlisted Leader at NR Office of Naval Intelligence, and Senior Enlisted Leader NR at NIOC Georgia – Pensacola. Following his tour at NR NIOC Georgia – Pensacola, he was commissioned as a CWO2 in 2019. Following his commissioning, he affiliated with NR C10FNIOCGA ORL and has been on active duty orders supporting US Special Operations Command J24. He has submitted a request for a religious accommodation and exemption from the United States outlining his sincerely held religious objections to receiving one of the COVID-19 vaccines because of their connection to aborted fetal cell lines. DEFENSE DEPARTMENT CONTRACTOR's request was supported by a Chaplain's recommendation and his supervisor's recommendation. DEFENSE DEPARTMENT CONTRACTOR has not received a response to his request for a religious accommodation but has been informed that it is not likely to be granted.

38. Plaintiff FEDERAL CIVILIAN ENGINEER CONTRACTOR is a citizen of the State of Georgia and employed by a large military defense contractor that provides LCD screens used in United States Armed Forces aircraft. FEDERAL CIVILIAN ENGINEER CONTRACTOR is a level-2 electrical engineer working

nearly exclusively on contracts for the United States Armed Forces. FEDERAL CIVILIAN ENGINEER CONTRACTOR is an active congregant of his church with sincerely held religious beliefs that compel him to abstain from accepting or receiving the COVID-19 vaccines. FEDERAL CIVILIAN ENGINEER CONTRACTOR would like to submit a request for a religious exemption and accommodation, but has has seen his employer's responses to some religious exemption requests submitted by colleagues stating a "waiver of required vaccination should be granted indefinitely, after which time you will need to be fully vaccinated," rendering any granted exemption potentially illusory, and subject to revocation at any time.

39. Plaintiff FEDERAL CIVILIAN CONTRACTOR EMPLOYER is a citizen of the State of Michigan who owns his own engineering company located in the Midwest. FEDERAL CIVILIAN CONTRACTOR EMPLOYER and his company develop and support military weapons systems, including current and next generation land vehicles for the Army and next generation Navy vessels. FEDERAL CIVILIAN CONTRACTOR EMPLOYER would like to request a religious exemption and accommodation from the Executive Order mandating that all government contractors mandate the COVID-19 vaccines, and he would like to be able to accommodate and exempt his employees that likewise have sincerely held religious objections to the COVID-19 vaccines. FEDERAL CIVILIAN CONTRACTOR EMPLOYER is concerned that as a result of his desire to provide religious exemptions and accommodations and the Executive Order mandating that all government

contractors and subcontractors require COVID-19 vaccines of their employees, his government contracts (future and current) will be terminated.

40. Plaintiff FEDERAL NUCLEAR CONTRACTOR EMPLOYEE is a citizen of the Commonwealth of Virginia and a young woman of child-bearing age. She holds sincere Christian religious beliefs about human life and marriage. She believes that mankind was created by God, that men and women are designed for a unique, complementary relationship within the context of marriage, and that as part of that relationship, God has designed the female body to fulfill the Creation mandate to "be fruitful and multiply." FEDERAL NUCLEAR CONTRACTOR EMPLOYEE believes abortion to be a great sin, and is morally opposed to the use of aborted fetal cells in the testing or development of vaccines, including the COVID vaccines. FEDERAL NUCLEAR CONTRACTOR EMPLOYEE is not married yet, but hopes to be one day, and in that relationship to have a child or children as God blesses her. She believes that "children are an heritage of the Lord," and that bearing a child or children in the context of marriage fulfils a Divine mandate. FEDERAL NUCLEAR CONTRACTOR EMPLOYEE is aware that no long-term studies have been performed on any of the COVID shots regarding their impact on female fertility, and given her religious beliefs about marriage and childbearing, cannot receive any of the COVID shots. FEDERAL NUCLEAR CONTRACTOR EMPLOYEE fears being placed in the position of having to choose between her job and her faith.

41. Plaintiff DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH is a citizen of the State of Texas and is an R&D Research Technician/Operations Technician for Material Physics Applications Quantum (MPA-Q) which is his group at the Los Alamos National Laboratory in New Mexico. He works with Radar Frequencies, Tesla Magnets, Class 3/4 Laser Operations and Experiments, as well as many other aspects of the DOE's nuclear programs. He has been employed at his current position for 12 years and is a faithful and exemplary employee. DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH requested a religious exemption and accommodation from Defendants' COVID-19 vaccine mandate on federal civilian contractors, and his request was denied. DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH was given until October 15 to accept one of the vaccines or face termination.

42. Defendant JOSEPH R. BIDEN, in his official capacity as President of the United States, is the head of the federal government and Commander in Chief of the United States Armed Forces, and is responsible for enacting, implementing, and enforcing the federal COVID-19 vaccine mandate for members of the United States Armed Forces and civilian federal employees and contractors. Specifically, President Biden issued two Executive Orders on September 9, 2021, mandating that all civilian federal employees and contractors receive a COVID-19 vaccine. President Biden is sued in his official capacity.

43. Defendant LLOYD AUSTIN, in his official capacity as the Secretary of the United States Department of Defense (DoD), is responsible for enacting, implementing, and enforcing the federal COVID-19 vaccine mandate for members of the United States Armed Forces under DoD authority. Specifically, Secretary Austin issued the August 24 Memorandum for Senior Pentagon Leadership and other officials mandating that all military servicemembers under Department of Defense authority receive a COVID-19 vaccine. Secretary Austin is sued in his official capacity.

44. ALEJANDRO MAYORKAS, in his official capacity as Secretary of the Department of Homeland Security, is responsible for enacting, implementing, and enforcing the federal COVID-19 vaccine mandate for members of the United States Coast Guard and other civilian federal employees and contractors. Secretary Austin issued a directive, in accordance with President Biden's September 6 Executive Orders, mandating that all Department of Homeland Security employees, including United States Coast Guard servicemembers, receive a COVID-19 vaccine. Secretary Mayorkas is sued in his official capacity.

JURISDICTION AND VENUE

45. This action arises under the First Amendment to the United States Constitution. This action also arises under federal statutory law, namely the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb to 2000bb-4, and under the Emergency Use Authorization provisions of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3.

46. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1343, and 1367.

47. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this district.

48. This Court is authorized to grant declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, implemented through Rule 57, Federal Rules of Civil Procedure.

49. This Court is authorized to grant Plaintiffs' prayer for a temporary restraining order (TRO) and preliminary and permanent injunctive relief pursuant to Rule 65 of the Federal Rules of Civil Procedure.

GENERAL ALLEGATIONS

A. THE FEDERAL COVID-19 VACCINE MANDATE.

50. On September 9, 2021, President Biden issued Executive Order 14043, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees, requiring all federal employees to receive one of the COVID-19 vaccines as a condition of employment. (A true and correct copy of Executive Order 14043 is attached hereto as **EXHIBIT A** and incorporated herein.)

51. In Executive Order 14043, President Biden stated: "I have determined that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID-19 vaccination for all Federal employees . . . ." (Ex. A at 2.)

52. Consistent with that determination, Executive Order 14043 states: "Each agency shall implement, to the extent consistent with applicable law, a program to require COVID-19 vaccination for all of its Federal employees . . . ." (Ex. A at 2.)

53. Also on September 9, 2021, President Biden issued Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, requiring that all federal contractors and subcontractors "comply with all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force." (A true and correct copy of Executive Order 14042 is attached hereto as **EXHIBIT B** and incorporated herein.) Pursuant to Executive Order 14042, the Safer Federal Workforce Task Force issued its *Guidance for Federal Contractors and Subcontractors* on September 24, 2021, requiring that all employees of federal contractors and subcontractors receive one of the COVID-19 vaccines as a condition of performing any contract for work for the Federal Government. (A true and correct copy of the *Guidance* is attached hereto as **Exhibit C** and incorporated herein.)

54. On August 24, 2021, Secretary Austin issued a Memorandum for Senior Pentagon Leadership, Commanders of the Combatant Commands, and Defense Agency and DoD Field Activity Directors, Subject: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members, mandating that all military servicemembers under DoD authority receive the COVID-19 vaccine. (A true and correct copy of the Secretary's August 24 Memorandum is attached hereto as **EXHIBIT D** and incorporated herein.)

55. In his Memorandum, Secretary Austin stated: "After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people." (Exhibit D at 1.)

56. Secretary Austin further stated: "I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19." (Exhibit D at 1.)

57. Though not even possible right now (*see infra*), the Secretary stated that mandatory vaccination "will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance." (Ex. D at 1.)

B. PLAINTIFFS' SINCERELY HELD RELIGIOUS BELIEFS.

58. Plaintiffs all have sincerely held religious beliefs, rooted in Scripture, that preclude them from complying with the Federal COVID-19 Vaccine Mandate because of the connections between the various COVID-19 vaccines and the cell lines of aborted fetuses, whether in the vaccines' origination, production, development, testing, or other inputs. Plaintiffs also have sincerely held religious beliefs, rooted in Scripture, that their bodies are temples of the Holy Spirit and that they cannot place anything into their Temples without confirmation and conviction from the Holy Spirit.

59. A fundamental component of Plaintiffs' sincerely held religious beliefs is that all life is sacred, from the moment of conception to natural death, and that abortion is the murder of an innocent life and a grave sin against God.

60. Plaintiffs' sincerely held religious beliefs are rooted in Scripture's teachings that "[a]ll Scripture is given by inspiration of God, and is profitable for doctrine, for reproof, for correction, [and] for instruction in righteousness." *2 Timothy* 3:16 (KJV).

61. Because of that sincerely held religious belief, Plaintiffs believe that they must conform their lives, including their decisions relating to medical care, to the commands and teaching of Scripture.

62. Plaintiffs have sincerely held religious beliefs that God forms children in the womb and knows them prior to birth, and that because of this, life is sacred from the moment of conception to natural death. *See Psalm* 139:13–14 (ESV) ("For you formed my inward parts; you knitted me together in my mother's womb. I praise you, for I am fearfully and wonderfully made."); *Psalm* 139:16 (ESV) ("Your eyes saw my unformed substance; in your book were written, every one of them, the days that were formed for me, when as yet there was none of them."); *Isaiah* 44:2 (ESV) ("Thus says the LORD who made you, who formed you from the womb . . . ."); *Isaiah* 44:24 (ESV) ("Thus says the LORD, your Redeemer, who formed you from the womb: 'I am the Lord, who made all things . . . .'"); *Isaiah* 49:1b (ESV) ("The LORD called me from the womb, from the body of my mother he named my name."); *Isaiah* 49:5 (ESV) ("And now the LORD says, he who formed me from the womb to be his servant . . . .");

Jeremiah 1:5 (ESV) ("'Before I formed you in the womb I knew you, and before you were born I consecrated you; I appointed you a prophet to the nations.'").

63. Plaintiffs also have sincerely held religious beliefs that every child's life is sacred because each is made in the image of God. *See Genesis* 1:26–27 (ESV) ("Then God said, 'Let us make man in our image, after our likeness. . . . So God created man in his own image, in the image of God he created him; male and female he created them.'" (footnote omitted)).

64. Plaintiffs have sincerely held religious beliefs that because life is sacred from the moment of conception, the killing of that innocent life is the murder of an innocent human in violation of Scripture. *See, e.g.*, *Exodus* 20:13 (ESV) ("'You shall not murder.'"); *Exodus* 21:22–23 (ESV) (imposing death penalty for killing of an unborn child); *Exodus* 23:7 (ESV) ("'[D]o not kill the innocent and righteous . . . .'"); *Genesis* 9:6 (ESV) ("'Whoever sheds the blood of man, by man shall his blood be shed, for God made man in his own image.'"); *Deuteronomy* 27:25 (ESV) ("Cursed be anyone who takes a bribe to shed innocent blood." (internal quotation marks omitted)); *Proverbs* 6:16–17 (ESV) ("There are six things that the LORD hates, seven that are an abomination to him: . . . hands that shed innocent blood . . . .").

65. The Hebrew word for "abomination" in the text above is תוֹעֵבָה (to`eba). The verbal form is "abhor," "loath," "detest," and "exclude." Twelve times the Book of Proverbs uses תוֹעֵבָה in reference to an "abomination to the LORD." (יהוה or Yahweh). The word is also used in conjunction with the Ammonites and the Ashtoreth, the Sidonians, Chemosth, and Moab. Some of these nations sacrificed their

children to Baal. Indeed, *Jeremiah* 19:4–9, refers to the shedding of innocent blood by sacrificing children as the reason for judgement against Judah. Abortion is the modern-day sacrifice of children made in the image of God. Plaintiffs do not want to be part of such an "abomination." They do not want indirectly or directly to be in any way associated with abortion. To do so is abhorrent, loathsome, detestable, abominable to God. In short, to require these employees to inject a substance into their bodies that has any association (no matter how near or remote to abortion) is a sin against their Creator, their Lord, and their Savior.

66. Plaintiffs also have sincerely held religious beliefs that it would be better to tie millstones around their necks and be drowned in the sea than to bring harm to an innocent child. *See Matthew* 18:6; *Luke* 17:2 (ESV).

67. Plaintiffs also have sincerely held religious beliefs that their bodies are temples of the Holy Spirit, and that to inject medical products that have any connection whatsoever to aborted fetal cell lines would be defiling the temple of the Holy Spirit. (*See 1 Corinthians* 6:15–20 (ESV) ("Do you not know that your bodies are members of Christ? . . . Or do you not know that your body is a temple of the Holy Spirit within you, whom you have from God? You are not your own, for you were bought with a price. So glorify God in your body.").

68. Plaintiffs' religious beliefs compel them to not condone, support, justify, or benefit (directly or indirectly) from the taking of innocent human life via abortion, and that to do so is sinning against God.

69. Plaintiffs' sincerely held religious beliefs preclude them from accepting any one of the three currently available COVID-19 vaccines derived from, produced or manufactured by, tested on, developed with, or otherwise connected to aborted fetal cell lines.

70. As reported by the North Dakota Department of Health, in its handout literature for those considering one of the COVID-19 vaccines, "[t]he non-replicating viral vector vaccine produced by Johnson & Johnson **did require the use of fetal cell cultures, specifically PER.C6, in order to produce and manufacture the vaccine**." *See* North Dakota Health, *COVID-19 Vaccines & Fetal Cell Lines* (Apr. 20, 2021), https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID-19_Vaccine_Fetal_Cell_Handout.pdf.

71. The Louisiana Department of Health likewise confirms that the Johnson & Johnson COVID-19 vaccine used the PER.C6 fetal cell line, which "is a retinal cell line that was **isolated from a terminated fetus in 1985**." La. Dep't of Public Health, *You Have Questions, We Have Answers: COVID-19 Vaccine FAQ* (Dec. 21, 2020), https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You_Have_Qs_COVID-19_Vaccine_FAQ.pdf (emphasis added).

72. Scientists at the American Association for the Advancement of Science have likewise published research showing that the Johnson & Johnson vaccine used aborted fetal cell lines in the development and production phases of the vaccine.

Meredith Wadman, *Vaccines that use human fetal cells draw fire*, Science (June 12, 2020), *available at* https://science.sciencemag.org/content/368/6496/1170.full.

73. The same is true of the Moderna and Pfizer-BioNTech mRNA vaccines. The Louisiana Department of Health's publications again confirm that aborted fetal cells lines were used in the "proof of concept" phase of the development of their mRNA vaccines. *See* La. Dep't of Public Health, *supra*.

74. The North Dakota Department of Health likewise confirms: "Early in the development of mRNA vaccine technology, **fetal cells were used for 'proof of concept' (to demonstrate how a cell could take up mRNA and produce the SARS-CoV-2 spike protein) or to characterize the SARS-CoV-2 spike protein**." N.D. Health, *supra* (emphasis added).

75. The Chief Scientific Officer and Senior Director of Worldwide Research for Pfizer have also been reported to demonstrate that its COVID-19 vaccine is derived from aborted fetal cells and have made statements that they wanted to keep that information from the public. *See PFIZER LEAKS: Whistleblower Goes On Record, Reveals Internal Emails from Chief Scientific Officer & Senior Director of Worldwide Research Discussing COVID Vaccine … 'We Want to Avoid Having the Information on the Fetal Cells Floating Out There'*, ProjectVeritas (Oct. 6, 2021), https://www.projectveritas.com/news/pfizer-leaks-whistleblower-goes-on-record-reveals-internal-emails-from-chief/.

76. Specifically, Vanessa Gelman, Pfizer Senior Director of Worldwide Research: "From the perspective of corporate affairs, we want to avoid having the information on fetal cells floating out there…The risk of communicating this right now outweighs any potential benefit we could see, particularly with general members of the public who may take this information and use it in ways we may not want out there. We have not received any questions from policy makers or media on this issue in the last few weeks, so we want to avoid raising this if possible." *Id.*

77. And, Philip Dormitzer, Pfizer's Chief Scientific Officer is reported as saying that he wanted to keep the information secret because of the objections that pro-life individuals, such as Plaintiffs in this action, would have: "HEK293T cells, used for the IVE assay, are ultimately derived from an aborted fetus. On the other hand, the Vatican doctrinal committee has confirmed that they consider it acceptable for Pro-Life believers to be immunized. Pfizer's official statement couches the answer well and is what should be provided in response to an outside inquiry." *Id.*

78. Because all three of the currently available COVID-19 vaccines are developed and produced from, tested with, researched on, or otherwise connected with the aborted fetal cell lines HEK-293 and PER.C6, Plaintiffs' sincerely held religious beliefs compel them to abstain from obtaining or injecting any of these products into their body, regardless of the perceived benefit or rationale.

79. Plaintiffs have sincerely held religious beliefs that their bodies are temples of the Holy Spirit, and that to inject medical products that have any connection whatsoever to aborted fetal cell lines would be defiling the temple of the Holy Spirit.

80. Plaintiffs sincerely religious beliefs that their bodies are temples of the Holy Spirit and that they are to glorify God with their bodies lays the foundation for everything they do, consume, or inject into their bodies. From this foundation they make studied and reasonable decisions about what is good and what is not good or may not be good for their bodies. To knowingly abuse their bodies by engaging in a dishonorable act, or consuming or injecting a substance that will or may produce adverse consequences, is a sin against God. Based on this foundation, Plaintiffs would consume pure water over a similarly clear liquid they know or reasonably conclude is harmful to the body. This belief and other sincerely held religious beliefs are foundational to all their decisions and actions and are not limited to aborted fetal cell lines.

81. Plaintiffs have sincerely held religious beliefs that the Holy Spirit—through prayer and the revelation of Scripture—guide them in all decisions they make in life.

82. Plaintiffs have sincerely held religious beliefs that Jesus Christ came to this earth, died on the cross for their sins, was resurrected three days later, and that when He ascended to Heaven, He sent the Holy Spirit to indwell His believers and to guide them in all aspects of their lives. *See John* 16:7 (ESV) ("Nevertheless, I tell you the truth: it is to your advantage that I go away, for if I do not go away, the Helper will not come to you. But if I go, I will send him to you."); *John* 14:26 (ESV) ("But the Helper, the Holy Spirit, whom the Father will send in my name, he will teach you all things and bring to your remembrance all that I have said to you.").

83. Plaintiffs have sincerely held religious beliefs that the Holy Spirit was given to them by God to reprove them of righteousness and sin and to guide them into all truth. *See John* 16:8–13 (ESV) ("And when he comes, he will convict the world concerning sin and righteousness and judgment . . . . When the Spirit of truth comes, he will guide you into all the truth, for he will not speak on his own authority, but whatever he hears he will speak, and he will declare to you the things that are to come.").

84. Plaintiffs also have sincerely held religious beliefs that they will receive answers to their questions through prayer and supplication, including for decisions governing their medical health. *See James* 1:5 (ESV) ("If any of you lacks wisdom, let him ask God, who gives generously to all without reproach, and it will be given him."); *Mark* 11:24 (ESV) ("Therefore I tell you, whatever you ask in prayer, believe that you have received it, and it will be yours."); *Philippians* 4:6–7 (ESV) ("[D]o not be anxious about anything, but in everything by prayer and supplication with thanksgiving let your requests be made known to God. And the peace of God, which surpasses all understanding, will guard your hearts and your minds in Christ Jesus."); *1 John* 4:14–15 (ESV) ("And we have seen and testify that the Father has sent his Son to be the Savior of the world. Whoever confesses that Jesus is the Son of God, God abides in him, and he in God.").

85. Through much prayer and reflection, Plaintiffs have sought wisdom, understanding, and guidance on the proper decisions to make concerning these COVID-19 vaccines, and Plaintiffs have been convicted by the Holy Spirit that

accepting any of the three currently available vaccines is against the teachings of Scripture and would be a sin.

86. Plaintiffs have sincerely held religious beliefs that compel them to follow the teachings of the Holy Spirit, who has not given them peace, comfort, or admonition to accept any of the three currently available COVID-19 vaccines.

87. Plaintiffs have sincerely held religious beliefs that they are being guided and instructed by the Holy Spirit not to accept any of the three currently available COVID-19 vaccines and that it would be a sin against God to do so.

88. Plaintiff CAPTAIN is of the Islamic faith whose sincerely held religious beliefs that require him to abstain from participation in that which is *haram* – forbidden – including the destruction and commoditization of innocent human life as exemplified by the use of human fetal cell lines derived from abortions. CAPTAIN desires to exercise "complete reliance on God" rather than in what he believes to be morally-tainted COVID shots

C. PLAINTIFFS' WILLINGNESS TO COMPLY WITH SAFE AND TESTED ALTERNATIVES TO UNIVERSAL VACCINATION AS ACCOMMODATION OF THEIR SINCERELY HELD RELIGIOUS BELIEFS.

89. Plaintiffs have offered, and are ready, willing, and able to comply with all reasonable health and safety requirements to facilitate their religious exemption and accommodation from the Federal COVID-19 Vaccine Mandate.

90. Plaintiffs have all informed their respective commanding officers and civilian supervisors that they are willing to comply with reasonable conditions that

were sufficient for nearly two years, permitting them to fulfill their sworn duties and faithful service to their employers and a grateful nation, and which reasonable conditions continued from the FDA's Emergency Use Authorization (EUA) of the first COVID-19 vaccine in December 2020, until August 24, 2021 for military servicemembers and September 9 for federal civilian employees and contractors. Nothing has changed except for the Mandate, and thus the past proves a good example of present and future reasonable accommodations.

91. The accommodations which have been ongoing for nearly two years are certainly reasonable under the accumulating scientific evidence. Indeed,

> A preliminary study has shown that in the case of a breakthrough infection, the Delta variant is able to grow in the noses of vaccinated people **to the same degree as if they were not vaccinated at all**. The virus that grows is just as infectious as that in unvaccinated people, meaning vaccinated people can transmit the virus and infect others.

Sanjay Mishra, *Evidence mounts that people with breakthrough infections can spread Delta easily*, National Geographic (Aug. 20, 2021), https://www.nationalgeographic.com/science/article/evidence-mounts-that-people-with-breakthrough-infections-can-spread-delta-easily (emphasis added); *see also Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR* (July 30, 2021), https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html (noting "**the Delta infection resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people**" (emphasis added).)

92. Other reasonable protocols beyond the currently-available COVID vaccines remain sufficient to prevent the spread of COVID-19 among military servicemembers, federal employees, and federal contractors, and constitute a reasonable alternative to mandatory, universal vaccination as an accommodation of sincerely held religious beliefs.

93. The United States District Court for the Western District of Louisiana recently issued a TRO against a medical school for the school's failure to grant religious exemptions when other reasonable accommodations were available and mandatory vaccination was not the least restrictive means of achieving the school's interest in protecting the school's student body. *See Magliulo v. Edward Via College of Osteopathic Medicine*, No. 3:21-CV-2304, 2021 WL 36799227 (W.D. La. Aug. 17, 2021).

94. The United States District Court for the Western District of Michigan issued a TRO against a university for its failure to allow students with religious objections to vaccination to participate in athletics and other extracurricular activities when other reasonable alternatives were available as a reasonable accommodation for their religious beliefs. *See Dahl v. Bd. of Trustees of W. Mich. Univ.*, No. 1:21-cv-757, 2021 WL 3891620, *2 (W.D. Mich. Aug. 31, 2021). The Sixth Circuit Court of Appeals affirmed that preliminary injunction in its order refusing to stay the preliminary injunction. *See Dahl v. Bd. of Trustees of W. Mich. Univ.*, No. 21-2945, 2021 WL 4618519 (6th Cir. Oct. 7, 2021).

95. The United States District Court for the Northern District of New York and the Second Circuit Court of Appeals have both entered injunctions against enforcement of New York's COVID-19 vaccine mandate on healthcare workers that expressly excluded any religious exemption. On October 12, 2021, the Northern District of New York entered a preliminary injunction enjoining state officials from enforcing the mandate. *See Dr. A. v. Hochul*, No. 1:21-CV-1009, 2021 WL 4734404 (N.D.N.Y. Oct. 12, 2021). The court had previously entered a TRO to the same effect. *See* 2021 WL 4189533 (N.D.N.Y. Sept. 14, 2021). On September 30, in between the Northern District's TRO and preliminary injunction, the Second Circuit gave its imprimatur to the *Dr. A.* TRO in *We The Patriots USA, Inc. v. Hochul*, No. 21-2179, dkt. 65 (2d Cir. Sept. 30, 2021). In *We The Patriots*, the Second Circuit issued an injunction pending appeal against New York's mandate, enjoining state officials from enforcing it "in a manner that would violate the terms of the temporary restraining order issued in *Dr. A v. Hochul*."

96. The United States Military Health System allows three different types of permanent *medical* exemptions from compulsory immunizations: (1) "Determination by a medical provider that further vaccination will seriously endanger patient's health;" (2) "Medical, Reactive exemption: Previously severe reaction after specific vaccine;" and (3) "Medical, Immune exemption: Evidence of existing immunity (e.g., by serologic antibody test, documentation of previous infection or natural infection presumed)." *See* Military Health System, *Immunization Exemption Guidance*, Health.mil, https://www.health.mil/Military-Health-Topics/Health-

Readiness/Immunization-Healthcare/Clinical-Consultation-Services/Exemption-Guidance (last visited October 14, 2021).

97. Several Plaintiffs and countless other class members were previously infected with COVID-19, have serologic test results demonstrating natural antibodies and immunity to COVID-19, and otherwise qualify for the exemptions ostensibly available for servicemembers. Plaintiffs, however, have been denied the ability to even requests the officially available exemptions.

D. PLAINTIFFS' REQUESTS FOR AN ACCOMMODATION FROM THE MANDATORY COVID-19 VACCINE POLICY.

98. On September 7, 2021, NAVY SEAL 1 submitted to the United States Navy a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. NAVY SEAL 1 articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. NAVY SEAL 1 met with his unit's Chaplain, who reviewed his request for a religious exemption and accommodation and found that NAVY SEAL 1's request was sincere. NAVY SEAL 1's Chaplain forwarded NAVY SEAL 1's request to the command. After review, NAVY SEAL 1's request for a religious exemption and accommodation was denied, and he was preemptively removed from his position as Platoon Chief. NAVY SEAL 1 faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

99. On September 14, 2021, NAVY SEAL 2 submitted to the United States Navy a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. NAVY SEAL 2's request for a religious exemption and accommodation detailed NAVY SEAL 2's religious beliefs and practices that compel him to abstain from receiving any of the currently available COVID-19 vaccines. NAVY SEAL 2's request for a religious accommodation was supported by a letter from a religious leader, which demonstrated the sincerity of NAVY SEAL 2's personal beliefs. NAVY SEAL 2's commander noted that NAVY SEAL 2's religious beliefs were sincere and strongly held, but recommended that his request be disapproved. NAVY SEAL 2's request for an accommodation has been forwarded to the officers responsible for making the final determination, but he has been informed that his request will not be approved because of his direct commander's recommendation of denial. NAVY SEAL 2 faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination

100. On September 15, 2021, NAVY EOD OFFICER submitted to the United States Navy a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. NAVY EOD OFFICER articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. NAVY EOD OFFICER's request for a religious exemption and accommodation has not been approved, and he faces potential court martial,

dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

101. On September 16, 2021, LIEUTENANT COLONEL 1, United States Marine Corps, submitted to the United States Marine Corps a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. LIEUTENANT COLONEL 1 articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. LIEUTENANT COLONEL 1 met with his unit's Chaplain, who reviewed his request for a religious exemption and accommodation and found that LIEUTENANT COLONEL's request was made from a position of "absolute sincerity." LIEUTENANT COLONEL 1's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

102. LIEUTENANT COLONEL 2, United States Marine Corps, submitted to the United States Marine Corps a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of her sincerely held beliefs. LIEUTENANT COLONEL 2 articulated to his command that she has and exercises sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. LIEUTENANT COLONEL 1's request for a

religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination

103. On September 16, 2021, ARMY RANGER submitted to the United States Army a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. ARMY RANGER articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. ARMY RANGER met with his unit's Chaplain, who reviewed his request for a religious exemption and accommodation and who found that ARMY RANGER's request was sincere. ARMY RANGER also submitted a pastor's verification letter with his request. ARMY RANGER's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

104. On September 9, 2016, LANCE CORPORAL submitted to the United States Marine Corps a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. LANCE CORPORAL articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently

available COVID-19 vaccines. LANCE CORPORAL's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

105. On October 4, 2021, NATIONAL GUARDSMAN submitted to the Virginia Army National Guard a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. NATIONAL GUARDSMAN articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. NATIONAL GUARDSMAN's request for a religious exemption and accommodation has not been approved, and he has already been removed from his scheduled deployment because of his request. NATIONAL GUARDSMAN additionally faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination. NATIONAL GUARDSMAN has also been removed from his scheduled deployment because of his request for an accommodation and exemption.

106. LIEUTENANT, United States Coast Guard submitted a request for a religious accommodation and exemption from the United States Coast Guard outlining her sincerely held religious objections to receiving one of the COVID-19 vaccines. Although she is currently under a temporary medical exemption while

breastfeeding her child born earlier this year and undergoing testing for allergies to vaccine components, LIEUTENANT has been informed that should these waivers be denied, she will may face dishonorable discharge, loss of benefits, and other disciplinary measures if she does not accept the COVID-19 vaccine. LIEUTENANT has also been informed that even if the medical waivers are approved, she may be determined medically unfit for service and discharged.

107. On September 28, 2021, COLONEL submitted to the United States Army a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. COLONEL articulated to his command that he has and exercises sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. COLONEL met with his unit's Chaplain, who reviewed his request for a religious exemption and accommodation and found that COLONEL's request was sincere. COLONEL's request for a religious exemption and accommodation has not been approved, and he faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

108. TECHNICAL SERGEANT submitted to the United States Air Force a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of her sincerely held beliefs. TECHNICAL SERGEANT articulated to her command that she has and exercises sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines.

TECHNICAL SERGEANT also requested and was granted a temporary medical exemption because she is seven months pregnant, which will expire at the end of her pregnancy. TECHNICAL SERGEANT's request for a religious exemption and accommodation has not been approved, and she faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs against COVID-19 vaccination.

109. On October 2, 2021, DEFENSE DEPARTMENT CONTRACTOR submitted to the United States Department of Defense a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs. DEFENSE DEPARTMENT CONTRACTOR's request for a religious accommodation and exemption outlined his sincerely held religious objections to receiving any of the COVID-19 vaccines because of their connections to aborted fetal cell lines. DEFENSE DEPARTMENT CONTRACTOR's request was supported by a Chaplain's and supervisor's recommendations. DEFENSE DEPARTMENT CONTRACTOR's request has not been approved, and he has been informed that it is likely to be denied. DEFENSE DEPARTMENT CONTRACTOR faces potential court martial, dishonorable discharge, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

110. FEDERAL CIVILIAN ENGINEER CONTRACTOR would like to submit a request for religious exemption from the Federal COVID-19 Vaccine

Mandate as an accommodation of his sincerely held beliefs, but has been deprived of guidance on how and to whom to submit such a request. FEDERAL CIVILIAN ENGINEER CONTRACTOR has also been informed that there is little chance such requests will be approved. FEDERAL CIVILIAN ENGINEER CONTRACTOR faces termination for exercising and seeking accommodation of his sincerely held religious beliefs against COVID-19 vaccination.

111. FEDERAL CIVILIAN CONTRACTOR EMPLOYER would like to submit a request for religious exemption from the Federal COVID-19 Vaccine Mandate as an accommodation of his sincerely held beliefs, and to be able to provide religious exemptions and accommodations to his employees who have sincerely held religious objections to the COVID-19 vaccines, but has been deprived of guidance on how and to whom to submit such a request. Given the Mandate's requirement that all employees of federal government contractors and subcontractors receive a COVID-19 vaccine, FEDERAL CIVILIAN CONTRACTOR EMPLOYER faces termination of his current government contracts and disqualification from future contracts as a result of his exercising and seeking accommodation of his and his employees' sincerely held religious beliefs against COVID-19 vaccination.

112. FEDERAL NUCLEAR CONTRACTOR EMPLOYEE is not married yet, but hopes to be one day, and in that relationship to have a child or children as God blesses her. She believes that "children are an heritage of the Lord," and that bearing a child or children in the context of marriage fulfils a Divine mandate.

FEDERAL NUCLEAR CONTRACTOR EMPLOYEE is aware that no long-term studies have been performed on any of the COVID shots regarding their impact on female fertility, and given her religious beliefs about marriage and childbearing, cannot receive any of the COVID shots. FEDERAL NUCLEAR CONTRACTOR EMPLOYEE fears being placed in the position of having to choose between her job and her faith.

113. DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH requested a religious exemption and accommodation from Defendants' COVID-19 vaccine mandate on federal civilian contractors, and his request was denied. DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH was given until October 15 to accept one of the vaccine or face termination.

114. While many Plaintiffs' and class members' religious exemption requests have already been denied, the still pending requests have been effectively denied, as Plaintiffs and class members with pending requests have been threatened with dishonorable discharge, court martial, termination, or other life-altering disciplinary measures for merely seeking accommodation of their sincerely held religious beliefs, and some of these Plaintiffs have been informed by their superiors that **no religious exemption or accommodation will be given so there is no point in even making a request**.

115. For example, on October 14, 2021, Vice Admiral William Galinis, Commander, Naval Sea Systems Command (NAVSEA), sent a warning to his entire

command, comprising more than 85,000 civilian and military personnel: "The Executive Order mandating vaccinations for all federal employees has provided clear direction. We are moving quickly toward a workforce where vaccinations are a condition of employment. Frankly, if you are not vaccinated, you will not work for the U.S. Navy."

E. THE ONLY COVID-19 VACCINES AVAILABLE IN THE UNITED STATES ARE ADMINISTERED UNDER EMERGENCY USE AUTHORIZATION BECAUSE THERE IS NO FDA APPROVED COVID-19 VACCINE CURRENTLY AVAILABLE IN THE UNITED STATES.

116. Despite the misreporting, there is no COVID-19 vaccine available in the United States that has received full FDA licensing and approval.

117. On August 23, 2021, the United States Food and Drug Administration issued two separate letters pertaining to two separate COVID-19 vaccines. *See* Letter, United States Food and Drug Administration to BioNTech Manufacturing GmbH (Aug. 23, 2021), https://www.fda.gov/media/151710/download ("BioNTech Letter"); Letter, United States Food and Drug Administration to Pfizer, Inc. (Aug. 23, 2021), https://www.fda.gov/media/150386/download ("Pfizer Letter"). (A true and correct copy of the BioNTech Letter is attached hereto as **EXHIBIT E** and incorporated herein. A true and correct copy of the Pfizer Letter is attached hereto as **EXHIBIT F** and incorporated herein.)

118. In the Pfizer Letter, the FDA confirms that, on December 11, 2020, it granted Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19

Vaccine. (Pfizer Letter at 1.) It also notes that the EUA was continued on December 23, 2020, February 25, 2020, May 10, 2021, June 25, 2021, and August 12, 2021. (Pfizer Letter at 1-2.)

119. The Pfizer Letter also makes clear that there are scientific, manufacturing, and **legal** differences between the Pfizer-BioNTech COVID-19 Vaccine and the newly approved BioNTech COMIRNATY, COVID-19 Vaccine, mRNA. (Pfizer Letter at 2 n.9, 3 n.10.)

120. Specifically, the FDA stated that although COMIRNATY was granted full approval by the FDA, the Pfizer-BioNTech COVID-19 Vaccine was still only authorized under the EUA. (Pfizer Letter at 2 n.9 ("In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, **this EUA would remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses**. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA)." (emphasis added).

121. All existing vials of the Pfizer-BioNTech COVID-19 Vaccine remain available only under the authorization of the EUA. (Pfizer Letter at 2 n.9.)

122. On information and belief, the existing vials of Pfizer-BioNTech COVID-19 Vaccine in the United States number in the millions, and that all of these EUA vaccine doses will be administered **before any does of the fully approved**

COMIRNATY, meaning the fully approved COMIRNATY will not be available for administration in the United States in the near future.

123. There are currently no available doses of COMIRNATY in the United States, and **COMIRNATY is not being manufactured for production or distribution in the United States at this time**.

124. **In fact, the FDA Pfizer Letter plainly states that COMIRNATY is not available in the United States: "Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is no sufficient approved vaccine for distribution to the population**." (Pfizer Letter at 6 n.12 (emphasis added).)

125. Thus, the FDA has admitted and acknowledged that COMIRNATY is not available for the population in the United States, and thus extended the EUA for the Pfizer-BioNTech Covid-19 Vaccine. (*Id.*)

126. Indeed, in order for the FDA to have extended the EUA for the Pfizer-BioNTech Covid-19 Vaccine, **it was required to find that there were no alternatives available for the Pfizer-BioNTech Vaccine**. (*See* Pfizer Letter at 6 ("There is no adequate, approved, and **available alternative** to the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19." (emphasis added).)

127. Moreover, though Secretary Austin stated that the Federal COVID-19 Vaccine Mandate "will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved

labeling and guidance," (Ex. D at 1), additional military documents reveal that the Department of Defense is not following its own directive and is, instead, using EUA vaccines because there is no FDA approved vaccine available. In a Memorandum for Assistant Secretary of the Army (Manpower and Reserve Affairs), Assistant Secretary of the Navy (Manpower and Reserve Affairs), Assistant Secretary of the Air Force (Manpower and Reserve Affairs), and the Director of the Defense Health Agency, Terry Adirim, Acting Assistant Secretary of Defense for Health Affairs, admitted that the Department of Defense was not administering a fully licensed and approved vaccine to the heroes in the United States Armed Forces, but was instead skirting federal law by mandating an EUA vaccine instead. (A true and correct copy of Acting Assistant Secretary Adirim's Memorandum is attached hereto as **EXHIBIT G** and incorporated herein.)

128. Specifically, the Memorandum stated that Department of Defense health care providers "**should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine**." (Ex. G at 1 (emphasis added).)

129. Thus, the only currently available COVID-19 vaccines are authorized under EUA only, and therefore cannot be mandated by Secretary Austin. (*See infra* Count I.)

130. The Federal Food, Drug, And Cosmetic Act provides that

> **subject to the provisions of this section**, the Secretary (of the Department of Health and Human Services) may authorize the

> introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use."

21 U.S.C. § 360bbb-3(a)(1) (emphasis added) [hereinafter EUA Statute].

131. As an essential part of the explicit statutory conditions for EUA**, the EUA Statute mandates that all individuals to whom the EUA product may be administered be given the option to accept or refuse administration of the product**:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> . . . .
>
> (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)–(III) (emphasis added).

132. The statutorily required Fact Sheets for each of the EUA COVID-19 vaccines acknowledge that individuals cannot be compelled to accept or receive the

vaccine. *See, e.g.*, Pfizer-BioNTech, *Fact Sheet for Recipients and Caregivers* (June 25, 2021), https://www.fda.gov/media/144414/download ("**It is your choice to receive or not to receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care**." (emphasis added)).

133. Because all COVID-19 vaccines available in the United States are subject to the EUA Statute restrictions and limitations, all individuals—**including military servicemembers, federal employees, and federal civilian contractors**—have the explicit right under the EUA Statute to accept or refuse administration of the products.

F. IRREPARABLE HARM TO PLAINTIFFS.

134. Because of Defendants' refusal to grant Plaintiffs merited religious exemptions from the Federal COVID-19 Vaccine Mandate, Plaintiff servicemembers face the unconscionable choice of violating their sincerely held religious beliefs or facing court martial and dishonorable discharge from their faithful service to the Nation or, in the case of Plaintiff civilian employees and contractors, termination from their employment and contracts.

135. As a result of the Federal COVID-19 Vaccine Mandate, Plaintiffs have suffered and are suffering irreparable injury by being prohibited from engaging in their constitutionally and statutorily protected rights to the free exercise of their sincerely held religious beliefs.

136. As a result of the Federal COVID-19 Vaccine Mandate, Plaintiffs have suffered and are suffering irreparable injury by being forced to choose between

maintaining the ability to feed their families and the free exercise of their sincerely held religious beliefs.

137. As a result of the Federal COVID-19 Vaccine Mandate, Plaintiffs have suffered and are suffering irreparable injury by being stripped of their rights to equal protection of the law and being subjected to disfavored class status in the United States Armed Forces, federal employment, and federal contracting.

138. Military servicemember Plaintiffs also face the prospect of irreparable medical injury as a result of the Federal COVID-19 Vaccine Mandate. A recent study conducted by the Department of Defense found "**higher than expected rates of heart inflammation following receipt of COVID-19 vaccines**" among military servicemembers. *See* Patricia Kime, *DoD Confirms: Rare Heart Inflammation Cases Linked to COVID-19 Vaccines*, Military.com (June 30, 2021), https://www.military.com/daily-news/2021/06/30/dod-confirms-rare-heart-inflammation-cases-linked-covid-19-vaccines.html (emphasis added).

> In fact, on or about June 29, 2021, Defendants knew that the mRNA vaccines would causing myocarditis/pericarditis (a potentially serious and deadly heart inflammation) in certain members of the military, particularly in males 30 and under. In a study conducted by United States Army, Navy, and Air Force physicians specifically found: A total of 23 male patients (22 currently serving in the military and 1 retiree; median [range] age, 25 [20-51] years) **presented with acute onset of marked chest pain within 4 days after receipt of an mRNA COVID-19 vaccine. All military members were previously healthy with a high level of fitness**. Seven received the BNT162b2-mRNA vaccine and 16 received the mRNA-1273 vaccine. A total of 20 patients had symptom onset following the second dose of an appropriately spaced 2-dose series. All patients had significantly elevated cardiac troponin levels. Among 8 patients who underwent cardiac magnetic resonance imaging within the

> acute phase of illness, all had findings consistent with the clinical diagnosis of myocarditis. . . . **While the observed number of myocarditis cases was small, the number was higher than expected among male military members after a second vaccine dose**.

Jay Montgomery, et al., *Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military*, Journal of American Medical Association Network (June 29, 2021), *available at* https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601 (emphasis added).

139. Dr. Matthew Oster, a member of the President's COVID-19 Task Force, confirmed the link between the COVID-19 vaccines and myocarditis, stating: "It does appear that mRNA vaccines may be a new trigger for myocarditis yet it does have some different characteristics." Jackie Salo, *COVID-19 mRNA vaccines likely linked to rare heart condition in kids: CDC panel*, (June 23, 2021), https://nypost.com/2021/06/23/covid-19-vaccines-from-pfizer-moderna-likely-linked-to-rare-heart-condition-cdc-panel/.

140. Indeed, it is now well confirmed by the CDC and other studies that males 30 and under have an unacceptable risk of developing myocarditis as a result of the COVID-19 vaccines. *See* **EXHIBIT H,** Declaration of Dr. Peter McCullough.

141. The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In other words, it is unknown whether or not these products will change human genetic material, cause birth defects, reduce fertility, or cause cancer. (Ex. H, McCullough Decl. ¶16.)

142. The Pfizer, Moderna, and JNJ vaccines are considered "genetic vaccines", or vaccines produced from gene therapy molecular platforms which according to US FDA regulatory guidance are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors. FDA. Food and Drug Administration. (*Id.* ¶17.)

143. The FDA has "advised sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational gene therapy product, specifying that the long-term follow-up observation should include a minimum of five years of annual examinations, followed by ten years of annual queries of study subjects, either in person or by questionnaire." (emphasis added) Thus, the administration of the Moderna, Pfizer, and JNJ vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up which are currently not offered in the US. (See, EUA briefing documents for commitments as to follow up: Moderna , Pfizer , J&J). They have a dangerous mechanism of action in that they all cause the body to make an uncontrolled quantity of the pathogenic wild-type spike protein from the SARS-CoV-2 virus for at least two weeks probably a longer period based on the late emergence of vaccine injury reports. This is unlike all other vaccines where there is a set amount of antigen or live-attenuated virus. This means for Pfizer, Moderna, and J&J vaccines it is not predictable among patients who will produce more or less of the spike protein. The Pfizer, Moderna, and JNJ vaccines because they are different, are expected to produce different libraries of limited antibodies to the now extinct wild-type spike protein. We know the spike protein

produced by the vaccines is obsolete because the 17th UK Technical Report on SARS-CoV-2 Variants issued June 25, 2021, and the CDC June 19, 2021, Variant Report both indicate the SARS-CoV-2 wild type virus to which all the vaccines were developed is now extinct. (*Id.* ¶18.)

144. The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells, in particular, causes the body's own immune system to attach to these organs. This is abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years. (*Id.*)

145. Because the US FDA and CDC have offered no interpretation of overall safety of the COVID-19 vaccines according to the manufacturer or as a group, nor have they offered methods of risk mitigation for these serious adverse effects which can lead to permanent disability or death, no one should be pressured, coerced, receive the threat or reprisal, or be mandated to receive one of these investigational products against their will. Because the vaccine centers, CDC, FDA, and the vaccine manufacturers ask for the vaccine recipient to grant indemnification on the consent form before injection, all injuries incurred by the person are at their own cost which can be prohibitive depending on the needed procedures, hospitalizations, rehabilitation, and medications. (*Id.*)

146. The COVID-19 public vaccination program operated by the CDC and the FDA is a clinical investigation and under no circumstance can any person receive pressure, coercion, or threat of reprisal on their free choice of participation. Violation of this principle of autonomy by any entity constitutes reckless endangerment with a reasonable expectation of causing personal injury resulting in damages. (*Id.* ¶21.)

147. The total safety reports in VAERS for all vaccines per year up to 2019 was 16,320. The total safety reports in VAERS for COVID-19 Vaccines alone through October 1, 2021, is 778,683. Based on VAERS as of October 1, 2021, there were 16,310 COVID-19 vaccine deaths reported and 75,605 hospitalizations reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) adult death reports for all vaccines combined. Thus, the COVID-19 mass vaccination is associated with at least a 39-fold increase in annualized vaccine deaths reported to VAERS. (*Id.* ¶28.)

148. COVID-19 vaccine adverse events account for 98% of all vaccine-related AEs from December 2020 through the present in VAERS. (*Id.* ¶29.)

149. The COVID-19 vaccines are not safe for general use and cannot be deployed indiscriminately or supported, recommended, or mandated among any group. (*Id.* ¶30.)

150. There are emerging trends showing that the vaccine is especially risky for those 12- 29 in my expert medical opinion with complications in the cardiovascular,

neurological, hematologic, and immune systems. (See, Rose J, et al). Increasingly the medical community is acknowledging the possible risks and side effects including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. See Chien-Te Tseng, Elena Sbrana, Naoko Iwata- Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus, https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine—United States, December 14– 23, 2020 (Jan 15, 2021). (*Id.* ¶31.)

151. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis. It is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage resulting in heart failure, arrhythmias, and cardiac death. These conditions could call for a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation. Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis. (*Id.* ¶32.)

152. COVID-19 vaccine-induced myocarditis has a predilection for young males below age 30 years. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis and the

US FDA has issued a warning on the Pfizer and Moderna vaccines for myocarditis. In the cases reviewed by the CDC and FDA, 90% of children with COVID-19 induced myocarditis developed symptoms and clinical findings sufficiently severe to warrant hospitalization. Because this risk is not predictable and the early reports may represent just the tip of the iceberg, no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines particularly the Pfizer and Moderna products. (*Id.* ¶33.)

153. Multiple recent studies and news reports detail people 18-29 dying from myocarditis after receiving the COVID-19 vaccine. According to the CDC, 475 cases of pericarditis and myocarditis have been identified in vaccinated citizens aged 30 and younger. See FDA, Vaccines and Related Biological Products Advisory Committee June 10, 2021, Meeting Presentation. The FDA found that people 12-24 account for 8.8% of the vaccines administrated, but 52% of the cases of myocarditis and pericarditis were reported. (*Id.* ¶¶34-35.)

154. The CDC recently released data stating that there have been 267 cases of myocarditis or pericarditis reported after receiving one dose of the COVID-19 vaccines and 827 reported cases after two doses through June 11. There are 132 additional cases where the number of doses received is unknown. Id. There have been 2466 reported cases of myocarditis that have occurred, and the median age is thirty. (*Id.* ¶37.) And, the CDC just announced that the vaccine is "likely linked" to myocarditis. Advisory

Board, CDC panel reports 'likely association' of heart inflammation and mRNA COVID-19 vaccines in young people. (*Id.* ¶36.)

155. The irreparable harm to Plaintiffs and the class members they represent is incalculable, unconscionable, and unconstitutional. As the Declaration of Nay Chaplain (attached hereto as **EXHIBIT I** and incorporated herein) demonstrates, the military heroes of this Nation are under inordinate strain from this forced mandate that violates their conscience, and it is having tremendous mental health effects, including a large number of military suicides. (Ex. I, ¶¶6-32.) The Declaration of COAST GUARD LIEUTENANT (attached hereto as **EXHIBIT J** and incorporated herein) likewise demonstrates immeasurable and irreparable injury.

CLASS ALLEGATIONS

156. Plaintiffs satisfy the requirements Fed. R. Civ. P. 23(a) because the class is so numerous that joinder of all members is impracticable, each member's claims involve common questions of law and fact, the claims of the representatives are typical of and identical to the claims of the other members of the class, and the representatives here will fairly and adequately protect the interests of the class in having the primarily legal questions addressed by this Court in an expeditious manner. Between Active Duty Military and Reserves, the United States Armed Forces comprise almost 2.3 million individuals, the federal government directly employees approximately 2.1 million, and federal contractors and subcontractors total about 3.7 million.

157. Plaintiffs have typicality with the other members of the class of military servicemembers, civilian federal employees, and civilian federal contractors who have

been denied religious exemption from the Federal COVID-19 Vaccine Mandate, estimated to number in the thousands or even tens of thousands, and who are threatened with the unconscionable choice between conformance with their sincerely held religious convictions adverse employment action.

158. Plaintiffs have commonality with the other members of the class because they are all members of the United States Armed Forces, civilian federal employees, or civilian federal contractors subject to the Federal COVID-19 Vaccine Mandate.

159. Plaintiffs' claims in this Court are representative of the claims of other class members and involve questions of fact and law that are common to all class members, including, *inter alia*,

(a) whether the EUA Statute requires that Plaintiffs be given the option to refuse a COVID-19 vaccine because there is currently no FDA approved COVID-19 vaccine available;

(b) whether Defendants violate the First Amendment to the United States Constitution by mandating that Plaintiffs accept and receive a COVID-19 vaccine regardless of whether Plaintiffs' and the other class members' sincerely held religious beliefs compel them to abstain from acceptance or receipt of the three currently available COVID-19 vaccines; and

(c) whether the federal Religious Freedom Restoration Act (RFRA) requires Defendants and all those in active concert with them to provide accommodations and exemptions to those Plaintiffs with sincerely held religious convictions that compel

them to abstain from receiving one of the three currently available COVID-19 vaccines.

160. Plaintiffs' claims are representative and common among all class members because the injury sustained—Defendants' refusals to grant exemption and accommodation for sincerely held religious objections to the COVID-19 vaccines and the resulting adverse employment actions—are categorically identical. Indeed, Plaintiffs and the other members of the class "have suffered the same injury." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011).

161. Plaintiffs will fairly and adequately protect the interests of the class because they are seeking a temporary restraining order, preliminary and permanent injunctive relief, and declaratory relief against enforcement of the Federal COVID-19 Vaccine Mandate and Defendants' refusals to entertain or grant religious exemptions and accommodations which will provide relief to all class members.

162. Plaintiffs likewise satisfy the requirements of Fed. R. Civ. P. 23(b) because Defendants have acted in a manner that applies to all members of the class with respect to the Federal COVID-19 Vaccine Mandate, and have refused to grant religious accommodations to the entire group of class members who have sincerely held religious objections to receiving a COVID-19 vaccine under the Mandate. Fed. R. Civ. P. 23(b)(2).

163. Additionally, Plaintiffs' requested injunctive and declaratory relief would appropriately protect of the entire class as a whole. Fed. R. Civ. P. 23(b)(2).

164. Moreover, Plaintiffs satisfy the requirements of Fed. R. Civ. P. 23(b) because the common questions of law and fact applicable to the class members' claims predominate over individualized questions pertaining to individual class members. Fed. R. Civ. P. 23(b)(3).

165. Adjudication of Plaintiffs and the other class members' claims are more fairly and efficiently adjudicated by a class action, as the claims for religious accommodation and exemption from the Federal COVID-19 Vaccine Mandate are virtually identical among all class members, the relevant facts applicable to each individual class member are substantially similar, and the applicable substantive law for the class members' claims is identical in all respects. Fed. R. Civ. P. 23(b)(3).

COUNT I – VIOLATION OF THE EMERGENCY USE AUTHORIZATION PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3

166. Plaintiffs hereby reallege and adopt each and every allegation in paragraphs 1-165 as if fully set forth herein.

167. The Federal Food, Drug, And Cosmetic Act provides that

> **subject to the provisions of this section**, the Secretary (of the Department of Health and Human Services) may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use."

21 U.S.C. § 360bbb-3(a)(1) (emphasis added).

168. For ease of reference, Plaintiffs will refer to the general provisions of 21 U.S.C. §360bbb-3 as the "Emergency Use Authorization Statute" or "EUA Statute."

169. The Emergency Use Authorization Statute further provides the limitations on when the Secretary may authorize the emergency use of an unapproved product for use in interstate commerce, and specifically limits such authorization to circumstances where the Secretary of Homeland Security has determined certain emergencies exits, where the Secretary of Defense has determined that certain military emergencies exist, where the Secretary of the Department of Health and Human services has determined that certain public health emergencies exist, and where there has been some identification of a material threat pursuant to other provisions of the United States Code. *See* 21 U.S.C. § 360bbb-3(b)(1)(A)-(D).

170. The Secretary's Emergency Use Authorization terminates whenever the circumstances described in 21 U.S.C. § 360bbb-3(b)(1)(A)-(D) cease to exist or where the product approved for Emergency Use under the statute receives a change in approval status. 21 U.S.C. § 360bbb-3(b)(2)(A)(i)-(ii).

171. As an essential part of the explicit statutory conditions for EUA**, the EUA Statute mandates that all individuals to whom the EUA product may be administered be given the option to accept or refuse administration of the product**:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> . . . .
>
> (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)–(III) (emphasis added).

172. Consistent with the requirement in the Emergency Use Authorization statute that all potential recipients of the COVID-19 vaccine be informed of the option to accept or refuse the vaccine, the Emergency Use Authorization Fact Sheet for all three of the currently available COVID-19 vaccines specifically states – **as required by the Emergency Use Authorization Statute** – that individuals have the right to refuse administration of the COVID-19 vaccine. A true and correct copy of the Emergency Use Authorization Fact Sheet for the Moderna COVID-19 Vaccine is attached hereto as EXHIBIT ## and incorporated herein. A true and correct copy of the Emergency Use Authorization Fact Sheet for the Pfizer- BioNTech COVID-19 Vaccine is attached hereto as EXHIBIT ## and incorporated herein. A true and correct copy of the Emergency Use Authorization Fact Sheet for the Janssen (Johnson & Johnson) COVID-19 Vaccine is attached hereto as EXHIBIT ## and incorporated herein.

173. Specifically, the Emergency Use Authorization Fact Sheets for all three COVID-19 vaccines state that it is the individual's right to refuse administration of the

vaccine. (*See* Exhibit H at 4 ("**It is your choice to receive or not to receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care**." (emphasis added)); Exhibit I at 5 ("**It is your choice to receive or not to receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care**." (emphasis added)); Exhibit J at 5 ("**It is your choice to receive or not to receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care**." (emphasis added))).)

174. "Congress has prohibited the administration of investigational drugs to service members without their consent." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004).

175. There is a very strict mechanism under which any military exception to the EUA statute may be deployed, and neither have occurred here.

176. First, the President can waive the informed consent requirement, but that Presidential waiver must be in writing and demonstrate that the President has determined "that obtaining consent is not in the interests of national security."

177. The strict criteria laid out in the statutory framework demonstrate the limited scope of the exceptions to the informed consent requirement. To start, the initial emergency declaration by the HHS Secretary must be based on one of four statutorily listed justifications – none of which apply here. The first requires the Secretary of Defense to find a **domestic emergency**, or significant potential for a

domestic emergency, based on heightened risk of attack with a **biological, chemical, radiological, or nuclear agent**. 21 U.S.C.A. § 360bbb–3(b)(1)(A) ("A "determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents.").

178. The second requires a finding that there is a **military emergency** involving a heightened risk to US military forces of an attack with a **biological, chemical, radiological, or nuclear agent**, or an agent that may cause an imminently life-threatening and specific risk to US military forces. 21 U.S.C. § 360bbb-3(b)(1)(B) ("A "determination by the Secretary of Defense that there is a **military emergency**, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of **attack with a biological, chemical, radiological, or nuclear agent or agents**; or an agent or agents that may cause, or are otherwise associated with, **an imminently life-threatening and specific risk** to United States military forces." (emphasis added)).

179. The third requires a finding that there is a public health emergency, or significant potential for a public health emergency that affects national security or the health and security of US citizens abroad that involves a **biological, chemical, radiological, or nuclear agent or a disease or condition attributable to one of those agents**. 21 U.S.C. §360bbb-3(b)(1)(C) (A "determination by the Secretary that there is

a **public health emergency**, or a significant potential for a public health emergency, **that affects**, or has a significant potential to affect, **national security** or the health and security of United States citizens living abroad, **and** that involves **a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents**." (emphasis added)).

180. The fourth requires the identification of a material threat involving **chemical, biological, radiological, and nuclear agents** sufficient to affect national security or the health and security of US citizens living abroad. 21 U.S.C. § 360bbb-3(b)(1)(D) ("The "identification of a **material threat** [involving chemical, biological, radiological, and nuclear agents] pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient **to affect national security** or the health and security of United States citizens living abroad." (emphasis added)).

181. Under the above statute, there is no legal basis on which the President may waive consent for the COVID-19 vaccines for the military. Indeed, he has not done so because he has no statutory authority under these facts to waive the EUA requirements for the military.

182. Even after the HHS Secretary establishes that one of the four criteria are satisfied, then under § 360bbb–3 the HHS Secretary then must make a separate determination that an "agent" referred to in the declaration can cause a serious or life-threatening disease or condition **and** that based on the scientific evidence available for the product authorized under the EUA (i) it may be effective in diagnosing, treating,

or preventing the disease or serious life-threatening disease, (ii) the known and potential benefits outweigh the risks; (iii) there is no adequate, approved, and available alternative to the product authorized under the EUA; (iv) **in the case of a military emergency based on a biological, chemical, radiological, or nuclear agent, the Secretary of Defense made the emergency use request**; and (v) other criteria established by regulation are satisfied.

183. None of the foregoing criteria has been satisfied.

184. Defendants have ignored their obligations under the EUA Statute.

185. There has been no Presidential declaration sufficient to invoke the consent exceptions of the EUA statute.

186. There has been no domestic emergency, military emergency, public health emergency, or material threat of a biological, chemical, radiological, or nuclear agent, or a disease attributable to one of those conditions.

187. As such, Defendants are prohibited by the EUA statute from mandating that any Plaintiffs or similarly situated military servicemembers receive or accept one of the COVID-19 vaccines.

188. Put simply, the Emergency Use Authorization Statute provides that, **as a condition of receiving authorization for emergency use, ALL individuals to whom the EUA product may be administered are given the right to accept or refuse administration of the product – and this includes members of the military. And, of**

course, the EUA right to accept or refuse applies and cannot be waived respecting the federal employees and federal civilian contractor Plaintiffs.

189. The only currently available COVID-19 vaccines (Janssen/Johnson & Johnson, Moderna, and Pfizer/BioNTech) are only authorized for use under the Emergency Use Authorization statute and have no general approval under the United States Code.

190. Because all three of the currently available COVID-19 vaccines are subject only to Emergency Use under the Emergency Use Authorization statute, the Emergency Use Authorization statute mandates that all individuals to whom the product may be administered, **including Plaintiffs**, be given the right to accept or refuse administration of the product.

191. Put simply, because all three of the currently available COVID-19 vaccines are subject only to Emergency Use under the Emergency Use Authorization statute, the Emergency Use Authorization statute prohibits Defendants from making the COVID-19 vaccines mandatory.

192. The Federal COVID-19 Vaccine Mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship on Plaintiffs' sincerely held religious beliefs.

193. Plaintiffs have no adequate remedy at law for the continuing deprivation of their most cherished constitutional liberties and sincerely held religious beliefs.

COUNT II – VIOLATION OF THE FIRST AMENDMENT TO THE UNITED STATES CONSTITUTION

194. Plaintiffs hereby reallege and adopt each and every allegation in paragraphs 1–165 above as if fully set forth herein.

195. The Free Exercise Clause of the First Amendment to the United States Constitution prohibits the government from abridging Plaintiffs' rights to free exercise of religion.

196. Plaintiffs have sincerely held religious beliefs that Scripture is the infallible, inerrant word of the Lord Jesus Christ, and that they are to follow its teachings.

197. Plaintiffs have and exercise sincerely held religious beliefs (articulated *supra* Section B) which compel them to abstain from receiving or accepting any of the currently available COVID-19 vaccines.

198. The Federal COVID-19 Vaccine Mandate, on its face and as applied, targets Plaintiffs' sincerely held religious beliefs by prohibiting Plaintiffs from seeking and receiving exemption and accommodation for their sincerely held religious beliefs against the COVID-19 vaccines.

199. The Federal COVID-19 Vaccine Mandate, on its face and as applied, impermissibly burdens Plaintiffs' sincerely held religious beliefs, compels Plaintiffs to either change those beliefs or act in contradiction to them, and forces Plaintiffs to choose between the teachings and requirements of their sincerely held religious beliefs in the commands of Scripture and the government's imposed value system.

200. The Federal COVID-19 Vaccine Mandate, on its face and as applied, places Plaintiffs in an irresolvable conflict between compliance with the mandate and their sincerely held religious beliefs.

201. The Federal COVID-19 Vaccine Mandate, on its face and as applied, puts substantial pressure on Plaintiffs to violate their sincerely held religious beliefs or face loss of their ability to feed their families.

202. The Federal COVID-19 Vaccine Mandate, on its face and as applied, is neither neutral nor generally applicable.

203. The Federal COVID-19 Vaccine Mandate, on its face and as applied, specifically targets Plaintiffs' religious beliefs for disparate and discriminatory treatment.

204. The Federal COVID-19 Vaccine Mandate, on its face and as applied, creates a system of individualized exemptions for preferred exemption requests while discriminating against requests for exemption and accommodation based on sincerely held religious beliefs. Regarding the federal employee and federal civilian contractor Plaintiffs, Defendant Biden imposed the Vaccine Mandate on them while exempting Congress, the Internal Revenue Service (IRS) and the United States Postal Service. Indeed, a certain husband and wife are both federal employees. One works for the IRS while the other works for the Veterans Administration (VA). Although husband and wife are working as federal employees, one is under the Vaccine Mandate, and one is not. The VA has used a simple one-page form on which an employee merely checks a box to request a religious exemption. Other federal employees are subject to a more

burdensome process or have received no guidance on submitting religious exemption requests. The civilian federal contractors face a deadline of November 22, but none have received any guidance on whether or where they might file a request for religious exemption and accommodation.

205. The Federal COVID-19 Vaccine Mandate, on its face and as applied, constitutes a religious gerrymander by unconstitutionally orphaning exemption and accommodation requests based solely on sincerely held religious beliefs of Plaintiffs while permitting the more favored medical exemptions to be granted.

206. The Federal COVID-19 Vaccine Mandate, on its face and as applied, constitutes a substantial burden on Plaintiffs' exercise of their sincerely held religious beliefs.

207. The Federal COVID-19 Vaccine Mandate, on its face and as applied, fails to accommodate Plaintiffs' sincerely held religious beliefs.

208. There is no legitimate, rational, or compelling interest in the Federal COVID-19 Vaccine Mandate's exclusion of exemptions and accommodations for sincerely held religious beliefs.

209. The Federal COVID-19 Vaccine Mandate is not the least restrictive means of achieving an otherwise permissible government interest.

210. The Federal COVID-19 Vaccine Mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship on Plaintiffs' sincerely held religious beliefs.

211. Plaintiffs have no adequate remedy at law to protect the continuing deprivation of their most cherished constitutional liberties and sincerely held religious beliefs.

WHEREFORE, Plaintiffs respectfully pray for relief against Defendant as hereinafter set forth in their prayer for relief

COUNT III - VIOLATION OF THE RELIGIOUS FREEDOM RESTORATION ACT, 42 U.S.C. § 2000bb-1, *et seq*.

212. Plaintiffs hereby reallege and adopt each and every allegation in paragraphs 1–165 above as if fully set forth herein.

213. The Religious Freedom Restoration Act (RFRA) provides that "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C. § 2000bb-1(a).

214. RFRA also demands that, should the government substantially burden a person's free exercise of religion, it bears the burden of demonstrating that its burden on religious exercise furthers a compelling government interest and is the least restrictive means of achieving that compelling government interest. 42 U.S.C. § 2000bb-1(b).

215. RFRA plainly applies to Defendants, as they constitute a "branch, department, agency, instrumentality, and official of the United States." 42 U.S.C. § 2000bb-2(1).

216. Congress enacted RFRA "to provide **very broad** protection for religious liberty," going "far beyond what [the Supreme Court] has held is constitutionally

required" under the First Amendment. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 693, 706 (2014) (emphasis added).

217. As such, RFRA encompasses a very broad definition of "exercise of religion," which includes "'any exercise of religion, whether or not compelled by, or central to, a system of religious belief.'" *Hobby Lobby*, 573 U.S. at 696 (quoting 42 U.S.C. § 2000bb—5(7)(A)).

218. RFRA mandated that the law "'be construed in favor of a broad protection of religious exercise, to the maximum extent permitted by the terms of this chapter and the Constitution.'" *Hobby Lobby*, 573 U.S. at 696 (quoting 42 U.S.C. § 2000cc—3(g)).

219. "RFRA operates as a kind of super statute, displacing the normal operation of other federal laws." *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1754 (2020).

220. Plaintiffs have sincerely held religious beliefs that Scripture is the infallible, inerrant word of the Lord Jesus Christ, and that they are to follow its teachings.

221. Plaintiffs have and exercise sincerely held religious beliefs (articulated *supra* Section B) which compel them to abstain from receiving or accepting any of the currently available COVID-19 vaccines.

222. The Federal COVID-19 Vaccine Mandate, on its face and as applied, targets Plaintiffs' sincerely held religious beliefs by prohibiting Plaintiffs from seeking and receiving exemption and accommodation for their sincerely held religious beliefs against the COVID-19 vaccines.

223. The Federal COVID-19 Vaccine Mandate, on its face and as applied, impermissibly burdens Plaintiffs' sincerely held religious beliefs, compels Plaintiffs to either change those beliefs or act in contradiction to them, and forces Plaintiffs to choose between the teachings and requirements of their sincerely held religious beliefs in the commands of Scripture and the government's imposed value system.

224. The Federal COVID-19 Vaccine Mandate, on its face and as applied, places Plaintiffs in an irresolvable conflict between compliance with the mandate and their sincerely held religious beliefs.

225. The Federal COVID-19 Vaccine Mandate, on its face and as applied, puts substantial pressure on Plaintiffs to violate their sincerely held religious beliefs or face loss of their ability to feed their families.

226. The Federal COVID-19 Vaccine Mandate, on its face and as applied, specifically targets Plaintiffs' religious beliefs for disparate and discriminatory treatment.

227. The Federal COVID-19 Vaccine Mandate, on its face and as applied, creates a system of individualized exemptions for preferred exemption requests while discriminating against requests for exemption and accommodation based on sincerely held religious beliefs.

228. The Federal COVID-19 Vaccine Mandate, on its face and as applied, constitutes a substantial burden on Plaintiffs' exercise of their sincerely held religious beliefs.

229. By forcing Plaintiffs into the unconscionable choice between violating their sincerely held religious convictions or facing dishonorable discharge, courts martial, termination, and other disciplinary measures, Defendants' mandate constitutes a substantial burden on Plaintiffs' exercise of religion.

230. The Federal COVID-19 Vaccine Mandate, on its face and as applied, fails to accommodate Plaintiffs' sincerely held religious beliefs.

231. There is no legitimate, rational, or compelling interest in the Federal COVID-19 Vaccine Mandate's exclusion of exemptions and accommodations for sincerely held religious beliefs.

232. The Federal COVID-19 Vaccine Mandate is not the least restrictive means of achieving an otherwise permissible government interest.

233. The Federal COVID-19 Vaccine Mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship on Plaintiffs' sincerely held religious beliefs.

234. Plaintiffs have no adequate remedy at law for the continuing deprivation of their most cherished constitutional liberties and sincerely held religious beliefs.

WHEREFORE, Plaintiffs respectfully pray for relief against Defendants as hereinafter set forth in their prayer for relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, respectfully pray for relief as follows:

A. That the Court issue a temporary restraining order restraining and enjoining Defendants and their officers, agents, employees, and attorneys, and all other persons in active concert or participation with them, from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Federal COVID-19 Vaccine Mandate such that:

i. Defendants will immediately comply with the Emergency Use Authorization Statute so that each individual has the "option to accept or refuse" administration of the COVID-19 vaccines as there is currently no FDA approved COVID-19 vaccine available to the population;

ii. Defendants will immediately cease in their refusal to consider, evaluate, or accept Plaintiffs' requests for exemption and accommodation for their sincerely held religious beliefs;

iii. Defendants' will immediately grant Plaintiffs' requests for religious exemption and accommodation from the Federal COVID-19 Vaccine Mandate; and

iv. Defendants will immediately cease any actions arising from or connected to the military servicemember Plaintiffs' religious exemption and accommodation requests, including current and ongoing punishment and threatening to dishonorably discharge, court martial, and impose other life-altering disciplinary actions

on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs;

v. Defendants will immediately cease any actions arising from or connected to the federal civilian employee and contractor Plaintiffs' religious exemption and accommodation requests, including demotion, termination, or other disciplinary actions on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs;

B. That the Court issue a preliminary injunction pending trial, and a permanent injunction upon judgment, restraining and enjoining Defendants and their officers, agents, employees, and attorneys, and all other persons in active concert or participation with them, from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Federal COVID-19 Vaccine Mandate such that:

i. Defendants will immediately comply with the Emergency Use Authorization Statute so that each individual has the "option to accept or refuse" administration of the COVID-19 vaccines as there is currently no FDA approved COVID-19 vaccine available to the population;

ii. Defendants will immediately cease in their refusal to consider, evaluate, or accept Plaintiffs' requests for exemption and accommodation for their sincerely held religious beliefs;

iii. Defendants' will immediately grant Plaintiffs' requests for religious exemption and accommodation from the Federal COVID-19 Vaccine Mandate; and

iv. Defendants will immediately cease any actions arising from or connected to the military servicemember Plaintiffs' religious exemption and accommodation requests, including current and ongoing punishment and threatening to dishonorably discharge, court martial, and impose other life-altering disciplinary actions on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs;

v. Defendants will immediately cease any actions arising from or connected to the federal civilian employee and contractor Plaintiffs' religious exemption and accommodation requests, including demotion, termination, or other disciplinary actions on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs;

C. That this Court render a declaratory judgment declaring that the Federal COVID-19 Vaccine Mandate, both on its face and as applied by Defendants, is illegal and unlawful in that it purports to remove federal civil rights and constitutional protections from military servicemembers and civilian federal employees and contractors, and further declaring—

i. the Federal COVID-19 Vaccine Mandate violates the federal Emergency Use Authorization provisions of the Federal Food, Drug, and Cosmetic Act by imposing a mandatory COVID-19 shot upon Plaintiffs without giving the "option to accept or refuse" the EUA product;

ii. the Federal COVID-19 Vaccine Mandate, without sufficient provision for exemption or accommodation for sincerely held religious beliefs, violates the First Amendment to the United States Constitution by imposing a substantial burden on Plaintiffs' sincerely held religious beliefs;

iii. the Federal COVID-19 Vaccine Mandate, without sufficient provision for exemption or accommodation for sincerely held religious beliefs, violates the federal Religious Freedom Restoration Act by imposing a substantial burden on Plaintiffs' sincerely held religious beliefs;

D. That this Court adjudge, decree, and declare the rights and other legal obligations and relations within the subject matter here in controversy so that such declaration shall have the full force and effect of final judgment;

E. That this Court retain jurisdiction over the matter for the purposes of enforcing the Court's order;

F. That this Court grant such other and further relief as the Court deems equitable and just under the circumstances.

Respectfully submitted,

/s/ Roger K. Gannam
Mathew D. Staver
Horatio G. Mihet
Roger K. Gannam
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rmast@lc.org*
*Application for Admission pro hac vice pending

Attorneys for Plaintiffs

VERIFICATION

I, NAVY SEAL 1, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ NAVY SEAL 1
NAVY SEAL 1
(Original Signature retained by Counsel)

VERIFICATION

I, NAVY SEAL 2, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ NAVY SEAL 2
NAVY SEAL 2
(Original Signature retained by Counsel)

VERIFICATION

I, NAVY EOD OFFICER, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ NAVY EOD OFFICER
NAVY EOD OFFICER
(Original Signature retained by Counsel)

VERIFICATION

I, NAVY CHIEF PETTY OFFICER, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ NAVY CHIEF PETTY OFFICER
NAVY CHIEF PETTY OFFICER
(Original Signature retained by Counsel)

VERIFICATION

I, NAVY CHAPLAIN, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ NAVY CHAPLAIN
NAVY CHAPLAIN
(Original Signature retained by Counsel)

VERIFICATION

I, LIEUTENANT COLONEL 1, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ LIEUTENANT COLONEL 1
LIEUTENANT COLONEL 1
(Original Signature retained by Counsel)

VERIFICATION

I, LIEUTENANT COLONEL 2, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ LIEUTENANT COLONEL 2
LIEUTENANT COLONEL 2
(Original Signature retained by Counsel)

VERIFICATION

I, USMC MAJOR, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ USMC MAJOR
USMC MAJOR
(Original Signature retained by Counsel)

VERIFICATION

I, CAPTAIN, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ CAPTAIN
CAPTAIN
(Original Signature retained by Counsel)

VERIFICATION

I, ARMY RANGER, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ ARMY RANGER
ARMY RANGER
(Original Signature retained by Counsel)

VERIFICATION

I, LANCE CORPORAL 1, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ LANCE CORPORAL 1
LANCE CORPORAL 1
(Original Signature retained by Counsel)

VERIFICATION

I, LANCE CORPORAL 2, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ LANCE CORPORAL 2
LANCE CORPORAL 2
(Original Signature retained by Counsel)

VERIFICATION

I, USMC LIEUTENANT, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ USMC LIEUTENANT
USMC LIEUTENANT
(Original Signature retained by Counsel)

VERIFICATION

I, Air Force MAJOR, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ Air Force MAJOR
Air Force MAJOR
(Original Signature retained by Counsel)

VERIFICATION

I, NATIONAL GUARDSMAN, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ NATIONAL GUARDSMAN
NATIONAL GUARDSMAN
(Original Signature retained by Counsel)

VERIFICATION

I, COAST GUARD LIEUTENANT, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ COAST GUARD LIEUTENANT
COAST GUARD LIEUTENANT
(Original Signature retained by Counsel)

VERIFICATION

I, COLONEL, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ COLONEL
COLONEL
(Original Signature retained by Counsel)

VERIFICATION

I, TECHNICAL SERGEANT, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ TECHNICAL SERGEANT
TECHNICAL SERGEANT
(Original Signature retained by Counsel)

VERIFICATION

I, DEFENSE DEPARTMENT CONTRACTOR, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ DEFENSE DEPARTMENT CONTRACTO
DEFENSE DEPARTMENT CONTRACTOR
(Original Signature retained by Counsel)

VERIFICATION

I, FEDERAL CIVILIAN ENGINEER CONTRACTOR, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ FEDERAL CIVILIAN ENGINEER CONTRACTOR
FEDERAL CIVILIAN ENGINEER CONTRACTOR
(Original Signature retained by Counsel)

VERIFICATION

I, FEDERAL CIVILIAN CONTRACTOR EMPLOYER, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ FEDERAL CIVILIAN CONTRACTOR EMPLOYER
FEDERAL CIVILIAN CONTRACTOR EMPLOYER
(Original Signature retained by Counsel)

VERIFICATION

I, FEDERAL NUCLEAR CONTRACTOR EMPLOYEE, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ FEDERAL NUCLEAR CONTRACTOR EMPLOYEE
FEDERAL NUCLEAR CONTRACTOR EMPLOYEE
(Original Signature retained by Counsel)

VERIFICATION

I, DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: October 15, 2021

/s/ DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH
DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH
(Original Signature retained by Counsel)

BRIEFING ROOM

Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees

SEPTEMBER 09, 2021 • PRESIDENTIAL ACTIONS

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 3301, 3302, and 7301 of title 5, United States Code, it is hereby ordered as follows:

Section 1. Policy. It is the policy of my Administration to halt the spread of coronavirus disease 2019 (COVID-19), including the B.1.617.2 (Delta) variant, by relying on the best available data and science-based public health measures. The Delta variant, currently the predominant variant of the virus in the United States, is highly contagious and has led to a rapid rise in cases and hospitalizations. The nationwide public health emergency, first declared by the Secretary of Health and Human Services on January 31, 2020, remains in effect, as does the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) declared pursuant to the National Emergencies Act in Proclamation 9994 of March 13, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak). The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services has determined that the best way to slow the spread of COVID-19 and to prevent infection by the Delta variant or other variants is to be vaccinated.

COVID-19 vaccines are widely available in the United States. They protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death. As of the date of this order, one of the COVID-19 vaccines, the Pfizer-BioNTech COVID-19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA), and two others, the Moderna COVID-19 Vaccine and the Janssen COVID-19 Vaccine, have been authorized by the FDA for emergency use. The FDA has determined that all three vaccines meet its rigorous standards for safety, effectiveness, and manufacturing quality.

The health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact, are foundational to the efficiency of the civil service. I have determined that ensuring the health and safety of the Federal workforce and the efficiency of

the civil service requires immediate action to protect the Federal workforce and individuals interacting with the Federal workforce. It is essential that Federal employees take all available steps to protect themselves and avoid spreading COVID-19 to their co-workers and members of the public. The CDC has found that the best way to do so is to be vaccinated.

The Safer Federal Workforce Task Force (Task Force), established by Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing), has issued important guidance to protect the Federal workforce and individuals interacting with the Federal workforce. Agencies have also taken important actions, including in some cases requiring COVID-19 vaccination for members of their workforce.

Accordingly, building on these actions, and in light of the public health guidance regarding the most effective and necessary defenses against COVID-19, I have determined that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID-19 vaccination for all Federal employees, subject to such exceptions as required by law.

Sec. 2. Mandatory Coronavirus Disease 2019 Vaccination for Federal Employees. Each agency shall implement, to the extent consistent with applicable law, a program to require COVID-19 vaccination for all of its Federal employees, with exceptions only as required by law. The Task Force shall issue guidance within 7 days of the date of this order on agency implementation of this requirement for all agencies covered by this order.

Sec. 3. Definitions. For the purposes of this order:

(a) The term "agency" means an Executive agency as defined in 5 U.S.C. 105 (excluding the Government Accountability Office).

(b) The term "employee" means an employee as defined in 5 U.S.C. 2105 (including an employee paid from nonappropriated funds as referenced in 5 U.S.C. 2105(c)).

Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or

circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

JOSEPH R. BIDEN JR.

THE WHITE HOUSE,
September 9, 2021.

BRIEFING ROOM

Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors

SEPTEMBER 09, 2021 • PRESIDENTIAL ACTIONS

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Property and Administrative Services Act, 40 U.S.C. 101 *et seq*., and section 301 of title 3, United States Code, and in order to promote economy and efficiency in procurement by contracting with sources that provide adequate COVID-19 safeguards for their workforce, it is hereby ordered as follows:

Section 1. Policy. This order promotes economy and efficiency in Federal procurement by ensuring that the parties that contract with the Federal Government provide adequate COVID-19 safeguards to their workers performing on or in connection with a Federal Government contract or contract-like instrument as described in section 5(a) of this order. These safeguards will decrease the spread of COVID-19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government. Accordingly, ensuring that Federal contractors and subcontractors are adequately protected from COVID-19 will bolster economy and efficiency in Federal procurement.

Sec. 2. Providing for Adequate COVID-19 Safety Protocols for Federal Contractors and Subcontractors. (a) Executive departments and agencies, including independent establishments subject to the Federal Property and Administrative Services Act, 40 U.S.C. 102(4)(A) (agencies), shall, to the extent permitted by law, ensure that contracts and contract-like instruments (as described in section 5(a) of this order) include a clause that the contractor and any subcontractors (at any tier) shall incorporate into lower-tier subcontracts. This clause shall specify that the contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force (Task Force Guidance or Guidance), provided that the Director of the Office of Management and Budget (Director) approves the Task Force Guidance and determines that the Guidance, if adhered to by contractors or subcontractors, will promote economy and efficiency in Federal contracting. This clause shall apply to any workplace locations (as specified by the Task Force Guidance) in which an individual is working on or in

connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order).

(b) By September 24, 2021, the Safer Federal Workforce Task Force (Task Force) shall, as part of its issuance of Task Force Guidance, provide definitions of relevant terms for contractors and subcontractors, explanations of protocols required of contractors and subcontractors to comply with workplace safety guidance, and any exceptions to Task Force Guidance that apply to contractor and subcontractor workplace locations and individuals in those locations working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order).

(c) Prior to the Task Force publishing new Guidance related to COVID-19 for contractor or subcontractor workplace locations, including the Guidance developed pursuant to subsection (b) of this section, the Director shall, as an exercise of the delegation of my authority under the Federal Property and Administrative Services Act, *see* 3 U.S.C. 301, determine whether such Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. Upon an affirmative determination by the Director, the Director's approval of the Guidance, and subsequent issuance of such Guidance by the Task Force, contractors and subcontractors working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order), shall adhere to the requirements of the newly published Guidance, in accordance with the clause described in subsection (a) of this section. The Director shall publish such determination in the *Federal Register*.

(d) Nothing in this order shall excuse noncompliance with any applicable State law or municipal ordinance establishing more protective safety protocols than those established under this order or with any more protective Federal law, regulation, or agency instructions for contractor or subcontractor employees working at a Federal building or a federally controlled workplace.

(e) For purposes of this order, the term "contract or contract-like instrument" shall have the meaning set forth in the Department of Labor's proposed rule, "Increasing the Minimum Wage for Federal Contractors, " 86 Fed. Reg. 38816, 38887 (July 22, 2021). If the Department of Labor issues a final rule relating to that proposed rule, that term shall have the meaning set forth in that final rule.

Sec. 3. Regulations and Implementation. (a) The Federal Acquisition Regulatory Council, to the extent permitted by law, shall amend the Federal Acquisition Regulation to provide for inclusion in Federal procurement solicitations and contracts subject to this order the clause described in section 2(a) of this order, and shall, by October 8, 2021, take initial steps to implement appropriate policy direction to acquisition offices for use of the clause by recommending that agencies exercise their authority under subpart 1.4 of the Federal Acquisition Regulation.

(b) By October 8, 2021, agencies shall take steps, to the extent permitted by law, to exercise any applicable authority to ensure that contracts and contract-like instruments as described in section 5(a) of this order that are not subject to the Federal Acquisition Regulation and that are entered into on or after October 15, 2021, consistent with the effective date of such agency action, include the clause described in section 2(a) of this order.

Sec. 4. Severability. If any provision of this order, or the application of any provision of this order to any person or circumstance, is held to be invalid, the remainder of this order and its application to any other person or circumstance shall not be affected thereby.

Sec. 5. Applicability. (a) This order shall apply to any new contract; new contract-like instrument; new solicitation for a contract or contract-like instrument; extension or renewal of an existing contract or contract-like instrument; and exercise of an option on an existing contract or contract-like instrument, if:

(i) it is a procurement contract or contract-like instrument for services, construction, or a leasehold interest in real property;

(ii) it is a contract or contract-like instrument for services covered by the Service Contract Act, 41 U.S.C. 6701 *et seq*.;

(iii) it is a contract or contract-like instrument for concessions, including any concessions contract excluded by Department of Labor regulations at 29 C.F.R. 4.133(b); or

(iv) it is a contract or contract-like instrument entered into with the Federal Government in connection with Federal property or lands and related to offering services for Federal employees, their dependents, or the general public;

(b) This order shall not apply to:

(i) grants;

(ii) contracts, contract-like instruments, or agreements with Indian Tribes under the Indian Self-Determination and Education Assistance Act (Public Law 93-638), as amended;

(iii) contracts or subcontracts whose value is equal to or less than the simplified acquisition threshold, as that term is defined in section 2.101 of the Federal Acquisition Regulation;

(iv) employees who perform work outside the United States or its outlying areas, as those terms are defined in section 2.101 of the Federal Acquisition Regulation; or

(v) subcontracts solely for the provision of products.

Sec. 6. Effective Date. (a) Except as provided in subsection (b) of this section, this order is effective immediately and shall apply to new contracts; new contract-like instruments; new solicitations for contracts or contract-like instruments; extensions or renewals of existing contracts or contract-like instruments; and exercises of options on existing contracts or contract-like instruments, as described in section 5(a) of this order, where the relevant

contract or contract-like instrument will be entered into, the relevant contract or contract-like instrument will be extended or renewed, or the relevant option will be exercised, on or after:

(i) October 15, 2021, consistent with the effective date for the action taken by the Federal Acquisition Regulatory Council pursuant to section 3(a) of this order; or

(ii) for contracts and contract-like instruments that are not subject to the Federal Acquisition Regulation and where an agency action is taken pursuant to section 3(b) of this order, October 15, 2021, consistent with the effective date for such action.

(b) As an exception to subsection (a) of this section, where agencies have issued a solicitation before the effective date for the relevant action taken pursuant to section 3 of this order and entered into a new contract or contract-like instrument resulting from such solicitation within 30 days of such effective date, such agencies are strongly encouraged to ensure that the safety protocols specified in section 2 of this order are applied in the new contract or contract-like instrument. But if that contract or contract-like instrument term is subsequently extended or renewed, or an option is subsequently exercised under that contract or contract-like instrument, the safety protocols specified in section 2 of this order shall apply to that extension, renewal, or option.

(c) For all existing contracts and contract-like instruments, solicitations issued between the date of this order and the effective dates set forth in this section, and contracts and contract-like instruments entered into between the date of this order and the effective dates set forth in this section, agencies are strongly encouraged, to the extent permitted by law, to ensure that the safety protocols required under those contracts and contract-like instruments are consistent with the requirements specified in section 2 of this order.

Sec. 7. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

JOSEPH R. BIDEN JR.

THE WHITE HOUSE,

September 9, 2021.

Safer Federal Workforce Task Force
COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors
Issued September 24, 2021

Introduction

On September 9, President Biden announced his Path Out of the Pandemic: COVID-19 Action Plan. One of the main goals of this science-based plan is to get more people vaccinated. As part of that plan, the President signed Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, ("the order") which directs executive departments and agencies, including independent establishments subject to the Federal Property and Administrative Services Act, 40 U.S.C. § 102(4)(A), to ensure that covered contracts and contract-like instruments include a clause ("the clause") that the contractor and any subcontractors (at any tier) shall incorporate into lower-tier subcontracts. This clause shall specify that the contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force ("Task Force"), provided that the Director of the Office of Management and Budget ("OMB") approves the Task Force Guidance (the or this "Guidance") and determines that the Guidance, if adhered to by covered contractors, will promote economy and efficiency in Federal contracting.

The actions directed by the order will ensure that parties who contract with the Federal Government provide COVID-19 safeguards in workplaces with individuals working on or in connection with a Federal Government contract or contract-like instrument. These workplace safety protocols will apply to all covered contractor employees, including contractor or subcontractor employees in covered contractor workplaces who are not working on a Federal Government contract or contract-like instrument. These safeguards will decrease the spread of SARS-CoV-2, the virus that causes COVID-19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors performing work for the Federal Government.

Pursuant to this Guidance, and in addition to any requirements or workplace safety protocols that are applicable because a contractor or subcontractor employee is present at a Federal workplace, Federal contractors and subcontractors with a covered contract will be required to conform to the following workplace safety protocols:

1. COVID-19 vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation;
2. Compliance by individuals, including covered contractor employees and visitors, with the Guidance related to masking and physical distancing while in covered contractor workplaces; and
3. Designation by covered contractors of a person or persons to coordinate COVID-19 workplace safety efforts at covered contractor workplaces.

The order also sets out a process for OMB and the Safer Federal Workforce Task Force to update the Guidance for covered contractors, which the Task Force will consider doing based on future changes to Centers for Disease Control and Prevention ("CDC") COVID-19 guidance and as warranted by the circumstances of the pandemic and public health conditions. It also sets out a process for the Federal Acquisition Regulatory Council ("FAR Council") to implement such protocols and guidance for covered Federal procurement solicitations and contracts subject to the Federal Acquisition Regulation ("FAR") and for agencies that are responsible for covered contracts and contract-like instruments not subject to the FAR to take prompt action to ensure that those covered contracts and contract-like instruments include the clause, consistent with the order.

Covered contractors shall adhere to the requirements of this Guidance. The Director of OMB has, as authorized by Executive Order 14042, approved this Guidance and has, an exercise of the delegation of authority (see 3 U.S.C. § 301) under the Federal Property and Administrative Services Act determined that this Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. The Director has published such determination in the Federal Register.

Definitions

Community transmission – means the level of community transmission as set forth in the CDC COVID-19 Data Tracker County View.

Contract and contract-like instrument – has the meaning set forth in the Department of Labor's proposed rule, "Increasing the Minimum Wage for Federal Contractors," 86 Fed. Reg. 38,816, 38,887 (July 22, 2021). If the Department of Labor issues a final rule relating to that proposed rule, this term shall have the meaning set forth in that final rule.

That proposed rule defines a contract or contract-like instrument as an agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law. This definition includes, but is not limited to, a mutually binding legal relationship obligating one party to furnish services (including construction) and another party to pay for them. The term contract includes all contracts and any subcontracts of any tier thereunder, whether negotiated or advertised, including any procurement actions, lease agreements, cooperative agreements, provider agreements, intergovernmental service agreements, service agreements, licenses, permits, or any other type of agreement, regardless of nomenclature, type, or particular form, and whether entered into verbally or in writing. The term contract shall be interpreted broadly as to include, but not be limited to, any contract within the definition provided in the FAR at 48 CFR chapter 1 or applicable Federal statutes. This definition includes, but is not limited to, any contract that may be covered under any Federal procurement statute. Contracts may be the result of competitive bidding or awarded to a single source under applicable authority to do so. In addition to bilateral instruments, contracts include, but are not limited to, awards and notices of awards; job orders or task letters issued under basic ordering agreements; letter contracts; orders, such as purchase orders, under which the contract becomes effective by written acceptance or performance; exercised contract options; and bilateral contract modifications. The term contract includes contracts covered by the Service Contract Act, contracts covered by the Davis-Bacon Act, concessions contracts not otherwise subject to the Service Contract Act, and contracts in connection with Federal property or land and related to offering services for Federal employees, their dependents, or the general public.

Contractor or subcontractor workplace location – means a location where covered contract employees work, including a covered contractor workplace or Federal workplace.

Covered contract – means any contract or contract-like instrument that includes the clause described in Section 2(a) of the order.

Covered contractor – means a prime contractor or subcontractor at any tier who is party to a covered contract.

Covered contractor employee – means any full-time or part-time employee of a covered contractor working on or in connection with a covered contract or working at a covered

contractor workplace. This includes employees of covered contractors who are not themselves working on or in connection with a covered contract.

Covered contractor workplace – means a location controlled by a covered contractor at which any employee of a covered contractor working on or in connection with a covered contract is likely to be present during the period of performance for a covered contract. A covered contractor workplace does not include a covered contractor employee's residence.

Federal workplace – means any place, site, installation, building, room, or facility in which any Federal executive department or agency conducts official business, or is within an executive department or agency's jurisdiction, custody, or control.

Fully vaccinated – People are considered fully vaccinated for COVID-19 two weeks after they have received the second dose in a two-dose series, or two weeks after they have received a single-dose vaccine. There is currently no post-vaccination time limit on fully vaccinated status; should such a limit be determined by the Centers for Disease Control and Prevention, that limit will be considered by the Task Force and OMB for possible updating of this Guidance.

For purposes of this Guidance, people are considered fully vaccinated if they have received COVID-19 vaccines currently approved or authorized for emergency use by the U.S. Food and Drug Administration (Pfizer-BioNTech, Moderna, and Johnson & Johnson [J&J]/Janssen COVID-19 vaccines) or COVID-19 vaccines that have been listed for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford). More information is available at Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.

Clinical trial participants from a U.S. site who are documented to have received the full series of an "active" (not placebo) COVID-19 vaccine candidate, for which vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board), can be considered fully vaccinated two weeks after they have completed the vaccine series. Currently, the Novavax COVID-19 vaccine meets these criteria. More information is available at the CDC website here.

Mask – means any mask that is consistent with CDC recommendations as set forth in Types of Masks and Respirators | CDC. This may include the following: disposable masks, masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face), masks made with breathable fabric (such as cotton), masks made with tightly woven fabric (i.e., fabrics that do not let light pass through when held up to a light source), masks with two or three layers, masks with inner filter pockets, and filtering facepiece respirators that are approved by the National Institute for Occupational Safety and Health or consistent with international standards. The following do not constitute masks for purposes of this Guidance: masks with exhalation valves, vents, or other openings; face shields only (without mask); or masks with single-layer fabric or thin fabric that does not block light.

Guidance

Covered contractors are responsible for ensuring that covered contractor employees comply with the workplace safety protocols detailed below. Covered contractor employees must also comply with agency COVID-19 workplace safety requirements while in Federal workplaces.

Consistent with applicable law, agencies are strongly encouraged to incorporate a clause requiring compliance with this Guidance into contracts that are not covered or directly addressed by the order because the contract is under the Simplified Acquisition Threshold as defined in section 2.101 of the FAR or is a contract or subcontract for the manufacturing of products. Agencies are also strongly encouraged to incorporate a clause requiring compliance with this Guidance into existing contracts and contract-like instruments prior to the date upon which the order requires inclusion of the clause.

1. *Vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation*

Covered contractors must ensure that all covered contractor employees are fully vaccinated for COVID-19, unless the employee is legally entitled to an accommodation. Covered contractor employees must be fully vaccinated no later than December 8, 2021. After that date, all covered contractor employees must be fully vaccinated by the first day of the period of performance on a newly awarded covered contract, and by the first day of the period of performance on an exercised option or extended or renewed contract when the clause has been incorporated into the covered contract.

A covered contractor may be required to provide an accommodation to covered contractor employees who communicate to the covered contractor that they are not vaccinated against COVID-19 because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer. Requests for "medical accommodation" or "medical exceptions" should be treated as requests for a disability accommodation.

Should a Federal agency have an urgent, mission-critical need for a covered contractor to have covered contractor employees begin work on a covered contract or at a covered workplace before becoming fully vaccinated, the agency head may approve an exception for the covered contractor —in the case of such limited exceptions, the covered contractor must ensure these covered contractor employees are fully vaccinated within 60 days of beginning work on a covered contract or at a covered workplace. The covered contractor must further ensure that such employees comply with masking and physical distancing requirements for not fully vaccinated individuals in covered workplaces prior to being fully vaccinated.

The covered contractor must review its covered employees' documentation to prove vaccination status. Covered contractors must require covered contractor employees to show or provide their

employer with one of the following documents: a copy of the record of immunization from a health care provider or pharmacy, a copy of the COVID-19 Vaccination Record Card (CDC Form MLS-319813_r, published on September 3, 2020), a copy of medical records documenting the vaccination, a copy of immunization records from a public health or State immunization information system, or a copy of any other official documentation verifying vaccination with information on the vaccine name, date(s) of administration, and the name of health care professional or clinic site administering vaccine. Covered contractors may allow covered contractor employees to show or provide to their employer a digital copy of such records, including, for example, a digital photograph, scanned image, or PDF of such a record.

The covered contractor shall ensure compliance with the requirements in this Guidance related to the showing or provision of proper vaccination documentation.

Covered contractors are strongly encouraged to incorporate similar vaccination requirements into their non-covered contracts and agreements with non-covered contractors whose employees perform work at covered contractor workplaces but who do not work on or in connection with a Federal contract, such as those contracts and agreements related to the provision of food services, onsite security, or groundskeeping services at covered contractor workplaces.

2. *Requirements related to masking and physical distancing while in covered contractor workplaces*

Covered contractors must ensure that all individuals, including covered contractor employees and visitors, comply with published CDC guidance for masking and physical distancing at a covered contractor workplace, as discussed further in this Guidance.

In addition to the guidance set forth below, CDC's guidance for mask wearing and physical distancing in specific settings, including healthcare, transportation, correctional and detention facilities, and schools, must be followed, as applicable.

In areas of high or substantial community transmission, fully vaccinated people must wear a mask in indoor settings, except for limited exceptions discussed in this Guidance. In areas of low or moderate community transmission, fully vaccinated people do not need to wear a mask. Fully vaccinated individuals do not need to physically distance regardless of the level of transmission in the area.

Individuals who are not fully vaccinated must wear a mask indoors and in certain outdoor settings (see below) regardless of the level of community transmission in the area. To the extent practicable, individuals who are not fully vaccinated should maintain a distance of at least six feet from others at all times, including in offices, conference rooms, and all other communal and work spaces.

Covered contractors must require individuals in covered contractor workplaces who are required to wear a mask to:

- Wear appropriate masks consistently and correctly (over mouth and nose).
- Wear appropriate masks in any common areas or shared workspaces (including open floorplan office space, cubicle embankments, and conference rooms).
- For individuals who are not fully vaccinated, wear a mask in crowded outdoor settings or during outdoor activities that involve sustained close contact with other people who are not fully vaccinated, consistent with CDC guidance.

A covered contractor may be required to provide an accommodation to covered contractor employees who communicate to the covered contractor that they cannot wear a mask because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer.

Covered contractors may provide for exceptions to mask wearing and/or physical distancing requirements consistent with CDC guidelines, for example, when an individual is alone in an office with floor to ceiling walls and a closed door, or for a limited time when eating or drinking and maintaining appropriate distancing. Covered contractors may also provide exceptions for covered contractor employees engaging in activities in which a mask may get wet; high intensity activities where covered contractor employees are unable to wear a mask because of difficulty breathing; or activities for which wearing a mask would create a risk to workplace health, safety, or job duty as determined by a workplace risk assessment. Any such exceptions must be approved in writing by a duly authorized representative of the covered contractor to ensure compliance with this Guidance at covered contractor workplaces, as discussed further below.

Masked individuals may be asked to lower their masks briefly for identification purposes in compliance with safety and security requirements.

Covered contractors must check the CDC COVID-19 Data Tracker County View website for community transmission information in all areas where they have a covered contractor workplace at least weekly to determine proper workplace safety protocols. When the level of community transmission in the area of a covered contractor workplace increases from low or moderate to substantial or high, contractors and subcontractors should put in place more protective workplace safety protocols consistent with published guidelines. However, when the level of community transmission in the area of a covered contractor workplace is reduced from high or substantial to moderate or low, the level of community transmission must remain at that lower level for at least two consecutive weeks before the covered contractor utilizes those protocols recommended for areas of moderate or low community transmission.

3. *Designation by covered contractors of a person or persons to coordinate COVID-19 workplace safety efforts at covered contractor workplaces.*

Covered contractors shall designate a person or persons to coordinate implementation of and compliance with this Guidance and the workplace safety protocols detailed herein at covered contractor workplaces. The designated person or persons may be the same individual(s) responsible for implementing any additional COVID-19 workplace safety protocols required by local, State, or Federal law, and their responsibilities to coordinate COVID-19 workplace safety protocols may comprise some or all of their regular duties.

The designated individual (or individuals) must ensure that information on required COVID-19 workplace safety protocols is provided to covered contractor employees and all other individuals likely to be present at covered contractor workplaces, including by communicating the required workplace safety protocols and related policies by email, websites, memoranda, flyers, or other means and posting signage at covered contractor workplaces that sets forth the requirements and workplace safety protocols in this Guidance in a readily understandable manner. This includes communicating the COVID-19 workplace safety protocols and requirements related to masking and physical distancing to visitors and all other individuals present at covered contractor workplaces. The designated individual (or individuals) must also ensure that covered contractor employees comply with the requirements in this guidance related to the showing or provision of proper vaccination documentation.

Frequently Asked Questions

Vaccination and Safety Protocols

Q1: How do covered contractors determine vaccination status of visitors to covered contractor workplaces?

A: Covered contractors should post signage at entrances to covered contractor workplaces providing information on safety protocols for fully vaccinated and not fully vaccinated individuals, including the protocols defined in the masking and physical distancing section above, and instruct individuals to follow the appropriate workplace safety protocols while at the covered contractor workplace. Covered contractors may take other reasonable steps, such as by communicating workplace safety protocols to visitors prior to their arrival at a covered contractor workplace or requiring all visitors to follow masking and physical distancing protocols for not fully vaccinated individuals.

Q2: Do covered contractors need to provide onsite vaccinations to their employees?

A: Covered contractors should ensure their employees are aware of convenient opportunities to be vaccinated. Although covered contractors may choose to provide vaccinations at their facilities or workplaces, given the widespread availability of vaccinations, covered contractors are not required to do so.

Q3: What should a contractor employee do if a covered contractor employee has lost or does not have a copy of required vaccination documentation?

A: If covered contractor employees need new vaccination cards or copies of other documentation proof of vaccination, they should contact the vaccination provider site where they received their vaccine. Their provider should be able to provide them with new cards or documentation with up-to-date information about the vaccinations they have received. If the location where the covered contractor employees received their COVID-19 vaccine is no longer operating, the covered contractor employees should contact their State or local health department's immunization information system (IIS) for assistance. Covered contractor employees should contact their State or local health department if they have additional questions about vaccination cards or vaccination records.

An attestation of vaccination by the covered contractor employee is not an acceptable substitute for documentation of proof of vaccination.

Q4: Who is responsible for determining if a covered contractor employee must be provided an accommodation because of a disability or because of a sincerely held religious belief, practice, or observance?

A: A covered contractor may be required to provide an accommodation to contractor employees who communicate to the covered contractor that they are not vaccinated for COVID-19, or that they cannot wear a mask, because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer. The contractor is responsible for considering, and dispositioning, such requests for accommodations regardless of the covered contractor employee's place of performance. If the agency that is the party to the covered contract is a "joint employer" for purposes of compliance with the Rehabilitation Act and Title VII of the Civil Rights Act, both the agency and the covered contractor should review and consider what, if any, accommodation they must offer.

Q5: Are covered contractor employees who have a prior COVID-19 infection required to be vaccinated?

A: Yes, covered contractor employees who have had a prior COVID-19 infection are required to be vaccinated. More information from CDC can be found here.

Q6: Can a covered contractor accept a recent antibody test from a covered contractor employee to prove vaccination status?

A: No. A covered contractor cannot accept a recent antibody test from a covered contractor employee to prove vaccination status.

Workplaces

Q7: Does this Guidance apply to outdoor contractor or subcontractor workplace locations?

A: Yes, this Guidance applies to contractor or subcontractor workplace locations that are outdoors.

Q8: If a covered contractor employee is likely to be present during the period of performance for a covered contract on only one floor or a separate area of a building, site, or facility controlled by a covered contractor, do other areas of the building, site, or facility controlled by a covered contractor constitute a covered contractor workplace?

A: Yes, unless a covered contractor can affirmatively determine that none of its employees on another floor or in separate areas of the building will come into contact with a covered contractor employee during the period of performance of a covered contract. This would include affirmatively determining that there will be no interactions between covered contractor employees and non-covered contractor employees in those locations during the period of performance on a covered contract, including interactions through use of common areas such as lobbies, security clearance areas, elevators, stairwells, meeting rooms, kitchens, dining areas, and parking garages.

Q9: If a covered contractor employee performs their duties in or at only one building, site, or facility on a campus controlled by a covered contractor with multiple buildings, sites, or facilities, are the other buildings, sites, or facility controlled by a covered contractor considered a covered contractor workplace?

A: Yes, unless a covered contractor can affirmatively determine that none of its employees in or at one building, site, or facility will come into contact with a covered contractor employee during the period of performance of a covered contract. This would include affirmatively determining that there will be no interactions between covered contractor employees and non-covered contractor employees in those locations during the period of performance on a covered contract, including interactions through use of common areas such as lobbies, security clearance areas, elevators, stairwells, meeting rooms, kitchens, dining areas, and parking garages.

Q10: Are the workplace safety protocols enumerated above the same irrespective of whether the work is performed at a covered contractor workplace or at a Federal workplace?

A: Yes. The Guidance applies to all covered contractor employees and to all contractor or subcontractor workplace locations. While at a Federal workplace, covered contractor employees must also comply with any additional agency workplace safety requirements for that workplace. Because covered contractor employees working on a covered contract need to be fully vaccinated after December 8, 2021, covered contractor employees who work only at a Federal workplace need to be fully vaccinated by that date as well, unless legally entitled to an accommodation.

Q11: How does this Guidance apply to covered contractor employees who are authorized under the covered contract to perform work remotely from their residence?

A: An individual working on a covered contract from their residence is a covered contractor employee, and must comply with the vaccination requirement for covered contractor employees, even if the employee never works at either a covered contractor workplace or Federal workplace during the performance of the contract. A covered contractor employee's residence is not a covered contractor workplace, so while in the residence the individual need not comply with requirements for covered contractor workplaces, including those related to masking and physical distancing, even while working on a covered contract.

Scope and Applicability

Q12: By when must the requirements of the order be reflected in contracts?

A: Section 6 of the order lays out a phase-in of the requirements for covered contracts as follows:

- *Contracts awarded prior to October 15 where performance is ongoing* – the requirements must be incorporated at the point at which an option is exercised or an extension is made.
- *New contracts* – the requirements must be incorporated into contracts awarded on or after November 14. Between October 15 and November 14, agencies must include the clause in the solicitation and are encouraged to include the clause in contracts awarded during this time period but are not required to do so unless the solicitation for such contract was issued on or after October 15.

Q13: Must the order's requirements be flowed down to all lower-tier subcontractors and, if so, who is responsible for flowing the clause down?

A: Yes. The requirements in the order apply to subcontractors at all tiers, except for subcontracts solely for the provision of products. The prime contractor must flow the clause down to first-tier subcontractors; higher-tier subcontractors must flow the clause down to the next lower-tier subcontractor, to the point at which subcontract requirements are solely for the provision of products.

Q14: Does the Guidance apply to small businesses?

A: Yes, the requirement to comply with this Guidance applies equally to covered contractors regardless of whether they are a small business. This broad application of COVID-19 guidance will more effectively decrease the spread of COVID-19, which, in turn, will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at workplaces where they are performing work for the Federal Government.

Q15: What steps are being taken to promote consistent application of the order's requirements across agencies?

A: The FAR Council will conduct a rulemaking to amend the FAR to include a clause that requires covered contractors performing under FAR-based contracts to comply with this Guidance for contractor and subcontractor workplace locations. Prior to rulemaking, by October 8, 2021, the FAR Council will develop a clause and recommend that agencies exercise their authority to deviate from the FAR using the procedures set forth in subpart 1.4. Agencies responsible for contracts and contract-like instruments that are not subject to the FAR, such as concession contracts, will be responsible for developing appropriate guidance by October 8, 2021 to incorporate requirements into their covered instruments entered into on or after October 15, 2021.

Q16: If the Safer Federal Workforce Task Force updates this Guidance to add new requirements, do those requirements apply to existing contracts?

A: Yes. Covered contractors are required to, for the duration of the contract, comply with all Task Force Guidance for contractor or subcontractor workplace locations, including any new

Guidance where the OMB Director approves the Guidance and determines that adherence to the Guidance will promote economy and efficiency in Federal contracting. The Task Force and OMB plan to ensure any workplace safety protocols reflect what is necessary to decrease the spread of COVID-19.

Q17: What constitutes work performed "in connection with" a covered contract?

A: Employees who perform duties necessary to the performance of the covered contract, but who are not directly engaged in performing the specific work called for by the covered contract, such as human resources, billing, and legal review, perform work in connection with a Federal Government contract.

Q18: Do the workplace safety protocols in the Guidance apply to covered contractor employees who perform work outside the United States?

A: No. The workplace safety protocols in the Guidance do not apply to covered contractor employees who only perform work outside the United States or its outlying areas, as those terms are defined in section 2.101 of the FAR.

Compliance

Q19: Does this clause apply in States or localities that seek to prohibit compliance with any of the workplace safety protocols set forth in this Guidance?

A: Yes. These requirements are promulgated pursuant to Federal law and supersede any contrary State or local law or ordinance. Additionally, nothing in this Guidance shall excuse noncompliance with any applicable State law or municipal ordinance establishing more protective workplace safety protocols than those established under this Guidance.

Q20: Can a covered contractor comply with workplace safety requirements from the Occupational Safety and Health Administration, including pursuant to any current or forthcoming Emergency Temporary Standard related to COVID-19, instead of the requirements of this Guidance?

A: No. Covered contractors must comply with the requirements set forth in this Guidance regardless of whether they are subject to other workplace safety standards.

Q21: What is the prime contractor's responsibility for verifying that subcontractors are adhering to the mandate?

A: The prime contractor is responsible for ensuring that the required clause is incorporated into its first-tier subcontracts in accordance with the implementation schedule set forth in section 6 of the order. When the clause is incorporated into a subcontract, a subcontractor is required to

comply with this Guidance and the workplace safety protocols detailed herein. Additionally, first-tier subcontractors are expected to flow the clause down to their lower-tier subcontractors in similar fashion so that accountability for compliance is fully established throughout the Federal contract supply chain for covered subcontractor employees and workplaces at all tiers through application of the clause.

SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 24 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

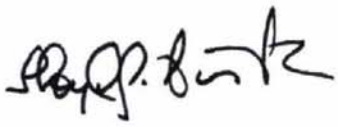
Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.

Mandatory vaccination requirements will be implemented consistent with DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019. The Military Departments should use existing policies and procedures to manage mandatory vaccination of Service members to the extent practicable. Mandatory vaccination of Service members will be subject to any identified contraindications and any administrative or other exemptions established in Military Department policy. The Military Departments may promulgate appropriate guidance to carry out the requirements set out above. The Under Secretary of Defense for Personnel and

Readiness may provide additional guidance to implement and comply with FDA requirements or Centers for Disease Control and Prevention recommendations.

The Secretaries of the Military Departments should impose ambitious timelines for implementation. Military Departments will report regularly on vaccination completion using established systems for other mandatory vaccine reporting.

Our vaccination of the Force will save lives. Thank you for your focus on this critical mission.



U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0 **BLA APPROVAL**

BioNTech Manufacturing GmbH August 23, 2021
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., (b) (4) and at Fresenius Kabi USA, LLC, (b) (4) .

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at Pharmacia & Upjohn Company LLC in Kalamazoo, Michigan, the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer Manufacturing Belgium NV in Puurs, Belgium, it is defined as the date of the (b) (4) Following the final sterile filtration, (b) (4) , no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

   Final Protocol Submission: February 8, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.
Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June 30, 2022

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

    Final Protocol Submission: March 22, 2021

    Study Completion: December 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

September 22, 2021

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd St
New York, NY 10017

Dear Mr. Patel:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act, 21 U.S.C. § 360bbb-3, February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] August 12, 2021,[7] and on August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA)[8] and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA).[9]

On September, 22 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 23, 2021 letter of authorization in its entirety with revisions incorporated to authorize for emergency use the administration of a single booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older;18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] COMIRNATY (COVID-19 Vaccine, mRNA) was approved for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

[9] In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[10]

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing Phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed that the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm that the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose

[10] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

(with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals for comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ

transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For the September 22, 2021 authorization of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 6 months after completing the primary series in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial in which 329 participants 18 through 75 years of age received a booster dose of the Pfizer-BioNTech COVID-19 Vaccine approximately 6 months (range 4.8 to 8.8 months) after completion of the primary series. FDA's review of the available safety data from 329 participants 18 through 75 years of age, who had been followed for a median of 2.6 months after receiving the booster dose, did not identify specific safety concerns that would preclude issuance of an EUA. The effectiveness of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine is based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). FDA's analysis of SARS-CoV-2 NT50 one month after the booster dose compared to 1 month after the primary series in study participants 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose confirmed noninferiority for both geometric mean ratio and difference in seroresponse rates. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a booster dose the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a single booster dose at least 6 months after completing the primary series outweigh the known and potential risks for individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of Pfizer-BioNTech COVID-19 Vaccine and of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine[11] for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative[12] Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[13]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[14] to emergency response stakeholders[15] as directed by the U.S.

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[11] In this section (Section I), references to Pfizer-BioNTech COVID-19 Vaccine also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

[12] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or to provide: an additional dose to the immunocompromised population, or a booster dose to the authorized population described in this EUA.

[13] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[14] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[15] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;

- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[16] and used only to prevent COVID-19 in individuals ages 12 and older with a two-dose regimen, to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, and to provide a single booster dose at least 6 months after completing the primary series of the vaccine to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Product Description[17]

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

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[16] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

[17] For COMIRNATY (COVID-19 Vaccine, mRNA) product description, please see the COMIRNATY (COVID-19 Vaccine, mRNA) prescribing information, found here: *https://www.fda.gov/media/151707/download*.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The dosing regimen is a primary series of two doses of 0.3 mL each, 3 weeks apart. A third primary series dose may be administered at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. A single booster dose (0.3 mL) may be administered at least 6 months after completing the primary series to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine,[18] when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a

[18] The conclusions supporting authorization stated in this Section (Section II) also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[19]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
   - Serious adverse events (irrespective of attribution to vaccination);
   - Cases of Multisystem Inflammatory Syndrome in children and adults; and
   - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

   These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and

[19] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), individuals that receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements

concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine.

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS
DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the Comirnaty vaccine, made by Pfizer-BioNTech, as a two-dose series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the Comirnaty vaccine. Per FDA guidance, these two vaccines are "interchangeable" and DoD health care providers should "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine."[1]

Consistent with FDA guidance, DoD health care providers will use both the Pfizer-BioNTech COVID-19 vaccine and the Comirnaty COVID-19 vaccine interchangeably for the purpose of vaccinating Service members in accordance with Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021.

My point of contact for this guidance is Colonel Michael J. Berecz, who may be reached at (703) 681-8463 or michael.j.berecz.mil@mail.mil.

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Terry Adirim, M.D., M.P.H., M.B.A.
Acting

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Joint Staff Surgeon

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[1] FDA, "Q&A for Comirnaty (COVID-19 Vaccine mRNA)," https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, accessed September 10, 2021.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, United States Navy, NAVY SEAL 2, United States Navy, EOD OFFICER, United States Navy, SENIOR CHIEF PETTY OFFICER, United States Navy, CHAPLAIN, United States Navy, LIEUTENANT COLONEL 1, United States Marine Corps, LIEUTENANT COLONEL 2, United States Marine Corps, MAJOR, United States Marine Corps, SECOND LIEUTENANT, United States Marine Corps, CAPTAIN, United States Marine Corps, ARMY RANGER, United States Army, LANCE CORPORAL 1, United States Marine Corps, LANCE CORPORAL 2, United States Marine Corps, MAJOR, UNITED STATES AIR FORCE, NATIONAL GUARDSMAN, Virginia Army National Guard, COAST GUARD LIEUTENANT, United States Coast Guard, COLONEL, United States Army, TECHNICAL SERGEANT, United States Air Force, DEFENSE DEPARTMENT CONTRACTOR, United States Department of Defense, FEDERAL CIVILIAN ENGINEER CONTRACTOR, FEDERAL CIVILIAN CONTRACTOR EMPLOYER, FEDERAL NUCLEAR CONTRACTOR EMPLOYEE, DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH, for themselves and all others similarly situated, Plaintiffs, v. JOSEPH R. BIDEN, in his official capacity as President of the United States, LLOYD AUSTIN, in his official capacity as Secretary of the United States Department of Defense, and ALEJANDRO MAYORKAS, in his official capacity as Secretary of the Department of Homeland Security, Defendants.	Case No. _____

DECLARATION OF DR. PETER MCCULLOUGH, MD, MPH IN SUPPORT OF PLAINTIFFS' PETITION FOR PRELIMINARY INJUNCTION

I, Dr. Peter McCullough, do hereby declare as follows:

1. I am over eighteen years of age, and I am not suffering under any mental disability and am competent to give this sworn declaration. I am able to read and write and to give this declaration voluntarily and on my own free will and accord. No one has used any threats, force, pressure, or intimidation to make me sign this affidavit. I understand that I am swearing or affirming under oath to the truthfulness of the claims made in this affidavit under penalties of perjury; that I have read these statements in this affidavit; and these statements are my understanding of the facts and that my opinion provided is based on a reasonable degree of medical certainty. I am working on this case Pro Bono; and have not been paid by anyone to provide this opinion. I am providing this declaration as I have serious, grave concerns for these municipal workers and the public-at-large.

2. I have personal knowledge and understanding of these matters and I make this affidavit in support of the truth of the contents contained herein. In short: I believe within a reasonable degree of medical certainty that the COVID-19 vaccine(s) are not safe generally. It is my belief based on a reasonable degree of medical certainty that the vaccine could cause the death of the Plaintiffs. I believe within a reasonable degree of medical certainty that the data upon which the City of

Gainesville has based its mandate upon is flawed and/or inaccurate; and imposing this vaccine is not only dangerous and could cause harm to the Plaintiffs, but to the public-at-large who depend on first responders and critical infrastructure workers. In support, I submit the following for the Court's consideration:

3. Attached to this Declaration as **EXHIBIT 1** is my Curriculum Vitae. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health in the field of epidemiology at The University of Michigan. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I participate in the maintenance of certification programs by the American Board of Internal Medicine for both Internal Medicine and Cardiovascular Diseases. I am an active scholar in medicine with roles as an author, editor-in-chief of a peer-reviewed journals, editorialist, and reviewer at dozens of major medical journals and textbooks.

4. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont

School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of in vitro natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of antidiabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

5. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my

work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in *Braunwald's Heart Disease Textbook*. My works have appeared in the *New England Journal of Medicine*, *Journal of the American Medical Association*, and other top-tier journals worldwide. I am a senior associate editor of the *American Journal of Cardiology*. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, The New Hampshire Senate, the Colorado House of Commons, and the Texas Senate Committee on Health and Human Services. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, the Cardiorenal Society of America, and the National Kidney Foundation; and I am also a Diplomate of the American Board of Clinical Lipidology. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am a founding member of Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease. I am the current President of the Cardiorenal

Society of America, an expert organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the former Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the Editor-in-Chief of Reviews in Cardiovascular Medicine, a widely read journal that publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

6. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the American Journal of Medicine and updated in *Reviews in Cardiovascular Medicine*. I have 47 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for *The Hill* in 2020. Starting in 2021, I publish a weekly contribution on *America Out Loud, The McCullough Report.* I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19,

2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 at the Colorado General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 18 months old with the review of hundreds of manuscripts and with the care of many patients with acute COVID-19, post-COVID-19 long-hauler syndromes, and COVID-19 vaccine injury syndromes including neurologic damage, myocarditis, and a variety of other internal medicine problems that have occurred after the mRNA and adenoviral DNA COVID-19 vaccines. I have formed my opinions in close communications with many clinicians around the world based on in part our collective clinical experience with acute and convalescent COVID-19 cases as well as closely following the preprint and published literature on the outbreak. I have specifically reviewed key published rare cases and reports concerning the possible recurrence of SARS- CoV-2 in patients who have survived an initial episode of COVID-19 illness. See attached Curriculum Vitae.

As to my Expert Opinion

7. The CDC recently reported the lowest number of cases since March of 2020 (the beginning of the COVID-19 pandemic). Sam Baker & Andrew

Witherspoon, COVID-19 cases hit lowest point in U.S. since pandemic began, AXIOS (June 3, 2021),[1]

8. Further, according to my research, herd immunity is calculated by a specific formula, as follows: ((CC*6) + V + (.15*P)) ÷ P = HIN.

CC= COVID-19 cases
in the state 6= the
current CDC multiplier
V= number of vaccinated in the state
15% = the number of people in a given state that will not get COVID-19 P=Population of a state
HIN=Herd Immunity Totals

By this method of calculation, the United States has achieved herd immunity meaning that the total of this calculation exceeds 100%. As vaccines continue to fail, we can expect cases of COVID-19 and the meaning of herd immunity applies to spread. Despite expected incidents and prevalent cases, my opinion is that spread will be minimized and there will be no more large outbreak curves as the country experienced in November through early January before the advent of widely deployed early treatment protocols. Because the randomized trials of all COVID-19 vaccines revealed < 1% absolute risk reductions, and the recent observation of widespread failure of COVID-19 vaccines in countries such as Israel which has a substantial population vaccinated early the pandemic, we can expect more vaccine

[1] https://www.axios.com/coronavirus-cases-infections-vaccines-success-fa7673a1-0582- 4e69-aefb-3b5170268048.html

failures in the United States and no fundamental impact of mass vaccination on the epidemic curves.

Table 1: COVID-19 Deaths by Age Group in the U.S. as of June 27, 2021: Source: https://COVID-19.cdc.gov/COVID-19-data-tracker/#demographics

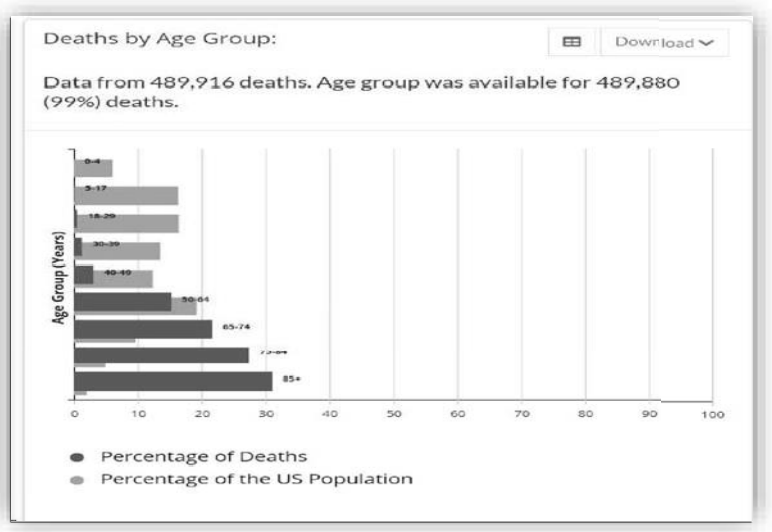
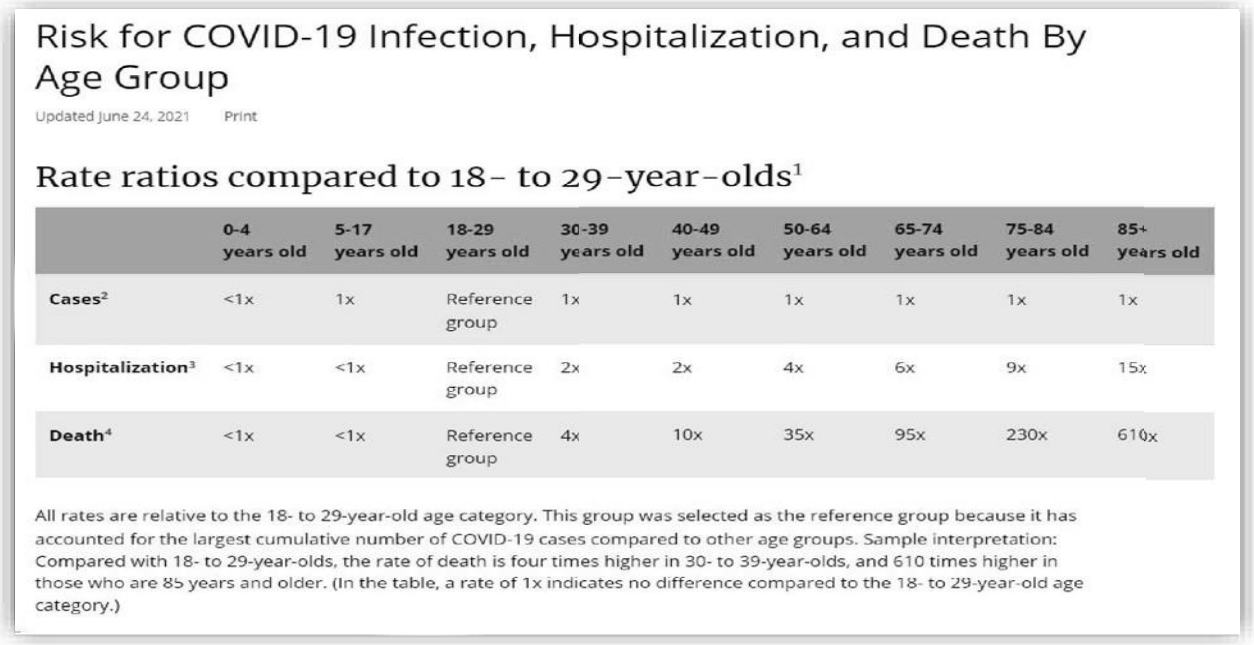


Table 2: COVID-19 Rate Ratios by Age.[2]

[2]https://www.cdc.gov/coronavirus/2019-ncov/COVID-19-data/investigations-discovery/hospitalizationdeath-by-age.html



Risk for COVID-19 Infection, Hospitalization, and Death By Age Group

Updated June 24, 2021 Print

Rate ratios compared to 18- to 29-year-olds[1]

	0-4 years old	5-17 years old	18-29 years old	30-39 years old	40-49 years old	50-64 years old	65-74 years old	75-84 years old	85+ years old
Cases[2]	<1x	1x	Reference group	1x	1x	1x	1x	1x	1x
Hospitalization[3]	<1x	<1x	Reference group	2x	2x	4x	6x	9x	15x
Death[4]	<1x	<1x	Reference group	4x	10x	35x	95x	230x	610x

All rates are relative to the 18- to 29-year-old age category. This group was selected as the reference group because it has accounted for the largest cumulative number of COVID-19 cases compared to other age groups. Sample interpretation: Compared with 18- to 29-year-olds, the rate of death is four times higher in 30- to 39-year-olds, and 610 times higher in those who are 85 years and older. (In the table, a rate of 1x indicates no difference compared to the 18- to 29-year-old age category.)

9. There is negligible risk for adults younger than the age of 60. For example, for each 18-29-year-old that dies from COVID-19, four 30-39 year old individuals die, ten 40-49-year-olds, thirty-five 50-64-year-olds die, ninety-five 65-74-year-olds die, 230 75-84-year-olds die, and 610 over 85 years of age die. See Table 2.

10. In my expert medical opinion, the epidemic spread of COVID-19, like all other respiratory viruses, notably influenza, is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential.

11. A meta-analysis of contact tracing studies published in The Journal of the American Medical Association showed asymptomatic COVID-19 spread was negligible at 0.7%. Zachary J. Madewell, Ph.D.; Yang Yang, Ph.D.; Ira M. Longini Jr, Ph.D.; M. Elizabeth Halloran, MD, DSc; Natalie E. Dean, Ph.D., Household

Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis, JAMA Network Open.[3] Accordingly, a rational and ethical prevention measure to reduce the spread of COVID-19 is a simple requirement, as part of formal policies, that persons with active symptomatic, febrile (feverish) respiratory illnesses, like COVID-19, should isolate themselves. Indeed, during the H1N1 influenza A pandemic, fully open, unmasked college campuses were advised by federal health officials, "Flu-stricken college students should stay out of circulation" and "if they can't avoid contact they need to wear surgical masks."[4]

Advances in COVID-19 Treatments

12. Even if the virus is contracted, the treatment of the infection has improved tremendously since the advent of COVID-19. Studies have shown several different treatment methods, which have proven effective. A combination of medications, supported by the Association of American Physicians and Surgeons, for a minimum of five days and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability) has proven effective. Brian C Procter, Casey Ross, Vanessa Pickard, Erica Smith, Cortney Hanson, Peter A McCullough, Clinical outcomes after early

[3] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited June 20, 2021).
[4] Great Falls Tribune, Advice: Flu-stricken college students should stay out of circulation, August 21, 2009, page 5, section A, available at https://www.newspapers.com/image/243611045

ambulatory multidrug therapy for high-risk SARS-CoV-2 (COVID-19) infection,[5] summarized in Table 3 below. This approach has resulted in an ~85% reduction in hospitalization and death in high-risk individuals presenting with COVID-19[6]:

Table 3: COVID-19 Treatments

Agent (drug)	Rationale
Zinc	Inhibits SARS-CoV-2 RNA synthesis
Hydroxychloroquine 200 mg po bid	Inhibits endosomal transfer of virions, anti-inflammatory
Ivermectin (200 mcg/kg) usual dose	Attenuates importin á/â-mediated nuclear12 mg po qd x 3 days transport of SARS-CoV-2 into nucleus
Azithromycin 250 mg po bid	Covers respiratory bacterial pathogens insecondary infection
Doxycycline 100 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Inhaled budesonide, Dexamethasone 8 mg IM	Treats cytokine storm
Folate, thiamine, vitamin B-12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion

13. I, along with my colleagues, conducted the study referenced in paragraph 23, which evaluated patients between the ages of 12 and 89 years. The average age was 50.5 and 61.6% were women. The study found that primary care physicians can

[5] Reviews in Cardiovascular Medicine (December 30, 2021), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited June 26, 2021)
[6] https://ijirms.in/index.php/ijirms/article/view/1100

treat COVID-19 patients resulting in rates of hospitalization and death. The study showed that administration of the medicines and supplements shown in Table 3 produces a less than 2% chance of facing hospitalization or death among high-risk adults (age over 50 with medical problems). As this study was done with mainly higher-risk patients at the peak of the pandemic, this is a highly successful treatment plan and just one of the many new treatments that have been used in the last year including those admitted for COVID-19 which are covered in the NIH COVID-19 Guidelines. Id.; see also National Institutes of Health, Therapeutic Management of Adults With COVID-19 (Updated May 24, 2021), https://www.COVID-1919treatmentguidelines.nih.gov/management/therapeutic- management/ (last visited June 21, 2021).

14. Treatment has improved so drastically for COVID-19 that according to the CDC AH Provisional COVID-19 Death Counts by Age, there were no deaths in Colorado for the 0-17 age group in 2020 or 2021. This is evidence of less virulent strains of SARS-CoV- 2 and better treatment and less risk for students and a generally lowered virulence for the SARS-CoV-2 strains as the pandemic progresses over time.

15. In my expert medical opinion, the combination of lowering COVID-19 rates, achievement of herd immunity, and the drastically improved treatment options make the Emergency Use Authorization for the investigational COVID-19 vaccine

sponsored by the US FDA and CDC, unreasonable from a scientific and medical perspective.

COVID-19 Vaccine Research and Development

16. The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In other words, it is unknown whether or not these products will change human genetic material, cause birth defects, reduce fertility, or cause cancer.

17. The Pfizer, Moderna, and JNJ vaccines are considered "genetic vaccines", or vaccines produced from gene therapy molecular platforms which according to US FDA regulatory guidance are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors. FDA. Food and Drug Administration. (Long Term Follow-up After Administration of Human Gene Therapy Products. Guidance for Industry.[7]

18. The FDA has "advised sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational gene therapy product, specifying that the long-term follow-up observation should include a minimum of five years of annual examinations, followed by ten years of annual

[7] FDA-2018-D-2173. 2020. Accessed July 13, 2021, at https://www.fda.gov/regulatory-information/search-fda-guidance- documents/long-term-follow-after-administration-human-gene-therapy-products

queries of study subjects, either in person or by questionnaire." (emphasis added) Thus, the administration of the Moderna, Pfizer, and JNJ vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up which are currently not offered in the US. (See, EUA briefing documents for commitments as to follow up: Moderna , Pfizer , J&J). They have a dangerous mechanism of action in that they all cause the body to make an uncontrolled quantity of the pathogenic wild-type spike protein from the SARS-CoV-2 virus for at least two weeks probably a longer period based on the late emergence of vaccine injury reports. This is unlike all other vaccines where there is a set amount of antigen or live-attenuated virus. This means for Pfizer, Moderna, and J&J vaccines it is not predictable among patients who will produce more or less of the spike protein. The Pfizer, Moderna, and JNJ vaccines because they are different, are expected to produce different libraries of limited antibodies to the now extinct wild-type spike protein. We know the spike protein produced by the vaccines is obsolete because the 17th UK Technical Report on SARS-CoV-2 Variants issued June 25, 2021, and the CDC June 19, 2021, Variant Report both indicate the SARS-CoV-2 wild type virus to which all the vaccines were developed is now extinct.[8]

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf; https://COVID-19.cdc.gov/COVID-19-datatracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019ncov%2Fcases-updates%2Fvariant-proportions.html#variant-proportions

The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells, in particular, causes the body's own immune system to attach to these organs. This is abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years.

Because the US FDA and CDC have offered no interpretation of overall safety of the COVID-19 vaccines according to the manufacturer or as a group, nor have they offered methods of risk mitigation for these serious adverse effects which can lead to permanent disability or death, no one should be pressured, coerced, receive the threat or reprisal, or be mandated to receive one of these investigational products against their will. Because the vaccine centers, CDC, FDA, and the vaccine manufacturers ask for the vaccine recipient to grant indemnification on the consent form before injection, all injuries incurred by the person are at their own cost which can be prohibitive depending on the needed procedures, hospitalizations, rehabilitation, and medications.

19. In general, it is never good clinical practice to widely utilize novel biological products in populations that have not been tested in registrational trials. For COVID-19 vaccines, this includes COVID-19 survivors, those with prior

suspected COVID-19 infection, those with positive SARS-CoV-2 serologies, pregnant women, and women of childbearing potential who cannot assure contraception.

20. It is never good research practice to perform a large-scale clinical investigation without the necessary structure to ensure the safety and protection of human subjects. These structures include a critical event committee, data safety monitoring board, and human ethics committee. These groups in large studies work to objectively assess the safety of the investigational product and research integrity. The goal is mitigating risk and protecting human subjects. It is my understanding that the COVID-19 vaccine program is sponsored by the CDC and FDA and has none of these safety structures in place. It is my assessment, that the COVID-19 clinical investigation has provided no meaningful risk mitigation for subjects (restricting groups, a special assessment of side effects, follow-up visits, or changes in the protocol to ensure or improve the safety of the program).

COVID-19 Vaccine Risks

21. The COVID-19 public vaccination program operated by the CDC and the FDA is a clinical investigation and under no circumstance can any person receive pressure, coercion, or threat of reprisal on their free choice of participation. Violation of this principle of autonomy by any entity constitutes reckless endangerment with a reasonable expectation of causing personal injury resulting in damages.

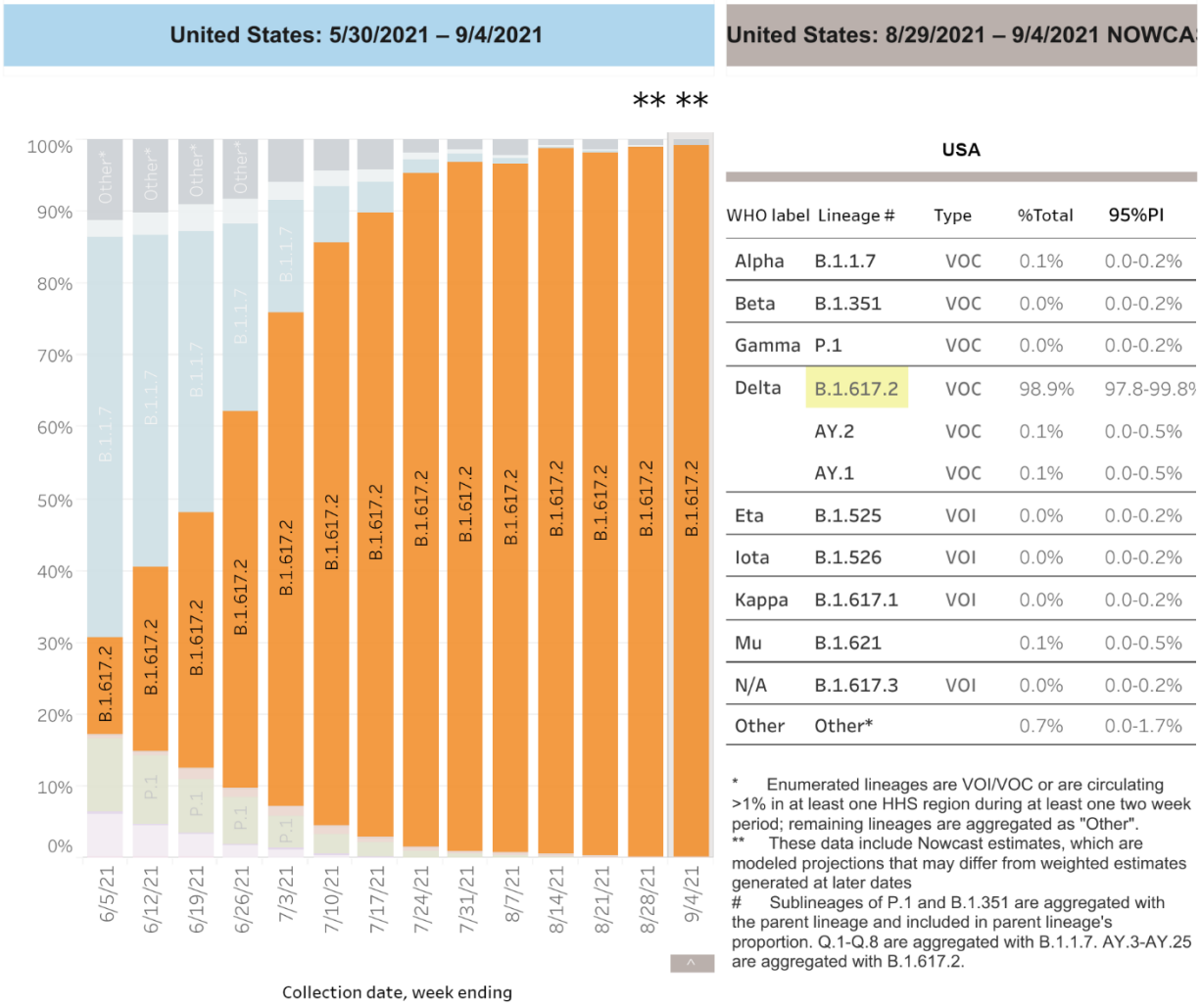
22. The current COVID-19 vaccines are not sufficiently protective against contracting COVID-19 to support its use beyond the current voluntary participation in the CDC- sponsored program. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died. Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range = 71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. Sequence data were available from 555 (5%) reported cases, 356 (64%) of which were identified as SARS-CoV-2 variants of concern, including B.1.1.7 (199; 56%), B.1.429 (88; 25%), B.1.427 (28; 8%), P.1 (28; 8%), and B.1.351 (13; 4%). None of these variants are encoded in the RNA or DNA of the current COVID-19 vaccines. In response to these numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC website[9] This

[9] (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm).

overt asymmetric reporting will create the false picture of only unvaccinated individuals developing COVID-19 when in reality patients who are fully vaccinated will be contracting breakthrough infections except for those vaccinated individuals who were previously immune from prior COVID-19 infection.

23. The Delta variant of SARS-CoV-2 accounts for the 98.9% of present cases in the United Kingdom, Israel, and the United States.[10] (Because of progressive mutation of the spike protein, the virus has achieved an immune escape from the COVID-19 vaccines with the most obvious example being Israel where indiscriminate vaccination achieved 80% immunization rates. *See* Table 4.

[10] (https://covid.cdc.gov/covid-data-tracker/#variant-proportions)



USA

WHO label	Lineage #	Type	%Total	95%PI
Alpha	B.1.1.7	VOC	0.1%	0.0-0.2%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	0.0%	0.0-0.2%
Delta	B.1.617.2	VOC	98.9%	97.8-99.8%
	AY.2	VOC	0.1%	0.0-0.5%
	AY.1	VOC	0.1%	0.0-0.5%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.0%	0.0-0.2%
Kappa	B.1.617.1	VOI	0.0%	0.0-0.2%
Mu	B.1.621		0.1%	0.0-0.5%
N/A	B.1.617.3	VOI	0.0%	0.0-0.2%
Other	Other*		0.7%	0.0-1.7%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Sublineages of P.1 and B.1.351 are aggregated with the parent lineage and included in parent lineage's proportion. Q.1-Q.8 are aggregated with B.1.1.7. AY.3-AY.25 are aggregated with B.1.617.2.

24. This has promoted the emergence of the Delta variant as the dominant strain and because it is not adequately covered by the Pfizer COVID-19 vaccine, >80% of Israeli COVID- 19 cases have occurred in persons fully vaccinated. This confirms the failure of the vaccines against COVID-19.

Table 4: Israel Confirmed Cases, Vaccinated vs. Unvaccinated Source: https://datadashboard.health.gov.il/COVID-19019/general

25. In the SARS-CoV-2 variants of concern and variants under investigation

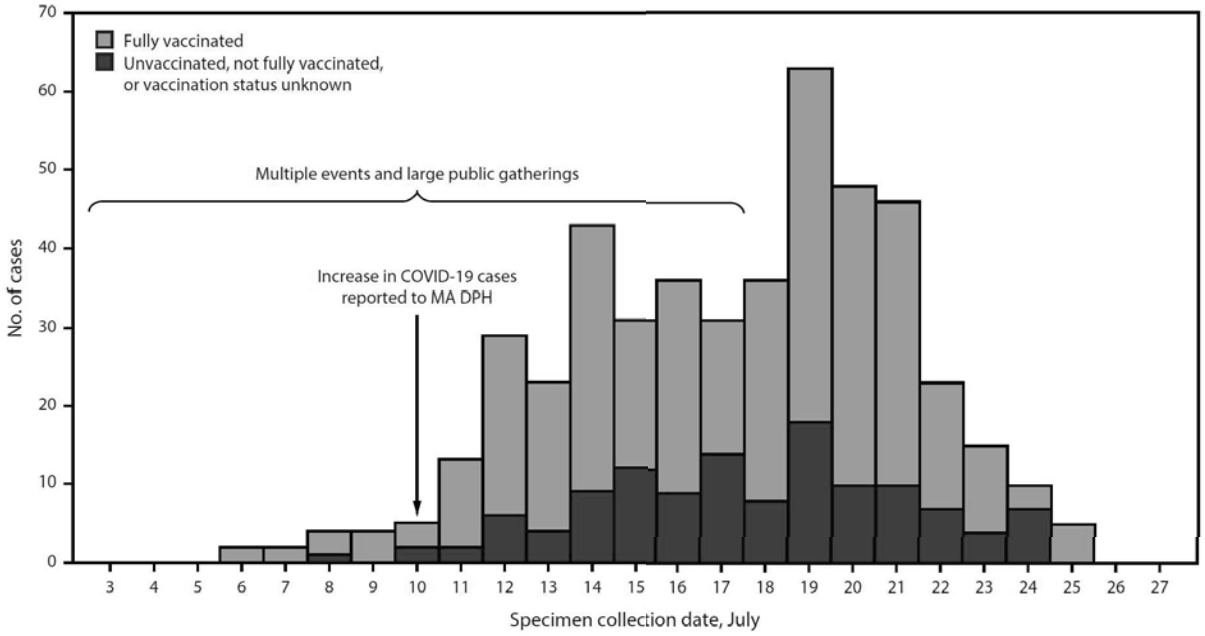
in England Technical briefing 17 25 June 2021, 92,056 cases had the Delta variant and 50/7235 fully vaccinated and 44/53,822 of the unvaccinated died. This indicates that the fully vaccinated who contract the Delta variant have an 8.6-fold increased risk for death, (95% CI 5.73-12.91), $p < 0.0001$, as compared to those who chose to remain unvaccinated.[11]

26. The CDC has published a report titled: "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021" demonstrating complete failure of the COVID-19 in controlled spread of SARS-CoV-2 in congregate settings. My interpretation of this report is that the vaccines are not sufficiently effective to make the elective, investigation vaccine recommended for use beyond individual preference.[12]

[11] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf

[12] https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf

FIGURE 1. SARS-CoV-2 infections (N = 469) associated with large public gatherings, by date of specimen collection and vaccination status* — Barnstable County, Massachusetts, July 2021



Abbreviation: MA DPH = Massachusetts Department of Public Health.
* Fully vaccinated was defined as ≥14 days after completion of state immunization registry–documented COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices.

27. In 1990, the Vaccine Adverse Event Reporting System ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines. VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to the CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

28. The total safety reports in VAERS for all vaccines per year up to 2019 was 16,320. The total safety reports in VAERS for COVID-19 Vaccines alone through October 1, 2021, is 778,683. Based on VAERS as of October 1, 2021, there

were 16,310 COVID-19 vaccine deaths reported and 75,605 hospitalizations reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) adult death reports for all vaccines combined. Thus, the COVID-19 mass vaccination is associated with at least a 39-fold increase in annualized vaccine deaths reported to VAERS

29. COVID-19 vaccine adverse events account for 98% of all vaccine-related AEs from December 2020 through the present in VAERS.

30. The COVID-19 vaccines are not safe for general use and cannot be deployed indiscriminately or supported, recommended, or mandated among any group.

31. There are emerging trends showing that the vaccine is especially risky for those 12- 29 in my expert medical opinion with complications in the cardiovascular, neurological, hematologic, and immune systems. (See, Rose J, et al). Increasingly the medical community is acknowledging the possible risks and side effects including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. See Chien-Te Tseng, Elena Sbrana, Naoko Iwata- Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge

with the SARS virus, https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine—United States, December 14– 23, 2020 (Jan 15, 2021).[13]

32. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis. It is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage resulting in heart failure, arrhythmias, and cardiac death. These conditions could call for a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation. Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis (ref McCullough PA Reach Study).

33. COVID-19 vaccine-induced myocarditis has a predilection for young males below age 30 years. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis and the US FDA has issued a warning on the Pfizer and Moderna vaccines for myocarditis. In the cases reviewed by the CDC and FDA, 90% of children with COVID-19 induced myocarditis developed symptoms and clinical findings sufficiently severe to warrant hospitalization. Because this risk is not predictable and the early reports

[13] https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (last visited June 26, 2021).

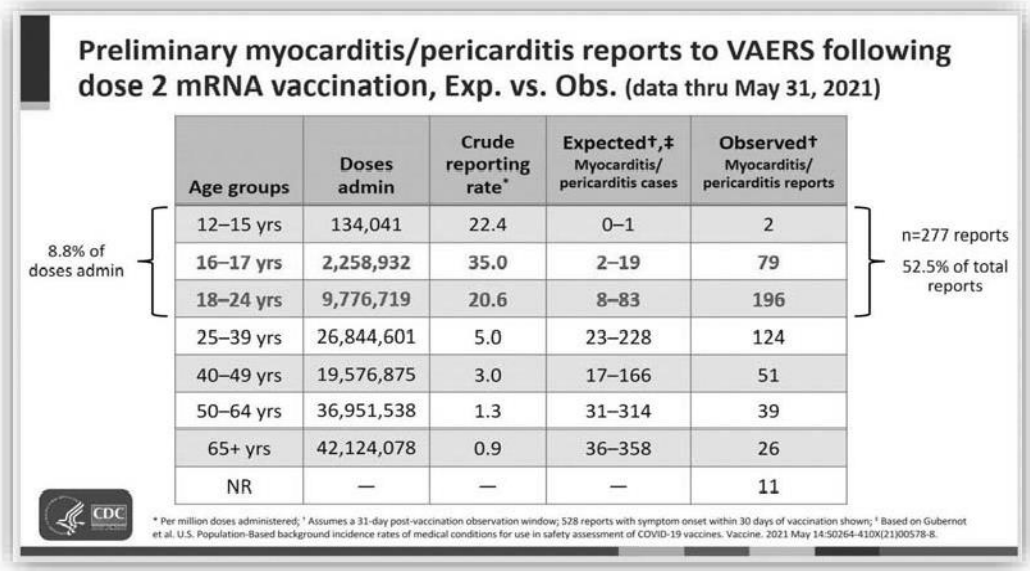
may represent just the tip of the iceberg, no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines particularly the Pfizer and Moderna products. https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update- june-25-2021.

34. Multiple recent studies and news reports detail people 18-29 dying from myocarditis after receiving the COVID-19 vaccine. According to the CDC, 475 cases of pericarditis and myocarditis have been identified in vaccinated citizens aged 30 and younger. See FDA, Vaccines and Related Biological Products Advisory Committee June 10, 2021, Meeting Presentation.[14]

35. The FDA found that people 12-24 account for 8.8% of the vaccines administrated, but 52% of the cases of myocarditis and pericarditis were reported. Id.

[14] https://www.fda.gov/media/150054/download#page=17 (last visited June 21, 2021).

Table 5: VAERS Report



Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. (data thru May 31, 2021)

Age groups	Doses admin	Crude reporting rate*	Expected†,‡ Myocarditis/ pericarditis cases	Observed† Myocarditis/ pericarditis reports
12–15 yrs	134,041	22.4	0–1	2
16–17 yrs	2,258,932	35.0	2–19	79
18–24 yrs	9,776,719	20.6	8–83	196
25–39 yrs	26,844,601	5.0	23–228	124
40–49 yrs	19,576,875	3.0	17–166	51
50–64 yrs	36,951,538	1.3	31–314	39
65+ yrs	42,124,078	0.9	36–358	26
NR	—	—	—	11

8.8% of doses admin

n=277 reports

52.5% of total reports

CDC

* Per million doses administered; † Assumes a 31-day post-vaccination observation window; 528 reports with symptom onset within 30 days of vaccination shown; ‡ Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.

36. Further, the CDC just announced that the vaccine is "likely linked" to myocarditis. Advisory Board, CDC panel reports 'likely association' of heart inflammation and mRNA COVID-19 vaccines in young people, (June 24, 2021).[15].

37. The CDC recently released data stating that there have been 267 cases of myocarditis or pericarditis reported after receiving one dose of the COVID-19 vaccines and 827 reported cases after two doses through June 11. There are 132 additional cases where the number of doses received is unknown. Id. There have been 2466 reported cases of myocarditis that have occurred, and the median age is thirty.[16]

[15] https://www.advisory.com/daily- briefing/2021/06/24/heart-inflammation.
[16] Id. https://www.openvaers.com/COVID-19-data (accessed July 17, 2021)

38. On June 23, 2021, Dr. Matthew Oster, who serves on President Joe Biden's CDC COVID-19 Task Force, stated in a PowerPoint presentation that the mRNA vaccines are causing myocarditis in "young men aged 16-30," adding, "It does appear that mRNA vaccines may be a new trigger for Myocarditis." See Matthew Oster, Overview of Myocarditis and Pericardits: ACP COVID-19 Vaccines Work Group June 23, 2021[17]

39. On June 29, 2021, the Defense Health Agency (DHA) published a report in the *Journal of the American Medical Association Cardiology* (JAMA) entitled, "Myocarditis Following Immunization with mRNA COVID-19 Vaccines in Members of the U.S. Military."[18] The study reports that previously healthy service members have developed myocarditis, a severe and life-threatening inflammation of the heart, within an average of just four days of receiving their first shot of either the Pfizer-BioNTech or the Moderna vaccine.

40. I have seen and examined adolescent patients with post-COVID-19 myocarditis which typically occurs two days after the injection, most frequently after the second injection of mRNA products (Pfizer, Moderna). The clinical manifestations can be chest pain, signs and symptoms of heart failure, and

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[17] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf (last visited October 12, 2021); see also https://nypost.com/2021/06/23/covid-19-vaccines-from-pfizer-moderna-likely-linked-to-rare-heart-condition-cdc-panel/

[18] https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601 (last visited October 12, 2021)

arrhythmias. The diagnosis usually requires a clinical or hospital encounter, 12-lead electrocardiogram, blood tests including cardiac troponin (test for heart muscle damage), ECG monitoring, and cardiac imaging with echocardiography or cardiac magnetic resonance imaging. Given the risks for either manifest or future left ventricular dysfunction, patients are commonly prescribed heart failure medications (beta-blockers, renin-angiotensin system, inhibitors), and aspirin. More complicated patients require diuretics and anticoagulants. For post- COVID-19 vaccine myocarditis, I follow current position papers on the topic and restrict physical activity and continue medications for approximately three months before blood biomarkers and cardiac imaging are reassessed. If there is concurrent pericarditis, non-steroidal anti-inflammatory agents and colchicine may additionally be prescribed. Multiple medical studies are starting to come out detailing this problem.[19] Acute myocarditis can lead to sudden death.

[19] See, e.g., Tommaso D'Angelo MD, Antonino Cattafi MD, Maria Ludovica Carerj MD, Christian Booz MD, Giorgio Ascenti MD, Giuseppe Cicero MD, Alfredo Blandino MD. Silvio Mazziotti MD, Myocarditis after SARS-CoV-2 Vaccination: A Vaccine-induced Reaction?, Pre-proof, Canadian Journal of Cardiology, https://www.onlinecjc.ca/article/S0828-282X(21)00286-5/fulltext (last visited June 26, 2021); Jeffrey Heller, Israel sees probable link between Pfizer vaccine and myocarditis cases (June 2, 2021), https://www.reuters.com/world/middle-east/israel-sees-probable-link-between-pfizer-vaccine-small-number-myoca rditis-cases-2021-06-01/(last visited June 26, 2021); Tschöpe C, Cooper LT, Torre-Amione G, Van Linthout S. Management of Myocarditis-Related Cardiomyopathy in Adults. Circ Res. 2019 May 24;124(11):1568-1583. doi: 10.1161/CIRCRESAHA.118.313578. PMID: 31120823. Caforio AL, Pankuweit S, Arbustini E, Basso C, Gimeno- Blanes J, Felix SB, Fu M, Heliö T, Heymans S, Jahns R, Klingel K, Linhart A, Maisch B, McKenna W, Mogensen J, Pinto YM, Ristic A, Schultheiss HP, Seggewiss H, Tavazzi L, Thiene G, Yilmaz A, Charron P, Elliott PM; European Society of Cardiology Working Group on Myocardial and Pericardial

The US FDA has given an update on the JNJ vaccine concerning the risk of cerebral venous sinus thrombosis and thrombosis with thrombocytopenia in women ages 18-48 associated with low platelet counts death.. This complication causes a variety of stroke-likesyndromes that can involve the cranial nerves, vision, and coordination. Blood clots in the venous sinuses of the brain are difficult to remove surgically and require blood thinners sometimes with only partial recovery. In some cases, special glasses are required to correct vision and these young adults can be expected to miss considerable time away from school undergoing neurological rehabilitation. Because this risk is not predictable no woman under age 48 under any set of circumstances should feel obliged to take this risk with the JNJ vaccine. Such catastrophic neurologic thrombotic events could occur in first responders or critical infrastructure employees while on duty. https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-COVID-19-vaccine.

41. Additionally, the US FDA has an additional warning for Guillen-Barre Syndrome or ascending paralysis for the JNJ vaccine which is not predictable and

Diseases. Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Eur Heart J. 2013 Sep;34(33):2636-48, 2648a- 2648d. doi: 10.1093/eurheartj/eht210. Epub 2013 Jul 3. PMID: 23824828

when it occurs can result in ascending paralysis, respiratory failure, the need for critical care, and death. Not all cases completely resolve, and some vaccine victims may require long term mechanical ventilation, or become quadra- or paraplegics. Prolonged neurological rehabilitation is commonly required, and this will call for time away from school and studies for those children injured from the JNJ vaccine with Guillen-Barre Syndrome. This syndrome is unpredictable and could occur in a critical worker while on duty and thus potentially harming others (passengers, coworkers, etc). https://www.fda.gov/media/150723/download.

42. The vaccine is also far less safe than previous vaccines like the meningococcal meningitis vaccine that is typically required on college campuses which in 2019 recorded zero deaths. The COVID-19 vaccines since their EUA approval on May 10, 2021, have already claimed the lives of 15 children and 79 young individuals under age 30 (VAERS).

43. For example, the VAERS (Vaccine Adverse Event Reporting System) data from the CDC shows, for 18-29-year-olds, there have been no deaths from the meningococcal vaccine from 1999 – 2019.[20]

44. The main side effects people reported from the meningitis vaccine are

[20] See, United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC)/Food and Drug Administration (FDA), Vaccine Adverse Reporting System (VAERS) 1990 - 06/11/2021, CDC WONDER On-line Database. Accessed at https://wonder.cdc.gov/vaers.html on June 23, 2021, 1:43:33 PM, ("Query Criteria"), Attached as Exhibit C.

headache, injection site pain, nausea, chills, and a fever, and even these were limited as no more than fifteen of each were reported. Id. The student population and their parents, in general, accept the requirements for meningococcal vaccination because the vaccines are safe, effective, and do not pose a risk of death, unlike the COVID-19 vaccines.

45. In the brief time the COVID-19 vaccines have been available, there have been many more serious symptoms and even a death of a healthy 13-year-old boy. (See Nationwide VAERS COVID-19 Vaccine Data through June 18, 2021, attached as **EXHIBIT 2**). Further, milder side effects from the vaccine include changes in hormone and menstrual cycles in women, fever, swelling at the injection site, etc.[21].

46. At the time of this report, the CDC/FDA as the US public vaccine sponsors have yet to present to America a comprehensive COVID-19 vaccine safety report according to manufacturer, region, and patient categories who have volunteered for vaccination. Likewise, there has been no comprehensive report on vaccine efficacy particularly in the present era of the Delta variant.

47. Recent studies from Tess Lawrie, MBBS, PhD, a highly respected

[21] Jill Seladi-Schulman, Ph.D., Can COVID-19 or the COVID-19 Vaccine Affect Your Period? (May 25, 2021), https://www.healthline.com/health/menstruation/can-COVID-19-affect-your-period#COVID-19-and-men%20strual-cycles (last visited June 26, 2021); Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, David R. Chadwick, Previous COVID-19 infection but not Long-COVID-19 is associated with increased adverse events following BNT162b2/Pfizer vaccination, (pre-print) https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 26, 2021)

evidence-based professional, on the UK's equivalent of the VAERS systems concluded that the vaccines were unsafe for use in humans due to the extensive side effects they are causing. Tess Lawrie, Re. Urgent preliminary report of Yellow Card data up to 26th May 2021, (June 9, 2021), http://www.skirsch.com/COVID-19/TessLawrieYellowCardAnalysis.pdf

Risks of COVID-19 Vaccines for Those Recovered from COVID-19

48. There is recent research on the fact that the COVID-19 vaccine is dangerous for those who have already had COVID-19 and have recovered with inferred robust, complete, and durable immunity. These patients were excluded from the FDA-approved clinical trials performed by Pfizer, Moderna, and J&J. From these trials the safety profile was unknown when the products for approved for Emergency Use Authorization in 2020. There has been no study demonstrating clinical benefit with COVID-19 vaccination in those who have well documented or even suspected prior COVID-19 illness.

49. A medical study of United Kingdom healthcare workers who had already had COVID-19 and then received the vaccine found that they suffered higher rates of side effects than the average population.[22].

50. The test group experienced more moderate to severe symptoms than the

[22] Rachel K. Raw, et al., Previous COVID-19 infection but not Long-COVID-19 is associated with increased adverse events following BNT162b2/Pfizer vaccination, medRxiv (preprint), https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 21, 2021)

study group that did not previously have COVID-19. Id. The symptoms included fever, fatigue, myalgia-arthralgia, and lymphadenopathy. Id. Raw found that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior history of SARS-CoV-2 or those who had positive antibodies at baseline had a higher rate of vaccine reactions than those who were COVID-19 naive. Id.

51. Mathioudakis et al. reported that in 2020 patients who underwent vaccination with either mRNA-based or vector-based COVID-19 vaccines, COVID-19-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.

52. Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: "Vaccine recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or joint pains, in order of decreasing frequency, $P < 0.001$ for all listed symptoms, Fisher's exact test, two-sided)."[23]

Natural Immunity to COVID-19

53. To my knowledge, there are no trustworthy studies that demonstrate the clinical benefit of COVID-19 vaccination in COVID-19 survivors or those with

[23] (https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1).

suspected COVID-19 illness or subclinical disease who have laboratory evidence of prior infection.

54. It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity which by comparison has demonstrated massive failure including over 10,000 well-documented vaccine failure cases as reported by the CDC before tracking was stopped on May 31, 2021. There are no studies demonstrating the clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors many of whom may be in the student population.

55. Multiple laboratory studies conducted by highly respected U.S. and European academic research groups have reported that convalescent mildly or severely infected COVID-19 patients who are unvaccinated can have greater virus-neutralizing immunity— especially more versatile, long-enduring T- cell immunity—relative to vaccinated individuals who were never infected.[24].

[24] See Athina Kilpeläinen, et al., Highly functional Cellular Immunity in SARS-CoV-2 Non-Seroconvertors is associated with immune protection, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.05.04.438781v1 (last visited June 26, 2021); Tongcui Ma, et al., Protracted yet coordinated differentiation of long-lived SARS- CoV-2-specific CD8+ T cells during COVID-19 convalescence, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1 (last visited June 26, 2021); Claudia Gonzalez, et al., Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2, medRxiv

56. Cleveland Clinic studied their employees for the effects of natural immunity in unvaccinated people.[25] They found zero SARS-CoV-2 reinfections during a 5-month follow-up among n=1359 infected employees who were naturally immune remained unvaccinated and concluded such persons are "unlikely to benefit from COVID-19 vaccination." Among those who were vaccinated, unlike the naturally immune, there were vaccine failure or breakthrough cases of COVID-19. Id.

57. An analysis by Murchu et al demonstrated in 615,777 individuals which included well-documented COVID-19 as well as subclinical infections with positive serologies, there was a negligible incidence (<1%) of COVID-19 over the long term. Murchu found no evidence of waning immunity over time suggesting no possibility that future vaccination would be indicated for any reason.

(pre-print), https://www.medrxiv.org/ content/10.1101/2021.05.11.21256578vl (last visited June 21, 2021); Carmen Camara, et al. Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1 (last visited June 26, 2021); Ellie N. Ivanova, et al., Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255677v1 (last visited June 26, 2021); Catherine J. Reynolds, et al, Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose, (pre-print), https://pubmed.ncbi.nlm.nih.gov/33931567/ (last visited June 21, 2021); Yair Goldberg, et al., Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670vl (last visited 06/2621)

[25] Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, Necessity of COVID-19 vaccination in previously infected individuals, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 (last visited June 21, 2021).

https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260.

58. A recently published article in Nature reported that prior infection induces long- lived bone marrow plasma cells which means the antibodies to prevent reinfection of COVID-19 are long-lasting.[26]

CONCLUSION

In my expert medical opinion which is and is within a reasonable degree of medical certainty, despite the current Delta variant outbreak, the increasing likelihood of herd immunity to COVID-19, the low risk to children and adolescents of serious complications or death due to COVID-19, the negligible risk of asymptomatic spread of COVID-19, the vastly improved COVID-19 treatments currently available all make the risks inherent in COVID-19 significantly lower than they were in 2020.

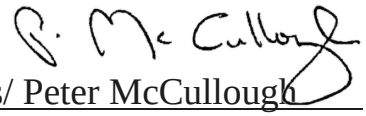
It is my expert medical opinion that the COVID-19 vaccines are progressively losing efficacy over the prevention of COVID-19 and in widely vaccinated countries (Israel, Iceland, Singapore) up to 80% of COVID-19 cases have been previously vaccinated implying the vaccines have become obsolete with antigenic escape or resistance to variants (e.g. Delta) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain.

[26] Jackson S. Turner et. al. SARS-CoV-2 infection induces long- lived bone marrow plasma cells in humans, (May 24, 2021) https://www.nature.com/articles/s41586-021-03647-4

It is my expert medical opinion that it is not good research or clinical practice to widely utilize novel biologic therapy (mRNA, adenoviral DNA COVID-19 vaccines) in populations where there is no information generated from the registrational trials with the FDA, specifically COVID-19 survivors, suspected COVID-19-recovered, pregnant or women who could become pregnant at any time after investigational vaccines. In my expert medical opinion, the risks associated with the investigational COVID-19 vaccines far outweigh any theoretical benefits, are not minor or unserious, and many of those risks are unknown or have not been adequately quantified nor has the duration of their consequences been evaluated or is calculable. Therefore, in my expert medical opinion, the Emergency Use Authorization and mandatory administration of COVID-19 vaccines creates an unethical, unreasonable, clinically unjustified, unsafe, and unnecessary risk to the Plaintiffs. Likewise, in my medical expert opinion, the mandatory administration of COVID-19 vaccines in municipal employees creates unnecessary risk to the employees and other citizens who rely on first responders and other critical infrastructure workers.

I declare under penalty of perjury of the laws of the United States and the State of Florida that the foregoing statements are true and correct.

Dated: 13th day of October, 2021:



13-OCT-2021

/s/ Peter McCullough

EXHIBIT 1

Tuesday, October 6, 2021

CURRICULUM VITAE

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

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Dallas, TX 75206

Birth date December 29, 1962
Birthplace Buffalo, NY, USA

EDUCATION

1) Certificate of Graduate Liberal Arts Studies: Southern Methodist University, December 17, 2016, principal faculty Dr. Anthony Picchioni, PhD, Adjunct Professor in Human Development, P.O. Box 750181, Dallas, TX 75275, 214-768-3417, www.smu.edu
   - Graduated with Honor

2) Master of Public Health: University of Michigan School of Public Health, August 19, 1994, Dean Noreen M. Clark, PhD, 109 Observatory Street, Ann Arbor, MI 48109-2029, phone 734-764-5454, www.sph.umich.edu
   - Major: General Epidemiology

3) Doctor of Medicine: University of Texas Southwestern Medical School, 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) Bachelor of Science: Baylor University, 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) Cardiovascular Diseases Fellowship: 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) Internal Medicine Residency: 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)

William Beaumont Hospital, 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)

University of Missouri-Kansas City (UMKC) School of Medicine, Truman Medical Center, 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), 23rd 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, MI, 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. 11th 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,* www.medreviews.com "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)
107) *Nature Clinical Practice Cardiovascular Medicine*, 2004 to present (4)
108) *Nature Clinical Practice Nephrology*, 2008 to present (1)
109) *Nature Reviews Nephrology,* 2009 to present (3)
110) *Nephron,* 2005 to present (1)
111) *Nephrology,* 2009 to present (1)
112) *Nephrology, Dialysis, and Transplantation,* 2005 to present (7)
113) *New England Journal of Medicine,* 2006 to present (8)
114) *Pharmacological Research (Italy),* 1999 (1)
115) *Pharmaceutical Sciences,* 2011 (1)
116) *PLoS Medicine,* 2005 (1)
117) *PLOS ONE,* 2013 (1)
118) *Prehospital Emergency Care*, 2015 (1)
119) *Preventive Medicine,* 2008 (1)
120) *Rejuvenation Research,* 2007 (1)
121) *Renal Failure*, 2011 (2)
122) *The Lancet,* 1999 to present (11)
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) Study Principal Investigator, Medicine vs Angiography for Thrombolytic Exclusion Patients (M.A.T.E.), 1994-1997, (multicenter, U.S., randomized controlled trial [RCT]). Status: closed.

2) Study Principal Investigator, The Resource Utilization Among Congestive Heart Failure Study (R.E.A.C.H.), 1998-2000, (single-center, prospective cohort study). Status: closed.

3) Study Principal Investigator, The Asthma, Beta-Agonists, and Congestive Heart Failure Study, (A.B.C.H.F.), 1998-1999, (single-center, case-control study). Status: closed.

4) Study Co-Principal Investigator, The Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation (P.R.I.N.C.E.) Study, 1995-1998, (single-center, RCT). Status: closed.

5) Study Co-Principal Investigator, BNP Multinational Study, Principal Investigator, Alan Maisel, MD, Biosite Diagnostics, Inc., 2000-2006, (multicenter, international, prospective cohort study). Status: closed.

6) Study Co-Investigator, 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.

7) Study Co-Investigator, 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) Chair, National Steering Committee, 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) Rotating Executive Committee Principal Investigator Member, 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) Overall Study Principal Investigator, 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) Member, Steering Committee, 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) Member, External Expert Panel, 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) Member, Global Expert Panel, 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

1) 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) Member, Study Endpoints Committee, A Phase II, Escalation Trial of Vasoflux™ 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) Member, Critical Endpoints Committee, 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) Member, Clinical Events Classification Committee, 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

7) Chair, Clinical Endpoints Committee, Alere San Diego, Inc, Alere Prospective Blinded Study of a Novel Troponin Assay (PEARL), status: closed 2015

8) Chair, Adjudication Committee, Myeloperoxidase In the Diagnosis of Acute coronary Syndromes (MIDAS) study, Alere, Inc., status: closed 2012

9) Independent Endpoint Adjudicator, 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) Chair, Data Adjudication Committee, Estimating versus Measuring Plasma Volume and Kidney Function in Acute Decompensated Congestive Heart Failure, Eudra-CT Number 2018-002638-18, Sponsor: Charite-Unversitatsmedizin Berlin, FAST Biomedical, Inc, 2018-present

Overall Study Responsibilities: Data Safety Monitoring Committees

1) 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 placebo-controlled 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 placebo-controlled 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) Chair, Independent Data Monitoring Committee, 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) Chair, Independent Data Monitoring Committee, 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) Chair, Independent Data Monitoring Committee, 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) Member, Data Safety and Monitoring Board, 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) Chair, Data Safety Monitoring Board, Neumedicines, Inc., A Phase 2, Single-Dose, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HemaMax™ (rHuIL-12) in Healthy Subjects, status: closed 2016

16) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., 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) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., 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) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., 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) Chair, Data Monitoring Committee, Renew Research, KAI Research, 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) Chair, Data Safety Monitoring Committee, Sanofi, Inc, 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

Dominant Polycystic Kidney Disease (ADPKD) STUDY NUMBER: EFC15392 STUDY NAME: SAVE-PKD COMPOUND: GZ/SAR402671, 2018 to present, status: open

24) Chair, Data Safety Monitoring Board, National Institutes of Health, National Heart, Lung and Blood Institute R34 NHLBI Clinical Trial Pilot Studies (R34) Reducing Arrhythmia in Dialysis by Adjusting the Rx Electrolytes/Ultrafiltration (RADAR), David Charytan, MD, PI, 2019 to present, status: open

25) Chair, Data Safety Monitoring Board, GZ402671 EFC15392 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 Dominant Polycystic Kidney Disease (ADPKD), Sanofi, status: open

26) Chair, Data Safety Monitoring Board, MEDI3506, Trials Portfolio, D9182C00001 A Phase 2 Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI3506 in Adult Subjects with Moderate-to-severe Atopic Dermatitis; D9181C00001 A Phase II, Randomised, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MEDI3506 in Adult Participants with Uncontrolled Moderate-to-severe Asthma; D9180C00002 A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety and Tolerability of MEDI3506 in Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4); D9183C00001 A Phase 2b Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy and Safety of MEDI3506 in Subjects with Diabetic Kidney Disease, Axio Inc, A Cytel Company, status: open

GRANT AWARDS

Original Research Grants

G1) London JF (PI), Bis KG, Juni JE, Wilke N, DiCarli MF, Shetty AN, **McCullough PA**, Timmis GC. Magnetic Resonance vs. Positron Emission Tomography for the Detection of Myocardial Viability. Bracco Diagnostics Inc./SCA&I Grant, $25,000 (WBH RC-453), 1997-98. Additional WBH Research Institute Mini-grant, $5,000 (WBH Grant #RC-748). Level of involvement: author of the variable definitions, endpoints, and data analysis sections, 0% FTE. Status: closed 1998

G2) **McCullough PA** (PI), Shah S, Noor H, Marks KR, McCabe KB, Zong L, McCord J, Khoury N, Ulcickas-Yood M, Ward RE. Diagnostic Accuracy of an Emergency Department Clinical Decision Unit in the Evaluation of Chest Pain. HFHS Small Projects Fund $10,000 (HFHS Grant #A30785), 0% FTE. Status: closed 1997

G3) Keteyian SJ (Co-PI), **McCullough PA** (Co-PI), Brawner CA, Rosman HS, Stein P, Weaver WD. A Prospective Study of Case Identification and Triage of Patients Eligible for Cardiac

Rehabilitation. Merck & Co., U.S. Human Health, $30,000 (HFHS Grant #E18037), 3% FTE. Status: closed 1998

G4) **McCullough PA.** Novel Methods for Identifying High-Risk Patients for Subsequent Cardiovascular Events. Merck & Co., U.S. Human Health, $20,000 (HFHS Grant #M1060), 0% FTE. Status: closed 1998

G5) **McCullough PA.** Cardiovascular Informatics Development Award. Pfizer, Inc., $10,000 (HFHS Grant #E60022), 0% FTE. Status: closed 1998

G6) **McCullough PA,** Yee J, Soman S, Sallach J, Borzak S, Foreback C, Monaghan K, Tisdale JE, Bailey E, Bola P, Chase G, Marks KR, Weaver WD. A Prospective Dose-Ranging Trial of Folic Acid to Reduce Total Homocyst(e)ine Levels in Patients with End-Stage Renal Disease Undergoing Hemodialysis. HFHS Project Development Fund $10,000 (HFHS Grant #A20003), 0% FTE. Status: closed 1999

G7) **McCullough PA.** NuStep Recumbent Cross Trainer Product Development Pilot Study, NuStep, Inc., (single center, prospective pilot study), $12,500.00, (WBH Grant #RC- 08-94847). Status: closed 2005

G8) **McCullough PA,** Secondary Analyses from the PRINCE Trial, (single center data analysis), $20,000, PLC Medical, Inc., (WBH #RC 08-94851) Status: closed 2005

G9) **McCullough PA**, Sullivan RA. A Systematic Review of Vascular Calcification in Patients with Chronic Kidney Disease and End-Stage Renal Disease, 2002-2003, Braintree Labs, Inc., $40,000, 25% FTE (WBH Grant #RC 08-94833) Status: closed 2003

G10) Pasas SA, Davies MI, **McCullough PA.** Determination of Protein-bound Homocysteine in Human Plasma using Capillary Electrophoresis with Electrochemical Detection in Patients with Chronic Kidney Disease, 2003-2004, AHA Predoctoral Fellowship Program (Pasas), $38,000, 15% FTE (UMKC Grant #). Status: closed 2003

G11) Collins AC, Gladstone E, Robitscher JW, **McCullough PA**, Klag M, Narva A, Gilberston D for the NKF. Demonstration project: state-based screening for chronic kidney disease. Response to CDC-RFA-DP06-004, demonstration project for identifying individuals at high-risk for CKD in the US. Centers for Disease Control, $1,199,609, 12% FTE Status: closed 2007

G12) **McCullough PA**, Principal Investigator. Neutrophil Gelatinase-Associated Lipocalin (NGAL): A Novel Blood Marker for Risk of Developing Contrast-Induced Nephropathy (ENCINO). Biosite/Inovise, Inc., $229,000.00 (WBH #RC-94862), 0% FTE Status: closed 2009

G13) Agrawal V, Barnes M, **McCullough PA.** Evaluation of CKD awareness in medical residents. WBH intramural mini-grant R/C# 98662, $10,000.00, 0% FTE Status: closed 2008

G14) **McCullough PA,** overall Principal Investigator transferred to Zalesin K. FDA Investigational New Drug Exemption (INDE) #060672. A Prospective, Randomized, Placebo-Controlled, Parallel-Group, Pilot Trial of Paricalcitol in the Treatment of Hyperparathyroidism in Patients after Roux-en-Y Gastric Bypass Surgery with Chronic Kidney Disease, Abbott Laboratories, Inc., $496,600.00 (WBH #RC-90290), 0% FTE Status: closed 2009

G15) **McCullough PA**, overall Principal Investigator transferred to Miller WM, FDA INDE #107750. Investigator Initiated Study. A Prospective, Double-Blind, Randomized, Parallel Group, Placebo-Controlled Trial of Aliskiren versus Placebo in Non-Diabetic, Normotensive Obese Patients with Microalbuminuria, Novartis, Inc., $339,400.00 (WBH #RC-90345), Status: closed 2010

G16) **McCullough PA,** overall Principal Investigator. Investigator Initiated Study, FDA Investigational New Drug (IND) #74707. A Phase 2, randomized, double-blind, placebo-controlled trial, to assess the efficacy and safety of deferiprone in the reduction of markers of contrast-induced acute oxidative kidney injury. Cormedix, Inc, $857,745 (includes $101,442 for Beaumont Research Coordinating Center). Study centers included Providence Hospital and Medical Center Southfield, St. John Hospital and Medical Center, Detroit, Northern Michigan Hospitals, Petoskey, MI, St. Vincent's Hospital, Indianapolis, IN, Fairfield Cardiac Cath Labs, LLC, Fairfield, OH, Oklahoma Heart Hospital, Oklahoma City, OK, Ohio Health Research Institute, Columbus, OH, Mercy St. Vincent Hospital, Toledo, OH, Status: closed 2011

G17) **McCullough PA,** overall study Principal Investigator, A Prospective Randomized Parallel-Group Controlled Trial of Multiple Blood Biomarkers in the Personalized Management of Chronic Heart Failure, Baylor IRB 014-252, Baylor Foundation, 2014, $78,639.20, status: closed 2016.

G18) **McCullough PA**, overall study Principal Investigator, Baylor Hypertrophic Cardiomyopathy Program Development Project: Time-resolved, 3D phase contrast magnetic resonance imaging (MRI) (4D Flow) and Advanced Strain Rate Echocardiography in Patients with Hypertrophic Cardiomyopathy, Baylor IRB 014-175, Baylor Foundation, 2014, $100,000.00, status: open

G19) **McCullough PA,** overall study Principal Investigator, Preventive Cardiology Registry: Role of Proprotein Convertase Subtilisin/kexin type 9 (PCSK9) and Other Catabolic Determinants in Hypercholesterolemia in Patients with Suspected Heterozygous Familial Hypercholesterolemia Baylor IRB 014-122, Baylor Foundation, $3,100.00, status: closed 2014

G20) **McCullough PA,** overall study Principal Investigator and Study Chairman, Investigator Initiated Trial, "A Prospective, Double-blind, Placebo Controlled, Parallel Group,

Randomized Trial of Extended Release Exenatide versus Placebo in Diabetic Patients with Type 4 Cardiorenal Syndrome: EXTEND-CRS", D5551L00004/ISSEXEN0013, FDA IND 123200, Baylor IRB 014-149, AstraZeneca, 2014, $1,597,901.93, status: open

G21) **McCullough PA**, overall study Principal Investigator, Iso-osmolar Contrast and the Timing of Coronary Angiography in the Multivariate Risk for Cardiac Surgery Associated with Acute Kidney Injury and Major Adverse Renal and Cardiac Events (MARCE), Baylor IRB 014-096, GE Healthcare, Inc, 2015, $145,885.00, status open

G22) **McCullough PA**, overall study Principal Investigator, Timing of coronary angiography and multivariate risk for cardiac surgery associated acute kidney injury and major adverse renal and cardiac events (MARCE), Baylor IRB 014-096, Baylor Foundation, $8,100.00, status: closed 2016

G23) Mendez J, **McCullough PA**, et al, co-investigator, Assessment of Multiple Blood Biomarkers in Patients with Advanced Heart Failure Undergoing Evaluation for Cardiac Transplantation and Mechanical Circulatory Support, Baylor IRB 014-300, Critical Diagnostics, Inc, $10,400.00, status: closed 2016

G24) Bottiglieri, T, **McCullough PA**, et al, co-investigator, Urinary 11dhTxB2 response to acetylsalicylic acid (aspirin) in cardiovascular disease progression and adverse outcomes, Baylor IRB 008-230, Corgenix, Inc., $99,087.00, status: closed 2016

G25) Schussler JM, Vasudevan A, **McCullough PA**, co-investigator, Clinical outcomes and metabolomic and damage associated molecular patterns of acute kidney injury in patients undergoing percutaneous coronary intervention via the radial versus femoral artery approach, Baylor IRB 014-299, Baylor Health Care System Foundation, $61,416.00, status: closed 2018

G26) Tecson K, **McCullough PA**, coinvestigator, Contribution of Chronic Kidney Disease and Acute Kidney Injury to Heart Failure Outcomes, Baylor IRB 015-296, Baylor Health Care System Foundation, $43,424.60, status: open

G27) Vasudevan A, **McCullough PA**, coinvestigator, Burden of Cardiovascular Events Follow Percutaneous Coronary Intervention, Baylor IRB 015-297, Baylor Health Care System Foundation, $40,000.00, status: closed 2018

G28) Tecson, K, **McCullough PA**, Therapeutic Intensity of Lipid Lowering Therapy in Response to Recurrent Cardiovascular Events, Baylor IRB 017-106, Amgen, Inc., $249,990.00 status: open

G29) **McCullough PA**, Principal Investigator, A Case Finding Study of Familial Chylomicronemia, Akcea Pharmaceuticals, $10,000.00, status: closed 2017

G30) **McCullough PA**, Bottiglieri T, Tecson K. Baylor Foundation $49,923.80. Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, status start-up 2019

Site Principal Investigator Contracts

G1) Jafri S, **McCullough PA**, and the WATCH Investigators. Warfarin and Antiplatelet Therapy in Chronic Heart Failure, (W.A.T.C.H.) Field Center, Veterans Administration Cooperative Studies Program and Sanofi Pharmaceuticals, $36,000.00 (HFHS Grant #B51008) status: closed 2000

G2) Jafri S, **McCullough PA**, and the CHARM Investigators. Candesartan Cilexetil (Candesartan) in Heart Failure Assessment of Reduction in Mortality and Morbidity (C.H.A.R.M.) Field Center, 1999-2000, Astra Pharmaceuticals, $56,000.00 (HFHS Grant #E09045) status: closed 2000

G3) Schuger C, **McCullough PA**, and the MADIT Investigators. Multicenter Automatic Defibrillator Implantation Trial II (M.A.D.I.T.-II), Guidant Corporation/Cardiac Pacemakers (CPI), $96,000 (HFHS Grant #G10087) status: closed 2000

G4) Schuger C, **McCullough PA**, and the MIRACLE Investigators. Multicenter InSync Randomized Clinical Evaluation (M.I.R.A.C.L.E.), Medtronic Inc., $195,000, (HFHS Grant #G12006) status: closed 2000

G5) **McCullough PA,** Shetty A, Soman S and the CHORUS Investigators. 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 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, $266,875.00 10% FTE (HFHS Grant #E05046) status: closed 2000

G6) **McCullough PA,** Manley HJ and the CHORUS Investigators. 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 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, $279,000 10% FTE (UMKC Grant #E05046) status: closed 2001

G7) Nowak R, McCord J, **McCullough PA** and the BNP Investigators. Breathing Not Properly Study (B.N.P. Multinational Study), Alan Maisel, MD, and Peter A. McCullough, MD, MPH, Co-Principal Investigators, Biosite Diagnostics, Inc., (prospective cohort study) Field Center Contract, Biosite Diagnostics, Inc., $180,000.00 (HFHS Site), $500,000.00, 0% FTE (HFHS Grant #E03005) status: closed 2001

G8) Ehrman JK, **McCullough PA.** A Prospective Randomized Trial of a Personal Health Assistant in the Secondary Prevention of Heart Disease. Merck, Inc., $220,961.00, 7% FTE (HFHS Grant #E41010) status: closed 2002

G9) **McCullough PA** and the CORC Investigators. Kansas City Cardiomyopathy Questionnaire Interpretability Study, John A. Spertus, MD, MPH, Principal Investigator, Cardiovascular Outcomes Research Consortium (C.O.R.C.), 2001 (multicenter, U.S., prospective cohort study), $21,400.00, status: closed 2002

G10) **McCullough PA**, Rutherford BD, and the OAT Investigators. Occluded Artery Trial, Judith Hochman, MD, and Gervasio Lamas, MD, Co-Principal Investigators, National Institutes of Health, National Heart Lung and Blood Institute, $54,000.00. 0% FTE (UMKC Grant #K531122) status: closed 2002

G11) **McCullough PA** site Principal Investigator and National Executive Committee Member. Rapid Emergency Department Heart Failure Outpatient Trial, Biosite Diagnostics, $21,000. 0% FTE (UMKC Grant #K531130) status: closed 2002

G12) **McCullough PA** site Principal Investigator. African-American Heart Failure Trial (AHEFT). A Placebo-Controlled Trial of BiDil added to Standard Therapy in African American Patients with Heart Failure, NitroMed, Inc., $20,000.00 (UMKC Proposal #9722, TMC Grant #261231) status: closed 2002

G13) **McCullough PA** and the IMAGING Investigators for Cardiology Clinical Studies, LLC. Investigation of Myocardial Gated SPECT Imaging as Initial Strategy in Heart Failure: The IMAGING in Heart Failure Trial, Dupont Pharmaceuticals Inc., $20,000.00 (UMKC Proposal #9825, UMKC Grant #KG001278) status: closed 2002

G14) **McCullough PA**, site Principal Investigator, and Ad Hoc Executive Committee Member. Heart Failure and a Controlled Trial Investigating Outcomes of Exercise Training. National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the Duke Clinical Research Institute, $665,000, (NIH Grant #1 U01 HL63747 01A2, WBH Grant # RC 08-94837, Site #301) status: closed 2005

G15) **McCullough PA**, site Principal Investigator, and Executive Committee Member. 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 (multicenter, U.S., randomized cross-over trial), $105,447.50, (WBH Grant # RC 08-94836) status: closed 2005

G16) **McCullough PA,** site Principal Investigator and National Co-Principal Investigator. 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 Inc., (multicenter, U.S., randomized trial), $63,649.90, (WBH Grant #RC 08-94838) status: closed 2006

G17) **McCullough PA,** and the ACCOMPLISH Investigators. Protocol No. CCIB002.12301. Avoiding Cardiovascular Events through Combination Therapy in Patients Living with Systolic Hypertension, Novartis, Inc., 2003 (multicenter, multinational, randomized trial) $159,241.00, (WBH Grant #RC 08-94844) status: closed 2006

G18) **McCullough PA**, site Principal Investigator. Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study with Tolvaptan, Protocol #156-03-236, IND #50,533, Otsuka Maryland Research Institute, (multicenter, international, randomized trial), $210,750.00, (WBH Grant #RC 08-94842 changed to #RC 08-94849) status: closed 2005

G19) **McCullough PA,** site Principal Investigator. A Multicenter, Double-Blind, Randomized, Parallel Group, 6-week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination versus Atorvastatin in Patients with Hypercholesterolemia, Protocol #051/EZT544, Merck, Inc., (multicenter, U.S., randomized trial), $18,840.00, (WBH Grant #RC 08-94843) status: closed 2006

G20) **McCullough PA,** site Principal Investigator, A multicenter, double-bind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., randomized trial), $30,700.00, (WBH Grant #RC 08-94845) status: closed 2007

G21) **McCullough PA,** site Principal Investigator. A multicenter, double-bind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy to pioglitazone 45 mg qd in patients with type 2 diabetes inadequately controlled with thiazolidinediones monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., phase III randomized trial) $30,700.00, (WBH Grant #RC 08-94846) status: closed 2006

G22) **McCullough PA,** site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter placebo and active controlled disease escalation study to evaluate the safety and efficacy of aliskiren in patients with hypertension, $47,100.00 (WBH #RC 08- 94852) status: closed 2007

G23) **McCullough PA,** site Principal Investigator. A randomized, double-blind study to compare the durability of glucose lowering and preservation of pancreatic beta-cell function of rosiglitazone monotherapy compared to metformin or glyburide/glibenclamide in patients with drug naïve, recently diagnosed type 2 diabetes, $140,100.00, Novartis Pharmaceuticals (WBH #RC 08-94849) status: closed 2008

G24) **McCullough PA,** site Principal Investigator. A multicenter, randomized, double-blind factorial study of the co-administration of MK-0431 and metformin in patients with type 2 diabetes who have inadequate glycemic control, $36,735.00, Merck Research Laboratories (WBH #RC 08-94853) status: closed 2008

G25) **McCullough PA**, site Principal Investigator. Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy & Safety of Ezetimibe/Simvastatin and Niacin Co-Administered in Patients with type IIa or Type IIb Hyperlipidemia, $46,960.00, Merck Research Laboratories, MRK-091, (WBH #RC 08-94854) status: closed 2008

G26) **McCullough PA,** site Principal Investigator. A Multi-Center, Randomized, Double-Blind, factorial Design study to evaluate the lipid-altering efficacy & safety of MK-0524B Combination Tablet in Patients with Primary Hypercholesterolemia or Mixed Hyperlipidemia $40,849.00, Merck Research Laboratories, MRK-022. (WBH #RC 08-94855) status: closed 2007

G27) **McCullough PA,** site investigator. An 8-week, multicenter, randomized, double-blind, parallel-group study to evaluate the efficacy and safety of the combination of valsartan/HCTZ/amlodipine compared to valsartan/HCTZ, valsartan/amlodipine, and HCTZ/amlodipine in patients with moderate to severe hypertension, $43,500.00, Novartis Pharmaceuticals (WBH #RC 08-94857) status: closed 2007

G28) **McCullough PA,** site Principal Investigator. A multicenter randomized, double-blind parallel arm, 6-week study to evaluate the efficacy and safety of ezetimibe/simvastatin versus atorvastatin in patients with metabolic syndrome and hypercholesterolemia at high risk for coronary heart disease, $32,010.00. Merck Research Laboratories (WBH #RC 08-94861) status: closed 2008

G29) **McCullough PA,** site Principal Investigator. A multicenter, randomized, double-blind study to evaluate the safety and efficacy of the initial therapy with coadministration of sitagliptin and pioglitazone in patients with type 2 diabetes mellitus, $24,036.00, Merck Research Laboratories, MRK-064 (WBH #RC 08-94860) status: closed 2008

G30) Dixon, SD, site PI, **McCullough PA**, Multinational Executive Committee. RENAL GUARD Pilot Trial. PLC Medical Systems, $37,610.00 (WBH #RC- 90771) status: closed 2008

G31) **McCullough, PA**, site Principal Investigator, A multi-center, randomized, double-blind, placebo and active controlled, parallel group, dose range study to evaluate the efficacy and safety of LCZ696 comparatively to valsartan, and to evaluate AHU377 to placebo after 8-week treatment in patients with essential hypertension. Novartis, Inc., $31,965.28. (WBH #RC-94863) status: closed 2008

G32) **McCullough PA,** site Principal Investigator. Paricalcitol capsules benefits in renal failure induced cardiac morbidity in subjects with chronic kidney disease stage 3b/4,

(PRIMO Abbott Laboratories, ABT-M-10-030, $157,992.00, (WBH #RC-94864) status: closed 2008

G33) **McCullough PA,** site Principal Investigator. A randomized, double-blind, parallel group study to evaluate the effects of high-dose statin therapy on fluorodeoxyglucose (FDG) uptake in arteries of patients with atherosclerotic vascular disease. Merck Research Laboratories, MRK-081, $86,994.00 (WBH #RC 08-90223) status: closed 2008

G34) **McCullough PA,** site Principal Investigator. Patient registry for the Liposorber LA-15 system. Kaneka, Inc., $7,515.00, (WBH #RC-90877) status: closed 2009

G35) **McCullough PA,** site Principal Investigator. A 30-week multicenter, randomized, double-blind. Parallel-group study of the combination of ABT-335 and Rosuvastatin compared to rosuvastatin monotherapy in dyslipidemic subjects with stage 3 chronic kidney disease, Abbott M10-313, $128,544.00, (WBH #RC-90212) status: closed 2009

G36) **McCullough PA,** site Principal Investigator. A multicenter, randomized open label, active-comparator controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to exenatide in patients with type 2 diabetes mellitus inadequately controlled with metformin, thiazolidinedione, or a combination of both, Roche BC 21625, $72,012.50, (WBC #RC-90245) status: closed 2010

G37) **McCullough PA,** site Principal Investigator. A multicenter, randomized double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to placebo in obese patients with type 2 diabetes mellitus inadequately controlled with metformin monotherapy, Roche BC 22092, $38,387.50, (WBH #RC-90258) status: closed 2009

G38) **McCullough PA,** site Principal Investigator. A safety and efficacy trial evaluating the use of apixaban for the extended treatment of deep vein thrombosis and pulmonary embolism, Bristol Myers Squibb-Pfizer CV185057, $173,750.00, (WBH #RC-90288) status: closed 2009

G39) **McCullough PA,** site Principal Investigator. A phase 3, active (warfarin) controlled, randomized, double-blind, parallel arm study to evaluate efficacy and safety of apixaban in preventing stroke and systemic embolism in subjects with nonvalvular atrial fibrillation, Bristol Myers Squibb-Pfizer CV1805030, $173,750.00, (WBH #RC-90275) status: 2009

G40) **McCullough PA,** site Principal Investigator. Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist Trial (TOPCAT), National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the New England Research Institutes, Inc., $86,250.00, (WBH #RC-90267) status: closed 2010

G41) **McCullough PA,** site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter, forced titration study to evaluate the efficacy and safety of aliskiren plus HCTZ verus aliskiren monotherapy in metabolic syndrome patients with stage 2 hypertension, Novartis, Inc., $107,362.44 (WBH #RC-90277) status: closed 2009

G42) **McCullough PA**, site Principal Investigator, Astute SAPPHIRE AST-111, Evaluation of Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury, Astute Medical, Inc, San Diego, CA, $23,195.50 status: closed 2012

G43) **McCullough PA**, site Principal Investigator, protocol number 156-10-292 titled "An Observational Prospective Registry to Identify Demographic and Clinical Characteristics of Patients Hospitalized with Euvolemic and Hypervolemic Hyponatremia and Assess the Comparative Effectiveness of Available Treatments and the Impact on Resource Utilization. Otsuka Inc., $21,262.60 status: initial contract fulfilled, reopened under extension and registry completed in 2013

G44) **McCullough PA**, site Principal Investigator, PROspective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE) Study, National Heart, Lung, and Blood Institute (NHLBI), Pamela Douglas, MD, Principal Investigator Clinical Coordinating Center, Duke Clinical Research Institute, $17,000.00 status: closed 2012

G45) **McCullough PA**, site Principal Investigator, ACZ885M/Canakinumab Clinical Trial Protocol CACZ885M2301 A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP. Novartis, Inc., 2011 $279,223.00 status: closed 2015

G46) **McCullough PA**, site Principal Investigator, AN-CVD2233 Evaluation of the Safety and Efficacy of Short-term A-002 (Varespladib) Treatment in Subjects with Acute Coronary Syndromes (VISTA-16) Anthera Pharmaceuticals, Inc., 2011 $72,600.00 status: closed 2011

G47) **McCullough PA**, site Principal Investigator, BC22140A Cardiovascular outcomes study to evaluate the potential of aleglitazar to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes mellitus (T2D), F. Hoffmann-La Roche Ltd, $307,500.00 status: closed 2012

G48) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study (Phase 2) to Evaluate the Safety and Efficacy of IV Infusion Treatment with Omecamtiv Mecarbil in Subjects with Left Ventricular Systolic Dysfunction Hospitalized for Acute Heart Failure (Protocol 20100754), Amgen, Inc, 253,464.00 status: closed 2012

G49) **McCullough PA**, site Principal Investigator, MB102-073 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and

Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with Inadequately Controlled Hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB), Bristol-Myers Squibb Research and Development, 2011 $34,115.00 status: closed 2012

G50) **McCullough PA,** site Principal Investigator, MB102-077 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) and an additional Antihypertensive medication, Bristol-Myers Squibb Research and Development, $34,115.00 status: closed 2011

G51) **McCullough PA**, site Principal Investigator, ABT M11350 RADAR: Reducing Residual Albuminuria in Subjects with Diabetes and Nephropathy with AtRasentan – A Phase 2b, Prospective, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Safety and Efficacy, Abbott Laboratories, $188,377.00 status: closed 2012

G52) **McCullough PA**, site Principal Investigator, PEGASUS TIMI 54 trial, A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events with Ticagrelor Compared to Placebo on a Background of Acetyl Salicylic Acid (ASA) Therapy in Patients with History of Myocardial Infarction, AstraZeneca, 2011 $98,530.00 status: transferred to PI Marcel Zughaib, MD

G53) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease AMG 145 Amgen Protocol Number 20110118 EudraCT number 2012-001398-97, Amgen, Inc., $1,732,062.80 status: closed 2016

G54) **McCullough PA,** site Principal Investigator, A single-blind, multi-site trial of the dietary supplement anatabine (RCP006) to determine the effects on peripheral markers of inflammation in patients with elevated levels of C-reactive protein (CRP). Roskamp Institute Protocol Number RI-11-01, $6700.00 status: closed 2012

G55) **McCullough PA**, site Principal Investigator, Long-term safety and tolerability of REGN727/SAR236553 in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid modifying therapy: a randomized, double-blind, placebo-controlled study LTS11717 Sanofi Aventis, $252,000.00 status: closed 2013

G56) **McCullough PA**, site Principal Investigator, Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition with Evacetrapib in Patients at a High Risk for Vascular Outcomes – the ACCELERATE Study, protocol I1V-MC-EIAN, Eli Lilly, $421,202.00 status: closed 2014

G57) **McCullough PA,** site Principal Investigator, AEGR-733-025, LOWER: Lomitapide Observational Worldwide Evaluation Registry, Aegerion, Inc., 2014, $23,478.00 status: open

G58) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316), In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-1), Pfizer, Inc., $145,343.90 status: closed 2016

G59) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316) In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-2), Pfizer, Inc., $145,343.90 status: closed 2016

G60) **McCullough PA,** site Principal Investigator, Long Term Observational Study in Patients with Homozygous Familial Hypercholesterolemia Treated with Kynamaro™, Genzyme-Sanofi, Inc., $61,260.00 status: closed 2018

G61) **McCullough PA**, site Principal Investigator, CUP14366, Alirocumab (SAR236553) Expanded Access Program for the Treatment of Severe Hypercholesteremia Not Controlled with Maximal Tolerated Dose of Lipid Lowering Therapy Administered According to Standard of Care, Sanofi-Regeneron, Inc., 2015 $8,500.00 status: closed 2015

G62) **McCullough PA,** site Principal Investigator, Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE), Patient-Centered Outcomes Research Institute, 2015 $29,400.00 status: open

G63) **McCullough PA**, site Principal Investigator, Assessment of Heart Failure using Condition-Specific Impact Assessments (PROMIS), Patient-Centered Outcomes Research Institute, 2015 $81,840.00 status: 2017 status: closed

G64) **McCullough PA**, site Principal Investigator, A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA), Merck, Inc, 2017 $878,163.90 status: closed

G65) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-PRESERVED, Boehringer-Ingleheim, 2017 $170,099.00, status: open

G66) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in

patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-REDUCED, Boehringer-Ingleheim, 2017 $170,099.00, status: open

G67) Schiffmann R, **McCullough PA** Sub-Investigator, 014-097 PB-102-F03 (Sponsor - Protalix - PRX-102 1mg/kg q 2 weeks) A Multi Center Extension Study of PRX-102 Administered by Intravenous Infusions Every 2 Weeks for 60 Months to Adult Fabry Patients, status: open

G68) Schiffmann R, **McCullough PA** Sub-Investigator, 014-288 AT1001-042 (Sponsor - Amicus - oral drug - chaperone) An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Migalastat Hydrochloride Monotherapy in Subjects with Fabry Disease, status: closed.

G69) Schiffmann R, **McCullough PA** Sub-Investigator, 016-153 PB-102-F20 (Sponsor - Protalix - BLINDED - ERT PRX-102 or Fabrazyme 1mg/kg q 2 weeks) A Randomized, Double blind, Active Control Study of the Safety and Efficacy of PRX-102 compared to Agalsidase Beta on Renal Function in Patients with Fabry Disease Previously Treated with Agalsidase Beta – Study Number PB-102-F20, status: open

G70) Schiffmann R, **McCullough PA** Sub-Investigator, 017-189 PB-102-F50 (Sponsor - Protalix - PRX-102 infusion - 2mg/kg monthly) A Phase 3, Open Label, Switch Over Study to Assess the Safety, Efficacy and Pharmacokinetics of pengunigalsidase alfa (PRX-102) 2 mg/kg Administered by Intravenous Infusion Every 4 Weeks for 52 weeks in Patients with Fabry Disease Currently Treated with Enzyme Replacement Therapy: Fabrazyme® (agalsidase beta) or Replagal (agalsidase alfa), status: open

G71) Schiffmann R, **McCullough PA** 018-150 MODIFY (Sponsor - Idorsia - oral drug - substrate reduction) A multicenter, double-blind, randomized, placebo controlled, parallel-group study to determine the efficacy and safety of lucerastat oral monotherapy in adult subjects with Fabry disease, status: open

G72) **McCullough PA**, site Principal Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Multicenter Study to Evaluate the Effects of Sotagliflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes Post Worsening Heart Failure (SAR 439954), Sanofi US Services, Inc, $214,600.00, 2019, status: open

G73) **McCullough PA**, site Sub-Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Alirocumab in Patients with Homozygous Familial Hypercholesterolemia (R727-CL-1628), Regeneron Pharmaceuticals, Inc, $143,503.00, 2019, status: closed

G74) **McCullough PA**, site Sub-Investigator, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Evinacumab in

Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1629) Regeneron Pharmaceuticals, Inc, $143,503.00, 2019, status: closed

G75) **McCullough PA**, site Sub-Investigator, An Open-Label Study to Evaluate the Long-Term Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1719) Regeneron Pharmaceuticals, Inc, $65,317.44, 2019, status: open

G76) Bottiglieri T, Tecson K, **McCullough PA**, Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, Baylor Health Care System Foundation, $49,293.80, 2020 status: open

G77) **McCullough PA**, Wheelan KE. BSWRI—Overall Principal Investigator, 001 A prospective clinical study of hydroxychloroquine in the prevention of SARS-COV-2 (COVID-19) infection in health care workers after high-risk exposures, FDA IND 149293, Baylor Health Care System Foundation, $506,506.00, 2020 status: open

G78) **McCullough PA**, Site Investigator, 4D-310-C001 entitled “An Open-label, Phase 1/2 Trial of Gene Therapy 4D-310 in Adult Males with Fabry Disease” 4D Molecular Therapeutics, Inc, $101,210.85, 2020 status: open

G79) **McCullough PA,** Site Investigator, TQJ230, Assessing the Impact of Lipoprotein (a) Lowering With TQJ230 on Major Cardiovascular Events in Patients With CVD (Lp(a)HORIZON) Novartis Pharmaceuticals Corporation, $3,475,000.00, 2020 status open

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A1) **McCullough PA**, O'Neill WW, May M, Lichtenberg A, Strzelecki M, Grines CG, Safian RD. Predictors of Acute Complications after Percutaneous Coronary Revascularization with New Devices. J Am Coll Cardiol 1994; 122-123A [oral].

A2) **McCullough PA**, O'Neill WW, Hoffman M, Glazier S, Safian RD. The "Protective Effect" of Restenosis Lesions on Angiographic Complications with New Devices. Circulation 1995;92:I-346 [poster].

A3) **McCullough PA**, Wolyn R, Rocher LL, Levin RN, O'Neill, WW. Acute Contrast Nephropathy After Coronary Intervention: Prediction of Dialysis and Related Mortality in the Elderly. American Journal of Geriatric Cardiology 1996;5:52 [poster].

A4) **McCullough PA**, Wolyn R, Rocher LL, Levin RN, O'Neill WW. Acute Contrast Nephropathy After Coronary Intervention: Incidence, Risk Factors, and Relationship to Mortality. J Am Coll Cardiol 1996;304-305A [oral].

A5) **McCullough PA**, Ayad O, Goldstein JA. Cost-Effectiveness Analysis of Patients Admitted with Chest Pain and Normal or Near-Normal Electrocardiograms. Cathet Cardiovasc Diag 1996;38:118 [poster].

A6) Aliabadi D, **McCullough PA**, Kaplan B, Grines CL, Safian RD, Pica M, O'Neill WW, Goldstein JA. A Novel Mobile Fluoroscopic Imaging System for Rapid Bedside Coronary Angiography. Cathet Cardiovasc Diag 1996;38:111 [oral].

A7) Thompson RJ, **McCullough PA**, Kahn JK, O'Neill WW. Early Prediction of Death and Neurologic Outcome in Out-of-Hospital Sudden Death Survivors in the Emergency Department. Circulation 1996;94:I-356 [poster].

A8) **McCullough PA**, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Grines CL. A Prospective Randomized Trial of Triage Angiography in Suspected Acute Myocardial Infarction Patients Who are Considered Ineligible for Reperfusion Therapy. Circulation 1996;94:I-570 [oral].

A9) Aliabadi D, **McCullough PA**, Grines CL, Safian RD, Pica MC, O'Neill WW, Goldstein JA. A Novel Mobile Fluoroscopic Imaging System for Rapid Bedside Coronary Angiography. J Am Coll Cardiol 1997;450A [poster].

A10) **McCullough PA**, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL. Late Outcomes in the Medicine vs. Angiography for Thrombolytic Exclusion (MATE) Study. Circulation, 1997;96:I-595-596 [oral].

A11) Redle JD, West AJ, Khurana S, Marzan R, **McCullough PA**, Frumin HI. Prophylactic Oral Amiodarone with Beta Blockade has Favorable Effects on Atrial Fibrillation Post Coronary Bypass Surgery. Circulation, 1997;96:I-125 [poster].

A12) Sharma ND, Gandhi RS, Philbin EF, Weaver WD, **McCullough PA**. Which Patients with Left Ventricular Dysfunction Require Chronic Anticoagulation? A Prospective Analysis. J Am Coll Cardiol 1998;31:33A. [poster].

A13) **McCullough PA**, Tobin KJ, Kahn JK, O'Neill WW, Thompson RJ. Prediction of In-hospital Survival after Sudden Cardiac Death: Derivation and Validation of a Clinical Model. J Am Coll Cardiol 1998;31:485A [poster].

A14) Stevens M, **McCullough PA**, Tobin KJ, Speck JP, Westveer DC, Guido-Allen DA, Hartenburg DS, Puchrowicz-Ochocki SB, O'Neill WW. A Randomized Trial of Prevention Measures in Patients at High Risk for Contrast Nephropathy: Initial Results of the PRINCE Study. J Am Coll Cardiol 1998;31:469A [poster].

A15) Tobin KJ, **McCullough PA**, Speck JP, Westveer DC, Guido-Allen DA, Hartenburg DS, Puchrowicz-Ochocki SB, O'Neill WW, Stevens M. What Role Does Mannitol Play in Preventing Contrast Nephropathy? A Prospective Analysis. J Am Coll Cardiol 1998;31:469A [poster].

A16) **McCullough PA**, Al-Zagoum M, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL, O'Neill WW. A Time to Treatment Analysis in the Medicine vs. Angiography for Thrombolytic Exclusion Trial. Cathet Cardiovasc Diag 1998;44:105 [oral].

A17) **McCullough PA**, Al-Zagoum M, O'Neill WW, Graham M, David S, Stomel R, Rogers F, Farhat A, Kazlauskaite R, Grines CL. A Program of Triage Angiography in Acute Coronary Syndromes Ineligible for Thrombolysis: An Efficacy Analysis. Cathet Cardiovasc Diag 1998;44:105[poster].

A18) Philbin EF, **McCullough PA**, Polanczyk CA, Jenkins PL, DiSalvo TG. Are Subjects in Heart Failure Trials Similar in Clinical Practice? Circulation, 1998;98:I-866 [moderated poster].

A19) **McCullough PA**, Smith S, Borzak S. Understanding the Risks Associated with Baseline Renal Function in the Coronary Care Unit. Circulation, 1998;98:I-413 [poster].

A20) Afzal A, Gunda M, Brawner CA, Havstad S, **McCullough PA**, Keteyian SJ. Race and the Rate of Referral to Cardiac Rehabilitation. Circulation, 1998;98:I-810-811 [poster].

A21) Borzak S, Every NR, Jankowski M, Havstad S, Chase GA, **McCullough PA**, Elston-Lafata J, Weaver WD. Elderly Patients with Unstable Angina Have Ongoing Risk for Future Events. Circulation, 1998;98:I-629 [oral].

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A24) Mehra P, Pasnoori V, Sengstock D, Obaidat O, Brawner CA, Keteyian SJ, Philbin EF, **McCullough PA.** The Effect of Reactive Airways Disease on Peak Oxygen Consumption in Congestive Heart Failure. J Am Coll Cardiol 1999;33:172A [poster].

A25) **McCullough PA,** Cingireddy U, Philbin EF, Weaver WD. Evidence for a Heart Failure Epidemic: Findings from the REACH Study. J Am Coll Cardiol 1999;33:179A [poster].

A26) **McCullough PA,** Cingireddy U, Philbin EF, Weaver WD. Secular Trends in the Management of Congestive Heart Failure by Primary Care Physicians and Cardiovascular Specialists. J Am Coll Cardiol 1999;33:247A [poster]

A27) Hassan SA, Borzak S, Philbin EF, Soman S, Shah S, Weaver WD, Yee J, Marks KR, **McCullough PA**. The Impact Chronic Renal Insufficiency on Heart Failure Mortality after Hospitalization. Journal of Cardiac Failure 1999;5 Suppl 1:70. [poster].

A28) Sengstock D, Obaidat O, Pasnoori V, Mehra P, **McCullough PA**. Asthma, Chronic Beta-Agonist Use, and the Development of Dilated Cardiomyopathy: Primary Results from the ABCHF Study. Journal of Cardiac Failure 1999;5 Suppl 1:64. [moderated poster].

A29) **McCullough PA,** Kuntz RE, Marks KR, Popma JJ. Should We Change from Aspirin and Ticlopidine to Aspirin and Clopidogrel after Routine Coronary Stenting? A Population-Based Decision Analysis. Circulation 1999;100:I-379.[oral].

A30) **McCullough PA,** Prakash R, Tobin KJ, O'Neill WW, Thompson RJ. Application of a Cardiac Arrest Score in Patients with Sudden Death and ST Segment Elevation for Triage Angiography and Intervention. Fighting Sudden Cardiac Death: A Worldwide Challenge, 1999;18:T-2.

A31) **McCullough PA,** Philbin EF, Czerska B, Spertus JA, Weaver WD. Population-based Medication Profiling in Heart Failure: Treatment Related Outcomes from the R.E.A.C.H. Study. J Am Coll Cardiol 2000; 35:542A [moderated poster].

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A34) Kadakia RA, **McCullough PA**, Soman S, Jankowski M, Borzak S, Keeley EC. Does Percutaneous Revascularization Confer a Long-Term Survival Benefit in Patients with Acute Renal Failure? J Inv Cardiol 2000;12(11):P1.

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A36) Pampati V, Shenkman HJ, McKinnon JE, Khandelwal AK, Nori DM, **McCullough PA**. The Significance of QRS Prolongation in Heart Failure: Findings from the CONQUEST Study. Chest2000;118(4):133S.

A37) Hassan SA, Bhatt S, Borzak S, Pallekonda V, Soman SS, Yee J, Marks K, **McCullough PA**. Clinical and Echocardiographic Determinants of Congestive Heart Failure with Renal Dysfunction.Chest2000;118(4):134S.

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37) Lepor NE, **McCullough PA.** Best of the ACC 2010 Scientific Session. Rev Cardiovasc Med. 2010 Summer;11(3):e153-63

38) Narala KR, LaLonde TA, Hassan S, **McCullough PA**. Management of Chronic Coronary Disease and Acute Coronary Syndromes in Patients with Chronic Kidney Disease. US Cardiology, 2011;8(2):123-31

39) Larsen T, Narala KR, **McCullough PA.** Type 4 Cardiorenal Syndrome: Myocardial Dysfunction, Fibrosis, and Heart Failure in Patients with Chronic Kidney Disease. J Clinic Experiment Cardiol 2012, 3:4. http://dx.doi.org/10.4172/2155-9880.1000186

INVITED LECTURES: NATIONAL AND INTERNATIONAL FORUMS

L1) "The Role of Triage Angiography in Acute Coronary Syndromes." Advances in Interventional Cardiology. WBH and the University of Maryland, Aruba, April, 1997.

L2) "New Understandings of Anticoagulation During Unstable Angina." Co-Chair, American College of Cardiology 47th Annual Scientific Session, Atlanta, Georgia, March 30, 1998.

L3) National Library of Medicine: The Emerging Health Information Infrastructure '99. "Electronic Outcomes", Washington, D.C., April 28, 1999.

L4) Kansas City Southwest Clinical Society, 77th Annual Clinical Conference, Overland Park, Kansas: "Cardiac-Renal Risk: Incorporating Scientific Evidence into Your Practice," October 29, 1999.

L5) The Health Forum, Best Practices, Chicago, Illinois. "Overview of Cardiovascular Health Fellowship," December 9, 1999.

L6) AHA Scientific Conference on Existing Databases: Do They Hold Answers to Clinical Questions in Geriatric Cardiovascular Disease and Stroke? "Resource Utilization Among Congestive Heart Failure (R.E.A.C.H.) Database Overview," Washington, DC, January 27, 2000.

L7) Health Forum Cardiovascular Health Fellowship Retreat: "Cardiovascular Risk and Health," Colorado Springs, CO, July 20, 2000.

L8) Third Annual Center for Health Futures Advisory Board Meeting: "Congestive Heart Failure," La Jolla, CA, August 24, 2000.

L9) Health Forum ACT Learning Collaborative Meeting: "Bridging Clinical, Community, and Population Health Strategies," St. Joseph, MO, September 20, 2000.

L10) "Renal Disease as an Independent Risk Factor for Cardiovascular Disease in Diabetes," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, November 4, 2000.

L11) "Atherosclerosis and Heart Disease," Winter Scientific Seminar, Missouri Society of the American College of Osteopathic Physicians, Kansas City, MO, January 27, 2001.

L12) "Routine vs Selective Intervention in Acute Coronary Syndromes," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2001.

L13) "Intervention in the Patient with Renal Insufficiency," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 16, 2001.

L14) "The Epidemic of Cardiovascular Disease and Cardiorenal Risk," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, February 24, 2001.

L15) "Cardiovascular Risk in Chronic Kidney Disease: Cardiorenal Risk," Symposium on Cardio-renal Consequences of Angiotensin II, Insights from AII Blockade, NKF Spring Clinical Meeting, Orlando, FL, April 18, 2001.

L16) Plenary Session: "Cardiac Emergencies and Cardiac Critical Care," American College of Chest Physicians, CHEST 2001, Philadelphia, PA, November 5, 2001.

L17) "Cardiorenal Risk," The 33rd Annual ACC Cardiovascular Conference at Snowmass, Snowmass, Colorado, January 18, 2002.

L18) "Epidemiology of Diabetes and Its Cardiovascular Risk" Eleventh Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2002.

L19) "Late-Breaking Clinical Trials II: A Prospective, Blinded Trial of B-Type Natriuretic Peptide as a Diagnostic Test for the Emergency Diagnosis of Heart Failure: The Breathing Not Properly (BNP) Multinational Study," March 19, 2002, 51st Annual Scientific Session of the American College of Cardiology, Atlanta, GA.

L20) "Scope of Cardiovascular Complications in Patients with Kidney Disease." Plenary Session III: Reversing Cardiovascular Complications in Patients with Kidney Disease. International Society on Hypertension in Blacks: 17th International Interdisciplinary Conference on Hypertension and Related Risk Factors in Ethnic Populations, Miami, FL, June 11, 2002.

L21) "Epidemiology: Renal—Chronic Kidney Disease." Atherosclerotic Vascular Disease Conference, AHA, Boston, MA, July 8, 2002.

L22) "B-type Natriuretic Peptide Should be a Part of the Diagnostic Evaluation of Heart Failure: Implications from the Breathing Not Properly (BNP) Multinational Study" International Academy of Cardiology 8th World Congress on Heart Failure—Mechanisms and Management, Washington, DC, July 15, 2002.

L23) "Epidemiology and Physiology of Radiocontrast Nephropathy and its Impact on Outcomes" Prevent the Event Transcatheter Therapeutics 2002 Satellite Symposium, Washington, DC, September 26, 2002.

L24) "Calcification or 'Phosphication'—Controversies of Calcium Phosphate Deposition: Invited Lecture: Coronary Calcification: A Predictor of Future Events or a Marker of Plaque Stability? American Society of Nephrology 2002 Annual Scientific Sessions Satellite Symposium, Philadelphia, PA, November 1, 2002.

L25) "Renal Insufficiency and Clinical Outcome" Cardiovascular Seminar, AHA Scientific Sessions, Chicago, IL, November 18, 2002.

L26) "Role of BNP in the Diagnosis of Heart Failure" ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.

L27) "Managing the Patient with Combined Heart and Renal Failure—the Importance of Anemia" ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.

L28) "The Emerging Healthcare Crisis of Obesity," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 10, 2003.

L29) "BNP in the Management of Heart Failure," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 11, 2003.

L30) "Contrast Nephropathy: Can it be Eliminated," Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 13, 2003.

L31) "How Subtle Degrees of Renal Dysfunction Work as a Cardiac Risk Factor" First Cardiovascular Prevention Symposium: Updates and New Guidelines. AHA, Puerto Rico Chapter, San Juan, PR, March 22, 2003.

L32) "What Is the Incremental Diagnostic Value of B-Type Natriuretic Peptide in Heart Failure?" Symposium. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.

L33) "Heart Failure Insights From Ejection Fraction" Session Co-Chair. Oral Contributions. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.

L34) "Chronic Renal Insufficiency as a Vascular Risk Factor" 14th Annual Scientific Sessions of the Society for Vascular Biology and Medicine, Chicago, IL, June 7, 2003.

L35) "Phosphate Control and Calcification from a Cardiologist's Perspective" World Congress of Nephrology Satellite Symposium, Berlin, Germany, June 12, 2003.

L36) "Renal Disease is a Risk Factor for Cardiovascular Disease" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L37) "Diagnosis of Congestive Heart Failure: Is BNP Needed in Every Case?" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L38) "How to Treat Combined Heart and Renal Failure with Hypertension" ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

L39) "Which Agents Prevent Contrast-Induced Nephropathy?" European Society of Cardiology 2003 Symposium: Managing Patients at Risk for Contrast-Induced Nephropathy, Vienna, Austria, September 2, 2003.

L40) "Epidemiology of Contrast Nephropathy" Symposium Chair for "A Contrast in Risk: Radiographic Imaging in the Renally Compromised Patient", Satellite Symposium at the Transcatheter and Therapeutics Scientific Meeting, Washington, DC, September 17, 2003.

L41) "Update on Cardiovascular Risk Reduction in Acute Coronary Syndrome Patients" 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.

L42) "Renal Function and Dysfunction in Coronary Arteriography" 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.

L43) "Interventional Cardiology 2003: Bench to Bedside and Beyond, Session III: Contrast Nephropathy: Separating the Hype from the Data. Antagonist: Contrast Nephropathy Can be Prevented." AHA Scientific Sessions 2003, November 9, 2003, Orlando, FL.

L44) "Reversing Diabetes and Its Consequences: Pipe Dream or Reality?" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L45) "Refining the Use of B-type Natriuretic Peptide as a Diagnostic Test in Clinical Practice" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L46) "Practical Management of Obesity for the Cardiologist: The Future of Dietary Management and Bariatric Surgery" The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.

L47) "Update from the Hypertension World: JNC 7—What's New and How Will it Influence Practice?" Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

L48) "The Lethal Couplet" Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

L49) "BNP to Differentiate Between Cardiac and Extracardiac Sources of Dyspnea" 33rd Critical Care Congress, Society of Critical Care Medicine, Orlando, Florida, February 23, 2004.

L50) "BNP Testing: Is It Ready for In-Hospital Monitoring of Therapy?" Point-of-Care Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.

L51) "Role of Brain Natriuretic Peptide Levels in Diagnosis" Natriuretic Peptides Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.

L52) "Renal Insufficiency and the Heart" Symposium Co-Chair, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L53) "Renal Insufficiency and Bypass Surgery" Renal Insufficiency and the Heart Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L54) "Causes and Consequences of Contrast-Induced Nephropathy and other Major Adverse Coronary Events" Contrast-Induced Nephropathy: Addressing the Needs of the High Risk Patient. A Satellite Symposium to the American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.

L55) "Chronic Kidney Disease as a Cardiovascular Risk Factor" 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004

L56) "Modern use of Angiotensin Receptor Blockade in Cardiovascular Disease" 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004

L57) "Chronic Kidney Disease and Cardiovascular Disease" Satellite Symposium: Impact of Anemia Correction in Cardiovascular Patients, American Society of Hypertension Annual Scientific Session, New York, NY, May 22, 2004.

L58) "Contrast-Induced Nephropathy—Clinical Anomaly or Reality" Satellite Symposium: Selecting Contrast Media - Implications for Patient outcomes, EuroPCR 2004, Paris, France, May 26, 2004.

L59) "Contrast Nephropathy" Intervention 2004. American College of Cardiology Nationwide Symposium, CNN Center, Atlanta, GA, June 2, 2004.

L60) "Technical Issues in Selection of the BNP Assay" Satellite Symposium of the American Association of Clinical Chemistry, Los Angeles, CA, July 28, 2004.

L61) "B-type Natriuretic Peptide in Clinical Practice" New Development in Cardiac Biomarkers for Detection and Management of Cardiovascular Diseases, EBAC Accredited Educational Programme, in conjunction with the European Society of Cardiology 2004 Annual Congress, Munich, Germany, August 30, 2004.

L62) "Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient" Session Moderator, Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

L63) "Definition and Pathophysiology of Contrast Nephropathy", "Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient" Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

L64) "Use of BNP in Clinical Practice" "Hot Topics: Clinical Utility of Biomarkers" Transcatheter Cardiovascular Therapeutics 2004, September 28, 2004.

L65) "Contrast Media, Renal Insufficiency, and Radiocontrast Nephropathy" Introduction to Cardiac Catheterization and Indications for Percutaneous Interventions, 7th Annual Interventional Cardiology Self Assessment and Review Course, Transcatheter Cardiovascular Therapeutics 2004, September 29, 2004.

L66) "Body Weight—Optimal Targets and How Good are We in Getting There" "Drug Combinations for Cardiovascular Disease" Duke Clinical Research Institute and U.S. Food and Drug Administration Think Tank, Washington, DC, October 8, 2004.

L67) "Does Coronary Calcification Imply Plaque Instability?" Managing Cardiovascular and Calcium/Phosphorus Complications of CKD. Official Luncheon Symposium, Renal Week 2004, American Society of Nephrology, St. Louis, MO, October 20, 2004.

L68) "B-type Natriuretic Peptide in the Diagnosis of Acute Heart Failure," New Advances in the Diagnosis and Management of Acute Decompensated Heart Failure, Satellite Symposium to the AHA Scientific Sessions 2004, New Orleans, LA, November 8, 2004.

L69) "Oportunidades para Aprimoramento no Tratamiento da Insuficiencia Cardiaca," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontró Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahía, Brasil, November 25-27, 2004.

L70) "Peptideo Natriuretico Intravenoso-Perspectivas para Emprego na IC Descompensada," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahia, Brasil, November 25-27, 2004.

L71) "Nesiritide (Peptideo Natriuretico Intravenoso) uma Nova Arma no Tratamento da IC Grave e Decompensada," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.

L72) "Conferenca Magna (Keynote Address): The Cardiorenal Intersection: Crossroads to the Future," 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insufiencia Cardiaca, I Encontro Multiporfissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.

L73) "Practical Use of BNP in the Diagnosis and Management of Heart Failure" Medical Grand Rounds, Olathe Regional Medical Center, Olathe, KS, December 3, 2004.

L74) "Management of Heart and Renal Failure" The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.

L75) "Contrast-Induced Nephropathy" The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.

L76) "Combined Heart and Kidney Failure" Cardiovascular Conference at Snowmass, Aspen, CO, January 18, 2005.

L77) "Practice Strategies and Protocols to Reduce Renal Complications" PCI: Understanding and Managing In-Hospital Cardiac and Renal Complications, 3rd European Summit, Chantily, France, February 11, 2005.

L78) "HDL Cholesterol: A Powerful New Therapeutic Target" 14th (Conference Chair) Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 14, 2005.

L79) "BNP-ology, is the Enthusiasm Warranted?" (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2005.

L80) "Anticoagulation for Atrial Fibrillation: Can Warfarin be Replaced?" (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 18, 2005.

L81) "New Multimarker Strategies in the Diagnosis of Acute Coronary Syndromes" Satellite Symposium to the 54th Annual American College of Cardiology Scientific Sessions 2005, Orlando, FL, March 7, 2005.

L82) "Effect of Lowering LDL Level on Progression of Vascular Calcification" Reducing the Burden of Cardiovascular Calcification in Chronic Kidney Disease, Satellite Symposium to the Renal Physicians Association Annual Meeting, Washington, DC, March 20, 2005.

L83) "Why Chronic Kidney disease is a CVD risk factor: Practical Implications in the Care of Cardiovascular Patients" Cardiology Grand Rounds, Clinical Science Institute, Galway, Ireland, UK, May 5, 2005.

L84) "Clinical Application of B-type Natriuretic Peptide Levels in the Care of Cardiovascular Patients" EuroLab 2005, Glasgow, Scotland, UK, May 9, 2005.

L85) "Anemia Is a Cardiovascular Risk Factor in Patients With Diabetic Nephropathy" The Kidney is a Key Link between Diabetes and Cardiovascular Disease: Managing Risk; Satellite Symposia to the Annual Scientific Sessions of the American Association of Clinical Endocrinology, Washington, DC, May 18, 2005.

L86) "CIN: Emerging Trends in Identifying and Managing the At-risk Patient" Cardiovascular and Interventional Radiology Society of Europe (CIRSE) 2005, Nice, France, September 13, 2005.

L87) "Recent Advances in Cardiac Markers and their Clinical Role in Cardiovascular Disease: Update of the BNP Consensus Panel Statements and Cost Effectiveness of BNP Testing" Turning Science into Caring Programme, Abbott European Laboratory Symposium, Wiesbaden-Delkenheim, Germany, October 14, 2005.

L88) "Epidemiology and Prevention of Contrast Nephropathy" Transcatheter Therapeutics Annual Scientific Sessions, Washington, DC, October 19, 2005.

L89) "BNP—What Does it All Mean?" Heart Failure 2005: What to Do for the Failing Left Ventricle" AHA Symposium in Conjunction with the 2005 Scientific Sessions, Dallas, TX, November 11, 2005.

L90) "How to Use Cardiac Biomarkers in Heart Failure" 2005 Annual Scientific Sessions of the AHA, Dallas, TX, November 14, 2005, broadcasted nationally as "Best of Sessions 2005 on Wednesday, November 30 from 1:00-2:30PM EST"

L91) "Chronic Kidney Disease as a Cardiovascular Risk State: Practical Management for the Cardiologist" St. Vincent's Hospital, University of British Columbia, Distinguished Speakers in Cardiovascular Medicine, 2005-2006, Vancouver, BC, Canada, December, 1, 2005.

L92) "Anemia, Chronic Kidney Disease, and Cardiovascular Disease: Diagnosis, Prognosis, and Treatment. Nephrology Grand Rounds, University of British Columbia, St. Vincent's Hospital, Vancouver, BC, Canada, December 2, 2005.

L93) "The Deadly Triangle of Anemia, Kidney and Heart Disease: Implications for Treatment and Management" 37th Annual Cardiovascular Conference at Snowmass, January 20, 2006, Snowmass, CO.

L94) "Anemia in Cardiovascular Patients: Diagnosis, Prognosis, and Therapy." AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 27, 2006, Orlando, FL.

L95) "Update on Bariatric Surgery" (Conference Chair) 15th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 17, 2006.

L96) "Multimarker Approach to Chest Pain." Satellite Symposium to the Annual Scientific Sessions of the American College of Cardiology, March 11, 2006, Atlanta, GA.

L97) " Preventing Contrast Nephropathy: What Works?" American College of Cardiology Annual Scientific Sessions (ACC.06 and the i2 Summit 2006), March 14, 2006, Atlanta, GA.

L98) "Consensus statements on strategies to reduce the risk of CIN." Satellite Symposium Society for Cardiac Angiography and Intervention 29th Annual Scientific Sessions (Symposium Chair): Consensus Statements on Contrast-Induced Nephropathy (CIN): Report of an International, Multidisciplinary Panel, Chicago, IL, May 11, 2006.

L99) "Contrast-induced nephropathy: identifying and managing the patient at risk." Euro PCR 2006 Satellite Symposium: The Underestimated Impact of Contrast Media on Patient Outcomes in PCI (Symposium Chair), Paris, France, May 27, 2006.

L100) "Debate: Acute Decompensated Heart Failure--Biomarker will suffice" 17th Annual Scientific Sessions of the American Society of Echocardiography, Baltimore, MD, June 6, 2006.

L101) "Heart and Kidney: Clinical Impact of Contrast Media" Update on Cardiovascular Disease 2006, Casa Di Cura Montevergine, Napoli Castel Dell'Ovo, Naples, Italy, June 19, 2006.

L102) "Cardiovascular Disease in CKD: Where Does Calcium Fit In?" Satellite Symposia: Current Strategies for the Management of Hyperphosphatemia in End-Stage Renal Disease. European Renal Association/European Dialysis and Transplantation Association Annual Scientific Meeting, Glasgow, Scotland, July 17, 2006.

L103) "Applications of BNP in Cardiovascular Disease" Satellite Symposia: New and Evolving Markers for Cardiovascular Disease: Myeloperoxidase (MPO) and BNP. American Association of Clinical Chemistry Annual Meeting, Chicago, IL, July 26, 2006.

L104) "Clinical Applications of B-type Natriuretic Peptide Testing" Clinical Biochemistry Satellite Symposium: The Role of Biochemical Markers in Clinical Cardiology, Sponsored by the Australasian Association of Clinical Biochemists at the 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 4, 2006.

L105) "Update on BNP in the Management of Heart Failure" 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 6, 2006.

L106) "Update on BNP in the Management of Heart Failure" Cardiology Grand Rounds, Royal North Shore Hospital, Sydney, Australia, August 7, 2006.

L107) "Contrast-Induced Nephropathy: Identifying and Managing the Patient at Risk" Advances in Contrast-Enhanced Imaging: Improving Outcomes and Reducing Risks of Iodinated Contrast (Chairman), a CME Satellite Symposium at the Transcatheter Therapeutics 2006 Conference, Washington, DC, October 24, 2006.

L108) "Cardiorenal Syndrome: Etiology, Therapy, and Prognosis" Unresolved Issues in Heart Failure, Cardiovascular Seminars, 2006 Annual Scientific Sessions of the AHA, Chicago, IL, November 14, 2006

L109) "Prevention and Management of CAD in CKD" Coronary Artery Disease in CKD: Updating the Pathophysiology and Management. Official Symposium of the American Society of Nephrology, Sand Diego, CA, November 16, 2006.

L110) "Pharmacologic Prevention of Sudden Death in Dialysis Patients" Sudden Death in Hemodialysis Patients: Towards Prevention. American Society of Nephrology Renal Week 2007, San Diego, CA, November 17, 2006.

L111) "Contrast Nephropathy: Finding Consensus on a Rational Approach" Radiology Grand Rounds, Hôpital Notre-Dame, University of Montreal, Canada, November 23, 2006.

L112) "Contrast Nephropathy: Finding Consensus on a Rational Approach" Radiology Grand Rounds, Hôpital St-Luc, University of Montreal, Canada, November 23, 2006.

L113) "Cardiorenal Syndrome and Anemia" 3rd Annual Heart Failure University (HFU) Cardiovascular Fellows Program, Los Angeles, CA, December 2, 2006.

L114) "Implications of Age-Related Decline in Renal Function" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2007.

L115) "Using BNP in Your Practice: Pearls and Pitfalls" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2007.

L116) "Consensus Panel Findings on Contrast Nephropathy" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 16, 2007.

L117) "Measuring BNP in ACS," American College of Cardiology Scientific Sessions Satellite Symposium, "ACS & Biomarkers: From Molecules to Patient Management", New Orleans, LA, March 24, 2007.

L118) "Anemia Correction and CVD Trials" "Ask the Experts" clinicaltrialresults.org, American College of Cardiology Scientific Sessions, New Orleans, LA, March 26, 2007.

L119) "CKD and CVD: Interaction and Risk Factors", Kidney Disease: The Unrecognized Silent Killer, NKF 2007 Scientific Meetings, Orlando, FL, April 11, 2007.

L120) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Special Lecture for the Radiological Society of the Republic of China, National Yang-Ming University, School of Medicine, Taipei, Taiwan, May 4, 2007.

L121) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Annual Meeting of Kaohsiung Society of Radiology, Chang Gung Memorial Hospital, Kaohsiung Hsien, Taiwan, May 5, 2007.

L122) "Meta-Analyses of the Renal Safety of Iodixanol", Plenary Session, 15th Annual Scientific Congress of the Hong Kong College of Cardiology, Hong Kong, SAR, May 6, 2007.

L123) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Cardiology Special Lecture, 12th Department of Cardiology, Beijing AnZhen Hospital, Beijing, Peoples Republic of China, May 7, 2007.

L124) "Prevention of CIN during PCI in Diabetic Patients: Proposal of a Guideline" (Prevencion del Fracaso Renal Inducido por Contraste en Pacientes Diabeticos Sometidos a Intervencionismo Coronario: Propestuesta de un Protocolo Actuacion), Optimizacion del Tratamiento de Revascularizacion Percutanea en Pacientes Diabeticos, TEAM (Terapia Endovascular & Miocardica), Hospital del Mar, Barcelona, Spain, May 11, 2007.

L125) "Acute Kidney Injury from Iodinated Contrast: Findings from an International Panel," Hungarian Society of Cardiology Annual Scientific Meeting (Magyar Kardiologusok Tarsasaga Tudomanyos Kongresszusa) Balatonfured, Hungary, May 12, 2007.

L126) "Which Types and Which Amount of Physical Activities to Achieve and Maintain a Healthy Body Weight?" 4th Metabolic Syndrome, Type II Diabetes, and Atherosclerosis Congress (MSDA), 2007, Lisbon, Portugal, May 19, 2007.

L127) "The Role of BNP in Patients with Shortness of Breath," Laboratory Diagnostic Technologies for Patients with Shortness of Breath, Satellite Symposium to the American Association of Clinical Chemistry Annual Scientific Meeting, San Diego, CA, July 18, 2007.

L128) "Acute Kidney Injury after Contrast: A Serious Problem by Any Name", Hemodynamics, Electrolytes, Acute Kidney Injury: Novel Considerations in Contrast Selection, Transcatheter Cardiovascular Therapeutics 2007 Annual Meeting Satellite Symposium, Washington, DC, October 23, 2007.

L129) "Vascular Calcification: Myth versus Realty: A Cardiologist's Perspective," Changing Paradigms: Evolving Bone and Mineral Metabolism Treatment in CKD, An American Society of Nephrology 2007 Official Symposia, San Francisco, CA, November 3, 2007.

L130) "Contrast-Induced Nephropathy" Cardiology Grand Rounds, Auckland City Hospital, Auckland, New Zealand, November 22, 2007.

L131) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" North Shore Hospital- Waitemata Health, Takapuna, Auckland, New Zealand, November 22, 2007.

L132) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" Waikato Hospital, Hamilton, New Zealand, November 23, 2007.

L133) "Practical Use of Natriuretic Peptides in Cardiovascular Disease" Wakefield Hospital, Adelaide, Australia, November 23, 2007.

L134) "Clinical Utilization of Cardiac Troponin and Natriuretic Peptides in ACS and CHF" Satellite Symposium to Australasian Emergency Meeting (ACEM), Gold Coast, Brisbane, Australia, November 27, 2007.

L135) "Clinical Utilisation of Cardiac Troponin and Natriuretic Peptides in ACS and CHF: Part 1: Congestive Heart Failure, Part 2: Acute Coronary Syndrome, Part 3: Cardio-Renal Syndrome, Kuala Lumpur, Malaysia, November 29, 2007.

L136) "Multimarker Strategies in the Management of Cardiovascular Emergencies," YMCA for Dr. H.F.Ho, Queen Elizabeth Hospital, Hong Kong, SAR, November 30, 2007.

L137) "Practical Management of Cardiovascular Disease in Patients with Kidney Disease" Williamsburg, Virginia for the 34th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 3, 2007.

L138) "New Cardiovascular Drugs" 17th Annual Cardiovascular Conference at Beaver Creek" Avon, CO, February 12, 2008.

L139) "New Insights into Atherosclerosis and Global CVD Risk," 17th Annual Cardiovascular Conference at Beaver Creek" Avon, CO, February 12, 2008.

L140) "Plenary 2 : Mini-Symposia: Acute Kidney Injury (AKI): Pathophysiology: Contrast Nephropathy: Epidemiology and Prognosis" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 28, 2008.

L141) "Heart Failure and Cardio-Renal Syndrome 1: Pathophysiology" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.

L142) "Hemodynamic Monitoring: Principles and Practice" 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.

L143) "Cardiovascular Calcification, Potential Strategies in Minimizing Cardiovascular Disease in CKD", Satellite Symposia at the 57th ACC Annual Scientific Sessions, Chicago, IL, March 30, 2008.

L144) "Emergency Evaluation of Chest Pain: Building a Better Mousetrap" Olathe Medical Center Annual Heartbeat Symposium, Olathe, KS, April 4, 2007.

L145) "Interventions and CVD Interactions in Diabetics with Proteinuria" Satellite Symposia (Chairman) Chronic Kidney Disease Interventions: Improving CKD and CVD Outcomes" NKF Clinical Meeting 2008, Dallas, TX, April 5, 2008.

L146) "Shifting Paradigms in PCI: Controversial Issues in High-Risk Patients" International Symposium (Chairman), Barcelona, Spain, April 10, 2008.

L147) "Success in Identifying Heart Failure" Satellite Symposia "Managing CVD: What Every Internist Needs to Know" Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 14, 2008.

L148) "Cardiovascular Calcification in Patients with Chronic Kidney Disease" Satellite Symposia "Cardiovascular Disease in CKD: Strategies for Minimizing Mortality" Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 15, 2008.

L149) "Clinical Trial Designs in Contrast Induced Acute Kidney Injury," Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

L150) "Neutrophil Gelatinase Associated Lipocalin (NGAL)" on Behalf of Inverness Medical, Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

L151) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Radiological Society of Taiwan, Taipei, Taiwan, July 17, 2008.

L152) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Radiological Society of Taiwan, Kaushiung, Taiwan, July 18, 2008.

L153) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Contrast-Induced Nephropathy Symposium, Professor Yalin Han, MD, Chairwoman of Military Cardiology Society of China, Shenyang, China, July 20, 2008.

L154) Cardiology Teaching Rounds, with Professor Runlin Gao, Beijing Fuwai Hospital, Beijing, China, July 21, 2008.

L155) Cardiology Teaching Rounds, with Professor Yujie Zhou, Beijing Anzhen Hospital, Beijing, China, July 21, 2008.

L156) Cardiology Teaching Rounds with Professor Yundai Chen, General Hospital of Military, Peoples Liberation Army, Beijing, China, July 21, 2008.

L157) "Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy" Contrast-Induced Nephropathy Symposium, Contrast-Induced Nephropathy Symposium, Professor Runlin Gao, Chairman of Chinese Cardiology Society, Beijing, China, July 22, 2008.K

L158) "New Insights on Accelerated Vascular Calcification in Patients with Kidney Disease" Plenary Session: Ischemic Heart Disease/Risk Assessment/New Treatment Strategies"

International Academy of Cardiology 14th World Congress on Heart Disease, Annual Scientific Sessions, Toronto, Ontario, Canada, July 29, 2008.

L159) "Cardiorenal Syndrome: the Diagnostic Value of Brain Natriuretic Peptide and Neutrophil Gelatinase Associated-Lipocalin in Interventional Cardiology," Cardiovascular Biomarkers which Enhance Clinical Practice in Emergency Medicine and Cardiology: the State of the Art for Markers of Necrosis, Hemodynamic Stress and Cardiorenal Syndrome, Satellite Symposium to the European Society of Cardiology Annual Scientific Sessions, Munich, Germany, September 2, 2008.

L160) "Diagnosis and Management of Diabetes, Hypertension, and Acute Dyspnea," 2008 CVD and CKD Intersection Consensus Conference, Chicago, IL, September 26, 2008.

L161) "Chronic Kidney Disease and Contrast Nephropathy (Contrast-Induced Acute Kidney Injury [CI-AKI]): From Prognostic Scores to the Latest Preventive Strategies" Complex Patients, Complex Lesions, 20th Annual Transcatheter Therapeutics Conference, Washington, DC, October 14, 2008.

L162) "Chronic Kidney Disease: a CHD Risk Equivalent" 2008 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 19, 2008.

L163) "Hyperphosphatemia as a Cardiovascular Risk Factor" Nephrology Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.

L164) "Cardiovascular Calcification in Patients with Chronic Kidney Disease" Nephrology Division-Wide Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.

L165) "Hyperphosphatemia and CVD Risk," Management of Hyperphosphatemia Across the Continuum of CKD, American Society of Nephrology Satellite Symposium, Philadelphia, PA, November 8, 2008.

L166) "Cardiovascular Calcification" Nephrology Grand Rounds, Humber River Regional Hospital, Toronto, Ontario, Canada, December 9, 2009.

L167) "Cardiovascular Calcification" Nephrology Grand Rounds, St. Joseph's Hospital, Toronto, Ontario, Canada, December 9, 2009.

L168) "Critical Concepts in the Progression of Atherosclerosis" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.

L169) "New Molecular Targets in the Treatment of Atherosclerosis" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.

L170) "Sudden Cardiac Death in Patients with Renal Disease" 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2009.

L171) "Cardiovascular and Renal Implications of Contrast Media" Radiology Grand Rounds, The Kingston Hospital, Queens University School of Medicine, Kingston, Ontario, Canada, March 3, 2009.

L172) "Recent Evidence into the Pathophysiology of Cardiovascular Calcification in Chronic Kidney Disease," NKF Symposium 2009 Spring Clinical Meetings, "Exploring Recent Evidence Related to Cardiovascular Calcification and Chronic Kidney Disease", Nashville, TN, March 27, 2009.

L173) "Chronic Kidney Disease: Implications For Patients With CAD" Managing the High Risk Coronary Patient, I2 Summit, American College of Cardiology Annual Scientific Sessions, Orlando, FL, March 30, 2009.

L174) "BNP and Cardiovascular Disease" Cardiology Grand Rounds, Hospital PróCardíaco, Rio deJaniero, Brasil, April 14, 2009.

L175) "Acute Cardiac Effects of Marathon Running" Special Guest Lecture, CLINIMEX - Clínica de Medicina do Exercício, Rio deJaniero, Brasil, April 14, 2009.

L176) "Interface entre doenca renal e cardiovascular: o rim mata o coracao ou o coracao mata o rim? Da para evitar esse extermino?" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L177) "A angiotomografia coronaria deve ser empregada em todo paciente com do toracica de risco baixo-moderado?" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L178) "Conferencia Internacional: Opportunidades para aperfeicoar o tratamento da insuficiencia cardiaca avancada/descompensada" Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.

L179) "Invasive Versus Non-invasive Coronary Angiography: Guidelines for Achieving Optimal Outcomes" Annual Scientific Sessions of the Society for Cardiac Angiography and Intervention, Las Vegas, NV, May 7, 2009.

L180) "Cardiorenal Syndrome" Moderator, American Society of Nephrology Annual Scientific Sessions, Renal Week 2009, San Diego, CA, October 29, 2009.

L181) "The Creatinine Changes: Now What?" Cardiorenal Syndromes, Annual Scientific Sessions, AHA, Orlando, FL, November 16, 2009.

L182) "Cardiorenal Syndromes: Strategies for Success" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L183) "Cardiomyopathy of Obesity" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L184) "Why Does Atherosclerosis Calcify: Clinical Implications" 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.

L185) "Prevention Trials in AKI" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

L186) "Cardiology Trials" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

L187) "Contrast Nephropathy: Prevention and Management" 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 26, 2010.

L188) "Lipoprotein-Associated Phospholipase A2 (Control#: 4599)" Symposium: Do New Markers & Genomics Enhance Risk Prediction? Annual Scientific Sessions of the ACC, Atlanta, GA, March 15, 2010.

L189) "New Insights Into the Role of Heart-Kidney Interactions in the Cardiorenal Syndrome" (Control#: 16660) Symposium: Recognition and Management of the Cardiorenal Syndrome in Advanced Heart Failure, Annual Scientific Sessions of the American College of Cardiology, Atlanta, GA, March 15, 2010.

L190) "B-Type Natriuretic Peptides in Cardiorenal Syndromes" 5th Annual Turning Science into Caring Symposium, Wiesbaden, Germany, March 25, 2010.

L191) "CKD and CVD Interaction in KEEP" KEEP Update: the Common Soil of CKD and CVD, NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

L192) "Cardio Renal Intersection, Crossroads to the Future - Novel Coronary Risk Factors" NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

L193) "Diagnostic Workup of suspected heart disease in CKD" NKF Spring Clinical Meetings, Orlando, FL, April 17, 2010.

L194) "BNP: Beyond Heart Failure (BNP más allá de la insuficiencia cardiaca)", XIX Chile 2010 Congreso Latinoamericano de Bioquimica Clinica, XVI Congreso Chileno de Quimica

Clinica, Biomarcadores en Enfermedades Cario-Renales COLABIOCLI 2010, Santiago del Chile, April 21, 2010.

L195) "Prevention of Cardiorenal Syndromes", 19th International Vicenza Course on Critical Care Nephrology, Vicenza, Italy, June 10, 2010.

L196) "La Pandemia de la Obesidad: Que podemos hacer aquí y ahora" "Importancia de la Evaluación previa y el monitoreo cardiaco en rehabilitación cardiaca" "Ergoespirometria: Diagnostico e implicaciones terapéuticas," Sociedad Columbiana de Cardiologica y Ciruga Cardiovacular Fundacion Columbiana del Corazon Comite de Prevencion y Rebabilitacion Cardiovascular Dia Mundial del Corazon, Santa Marta, Columbia, September 25, 2010.

L197) "CKD: A CHD Equivalent" 2010 Cardiometabolic Health Congress (CMHC), Boston MA, October 22, 2010.

L198) "Treatment Disparities in Patients with Acute Coronary Syndromes and Kidney Disease" AHA Scientific Sessions 2010, Chicago, IL, November 13, 2010.

L199) "Integration of Advanced Information Technology into Nephrology Practice" Moderator, at the American Society of Nephrology, Denver, CO, November 21, 2010.

L200) "Cardiorenal Syndromes" Special Lecture, Mansoura Nephrology and Urology Center, Mansoura, Egypt, November 29, 2010.

L201) "Neutrophil Gelatinase Associated Lipocalin." Al Mokhtabar Laboratories, Cairo, Egypt, December 1, 2010.

L202) "Cardiorenal Syndromes" ACC Williamsburg Conference, Williamsburg, VA, December 5, 2010.

L203) "Micronutrients and Cardiorenal Disease: Insights into Novel Assessments and Treatment" 13th International Conference on Dialysis, Advances in CKD 2011, Miami, FL, January 26, 2011.

L204) "Managing High Risk Patients in a i2 Spotlight entitled Cardiac Care Team Spotlight: Approaches for CAD Management" American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.

L205) "Lipid Management in Patients with Renal Insufficiency in a ACC Symposium entitled Lipid Management in Special Populations" American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.

L206) "KEEP Symposium 2011: KEEP A New Longitudinal Dimension for a New Decade" NKF Spring Clinical Meetings, April 29, 2011, Las Vegas, NV.

L207) "Disparities of Treatment for ACS and Heart Failure in CKD Patients" 20th International Vicenza Course on Hemodialysis and CKD, June 8, 2011, Vicenza, Italy.

L208) "AKI: Can We Prevent It?" 20th International Vicenza Course on Hemodialysis and CKD, June 9, 2011, Vicenza, Italy.

L209) "Measuring Natriuretic Peptides in Acute Coronary Syndromes" American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, July 26, 2011.

L210) "Biomarkers in Stable Angina and Microvascular Dysfunction", Emerging Role of Biomarkers in Cardiorenal Syndrome and Acute Coronary Syndrome: Diagnosis Stratification and Management, Siena Italy, September 2, 2011.

L211) "Cardiorenal Syndrome Definition and Scope: Cardiac Perspective" 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 20, 2011.

L212) "Targeted Hypertension Management for Optimal Cardiorenal Outcomes" 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 22, 2011.

L213) "The KEEP Experience" 3rd International Symposium on Albuminuria – The Prognostic Role of Albuminuria: Impact on Kidney and Cardiovascular Outcomes, Groningen, Netherlands, December 1, 2011.

L214) "Cardiorenal Syndromes" Cardiology Guest Lecture, University of Chicago, Pritzker School of Medicine, Chicago, IL, January 18, 2012.

L215) "Diagnosis of Cardiovascular Disease in CKD" 14th international conference on dialysis, advances in CKD 2012, Palm, Harbor, FL, January 26, 2012

L216) "Acute Kidney Injury Guidelines" KDIGO Clinical Practice Conference: KDIGO Guidelines on Acute Kidney Injury, Glomerulonephritis, and Anemia, Shanghai, China, February 5, 2012

L217) "Galectin-3: A Novel Blood Test for the Evaluation and Management of Heart Failure" Cardiology Grand Rounds, University of Arkansas for Medical Sciences, Little Rock, Arkansas, February 8, 2012

L218) "Contrast-Induced Acute Kidney Injury" 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 15, 2012

L219) "Recent Trials in the Prevention of Contrast-Induced AKI: Importance of Emerging Biomarkers" 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 17, 2012

L220) "Role of Galectin-3 in Heart Failure" Joint American Association of Cardiologists of Indian Origin and ACC Dinner Symposium, American College of Cardiology Scientific Sessions 2012, Chicago, IL, March 25, 2012

L221) "Bariatric Surgery: A Cure for Obesity?" American College of Cardiology Scientific Sessions 2012, Joint Symposium of the American Association of Clinical Endocrinologists and the ACC: Cardiologists as Endocrinologists – Emerging Management of the Diabetic Patient, Chicago, IL, March 26, 2012

L222) "Practical Management of Obesity for the Cardiologist" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

L223) "Prevention of Cardiovascular Events: Beyond Statins" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

L224) "Contrast Media and Patient Safety: The Clinical Impact" Swiss Congress of Radiology, Zurich, Switzerland, May 31, 2012

L225) "Importance of Methodological Rigor in CI-AKI Meta-Analyses" 48th Congresso Nazionale Italian Society of Radiology (SIRM), Torino, Italy, June 2, 2012

L226) "Chronic Kidney Disease and Heart Failure" 2012 Cardiometabolic Health Congress (CMHC) Boston, MA, October 12, 2012

L227) "Chronic Kidney Disease and Acute Myocardial Infarction" CKD a Recipe for CVD Disaster, Kidney Week, American Society of Nephrology, San Diego, CA, October 30, 2012

L228) "Epidemiology and Pathophysiology of Coronary Artery Disease in Chronic Kidney Disease" Scientific Sessions 2012, AHA, Los Angeles, CA, November 5, 2012

L229) "The Cardiorenal Syndrome" Acute Dialysis Quality Initiative 11: Cardiorenal Syndromes, Venice, Italy, November 30, 2012

L230) "Cardiorenal Syndromes" Cardiology Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012

L231) "Diagnosis and Management of Coronary Disease in Patients with Kidney Disease" Internal Medicine Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012

L232) "The Hypertension Epidemic: Are We Any Further Ahead?" 22nd Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 9-16, 2013

L233) "Cardiorenal Syndromes: The Cardiac Perspective" Inaugural Cardio Renal Society of America (CRSA), 14th Annual Southwest Nephrology Conference (SWNC), Chandler, AZ, March 2, 2013

L234) "Managing Hyponatremia in Cardiorenal Syndromes" Satellite Symposia to the NKF Spring Clinical Meetings, Orlando, FL, April 3, 2013

L235) "Session Title: Debate: To Screen or Not to Screen for CKD--PRO? NKF Spring Clinical Meetings, Orlando, FL, April 5, 2013

L236) "Galectin-3: A Novel Biomarker for the Assessment and Management of Heart Failure" Heart Failure Conference, University of Pittsburgh Medical Center, Pittsburgh, PA, May 28, 2013

L237) "The Kidney in Heart Failure" 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy

L238) "Contrast-Induced Acute Kidney Injury" 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy

L239) "Novel Biomarkers in the Prognosis and Management of Heart Failure" BUMC Medicine Grand Rounds, August 20, 2013, Dallas, TX

L240) "Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure" Cardiology Grand Rounds, University of Virginia Medical Center, August 26, 2013, Charlottesville, VA

L241) "Major Advances in the Treatment of Atherosclerosis: New Options for Patients with Familial Hypercholesterolemia and Those Intolerant to Conventional Lipid Lowering Therapy" Cardiology Update, University of Missouri School of Medicine, September 14, Columbia, MO

L242) "Keynote Address: Recent Advances in the Assessment of Acute Kidney Injury with Neutrophil Gelatinase Associated Lipocalin" 47th Brazilian Congress of Clinical Pathology and Laboratory Medicine, September 23, 2013, Sao Paulo, Brazil.

L243) "Advancements in Cardiometabolic Risk Assessment: Expert Analysis of Recent Evidence and Outcomes" 2013 Cardiometabolic Health Congress, October 2, 2013, Boston, MA.

L244) "Keynote Address: Cardiorenal Syndromes: New Insights to Patients with Combined Heart and Kidney Failure" Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.

L245) "Practical Experience with Galectin-3" Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.

L246) "Using Novel Biomarkers in the Assessment and Management of Heart Failure" Bon Secours Cardiovascular Conference, October 25, 2013, Williamsburg, VA

L247) "Detection and Consequences of Iron Deficiency Anemia in CKD Patients" Session Title: The Role of Iron in the Optimization of Anemia Management in CKD, American Society of Nephrology, Kidney Week, November 9, 2013, Atlanta, GA

L248) "Bench to Bedside: What Happens to the Physiologic Systems After an Acute Bout of High Intensity/Volume Exercise?" Session Title: Cardiovascular Seminar entitled Potential Cardiotoxicity of Extreme Endurance Exercise, Annual Scientific Sessions of the AHA, November, 20, 2013, Dallas, TX.

L249) "Atrasentan for the treatment of diabetic nephropathy: how to control the risk of heart failure?" Session Title: "Lessons Learned from First Post FDA Guidance Case Studies of Diabetes CV Outcomes Trials, 10th Global CardioVascular Clinical Trialists (CVCT) Forum, December 7, 2013, Paris, France.

L250) "Reflection: Biomarker-based modeling tools: safer drugs and faster development?" A workshop initiated by the TI-Pharma Escher project for academia, industry, and the European Medicines Agency, January 24, 2014, Amsterdam, the Netherlands.

L251) "Focus on lipids: HDL and Its Associated Lipoproteins in Cardiac and Renal Disease" Changing Paradigms in Acute Kidney Injury: From Mechanisms to Management Sponsored by UAB/UCSD O'Brien Center for AKI Research, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L252) "Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes" Targeting Recovery from Acute Kidney Injury:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L253) "Statins for AKI: Friend or Foe" Controversies in Critical Care Nephrology:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L254) "Managing Heart Failure and Cardiorenal Syndrome" Workshop, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.

L255) "ST2: A Novel Biomarker in the Assessment and Management of Heart Failure" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L256) "Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L257) "New Approaches to the Management of Cardiorenal Syndromes" 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

L258) "My New Favorite Biomarker: Galectin-3" 2014 UCSD Biomarkers in Clinical Practice Symposium, La Jolla, CA, April 5, 2014.

L259) "Changing Profile of Chronic Hyperkalemia" NKF Spring Clinical Meetings, Las Vegas, NV, April 24, 2014.

L260) "The Next Generation of Screening for Kidney Disease" NKF Spring Clinical Meetings, Las Vegas, NV, April 25, 2014.

L261) "Cardiorenal Syndromes" Cardiology, Diabetes & Nephrology at the Limits, Royal College of Physicians, London, UK, April 26, 2014.

L262) "Acute Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 22, 2014.

L263) "Fibrosis in the Heart and Kidneys in the Pathogenesis of Chronic Cardiorenal Syndromes" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 23, 2014.

L264) "Hyperkalemia: Old Foe with New Faces" 51st European Renal Association – European Dialysis and Transplantation Association Congress, Amsterdam, the Netherlands, June 2, 2014.

L265) "Contrast Induced Complications in the Cath Lab" Transcatheter Cardiovascular Therapeutics (TCT) Russia, Moscow, Russia, June 16, 2014.

L266) "The RAASi Debate: Should RAAS Continue with a Declining GFR?: Will the Path be Clearer" Co-Chair, European Society of Cardiology, Barcelona, Spain, August 31, 2014.

L267) "Novel Markers of Acute and Chronic Kidney Injury," Where Inflammation Meets Lipids: Broad Based Strategies for Risk Reduction, Cleveland Heart Labs, Cleveland, OH, September 12, 2014.

L268) "Advances in the Understanding of Acute and Chronic Cardiorenal Syndromes: Pathophysiological Crosstalk of Multiple Metabolic and Neurohormonal Systems" 41st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 7, 2014.

L269) "CHADS, CHADS-VASc, HAS-BLED, What Does it Mean and How Do We Use It? Atrial Fibrillation Session, Dallas-Leipzig Valve 2104, Dallas, TX, December 11, 2014.

L270) "Soup-to-Nuts Renal Failure: Caring for the Patient with Kidney Injury" Society of Critical Care Medicine, Phoenix, AZ, January 19, 2015.

L271) "RAASi Optimization in Heart Failure" 2nd Annual Cardiorenal Society of America Meeting, Phoenix, AS, February 28, 2015.

L272) "Cardiac Surgery Associated Acute Kidney Injury" Association of Physician Assistants in Cardiac Surgery, Las Vegas, NV, March 3, 2015.

L273) "The Potassium Challenge in CKD: Managing Acute and Chronic Hyperkalemia: Novel Polymer-Based Potassium Binders: Clinical Evidence" NKF Spring Clinical Meetings, March 27, 2015.

L274) "KEEP Healthy: Insights into CKD Care" NKF Spring Clinical Meetings, March 28, 2015.

L275) "The Heart of the Matter" NKF Spring Clinical Meetings, March 28, 2015.

L276) "Literature Review: CVD" NKF Spring Clinical Meetings, March 28, 2015.

L277) "Biomarkers of Kidney and Heart Injury in Cardiorenal Syndrome" Cardionephrology 2015, Rome, Italy, April 16, 2015.

L278) "AKI after Acute Myocardial Infarction: Contrast, Organ Crosstalk and Complications" 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.

L279) "A New Mechanism of Action for Addressing Hyperkalemia: New Data on Non-Polymer Hyperkalemia Therapies" 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.

L280) "Lp-PLA2 as a marker of Vascular Inflammation and CHD Risk Assessment" Symposium: Advances in Laboratory Testing for Coronary Heart Disease; The New PLAC Test for Lp-PLA2 Activity, American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

L281) "Galectin-3 in the Prognosis and Management of Heart Failure" American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

L282) "Cardio-Renal Syndrome and Clinical Implications" AKI from Pathophysiology to Clinical Implications, Global Research on Acute Conditions Team (GREAT) Annual Meeting, Rome, Italy, September 5, 2015.

L283) "Lp-PLA2 and Testing for Primary Prevention Risk Assessment" 2015 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 22, 2015.

L284) "Heart and Kidney: a Dangerous Liaison" Comorbidities in Heart Failure: From Guidelines to Clinical Practice, 775 Anniversary University of Sienna, Sienna, Italy, October 29, 2015.

L285) "Role of BNP, Pro-BNP, and Elevated Left Ventricular Mass in Cardiorenal Syndrome" American Society of Nephrology Kidney Week, San Diego, CA, November 6, 2015.

L286) "How to Use Urine Thromboxane B2 to Select and Monitor Aspirin Therapy" Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L287) "Putting it All Together: How to Use Urine 11-Dehydrothromboxane B2 In Clinical Practice" Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L288) "Neurogenic Orthostatic Hypotension" Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.

L289) "Cardiac Cachexia" Managing Disease Related Lean Body Mass Loss Through Clinical and Nutritional Interventions, The Sackler Institute for Nutrition Science The New York Academy of Sciences, New York, NY, December 4, 2015.

L290) "The Devastating Consequences of Systemic Hypertension and What To Do About It?" 42st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 6-8, 2015.

L291) "The Impact and Management of Malnutrition in Patients with Heart Failure" Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.

L292) "Acute and Chronic Cardiovascular Effects of Hyperkalemia: New Insights Into Prevention and Clinical Management" Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.

L293) "Lipoic Acid in the Prevention of Acute Kidney Injury" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L294) "Novel Approaches for Recognition and Management of Life Threatening Complications of AKI and CKD" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L295) "Making Iodinated Contrast Less Nephrotoxic with Cyclodextrin" 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

L296) "Cardiorenal Syndrome" 4th Annual Cardio-Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ, March 13, 2016.

L297) "Cardiorenal Syndromes Identification: Prevention and Management of CI-AKI" China Interventional Therapeutics (CIT), Beijing, Shanghai Zhong Shan Hospital, Shanghai, The 2nd Affiliated Hospital of Zhejiang University, Hangzhou, Xi Jing Hospital, Xi'an, Nanjing 1st Hospital, Nanjing, Peoples Republic of China, March 14-21, 2016.

L298) "Cardiorenal Syndromes" Keynote Address, Inaugural Cardio-Renal Connections Meeting, San Antonio, TX , April 16, 2016.

L299) "Galectin-3 in the Prognosis and Management of Heart Failure" American Association of Clinical Chemistry Annual Scientific Meeting, Philadelphia, PA, August 1, 2016.

L300) Hemodialysis University, "Is It Heart Failure or Fluid Overload?", Chicago, IL, September 10, 2016.

L301) "Novel Agents for the Treatment of Hyperkalemia" Heart Failure Society of America Annual Scientific Meeting, Orlando, FL, September 18, 2016.

L302) Symposium "Hyperkalemia in the Emergency Department: Updates on the Current Management of a Complex Condition." "Novel Agents for the Prevention and Treatment of Hyperkalemia" American College of Emergency Physicians Scientific Assembly, Las Vegas, NV, October 14, 2016

L303) Moderator "CVD in Patients with CKD: Update from the CRIC Study" Annual Scientific Sessions of the AHA, New Orleans, LA, November 13, 2016

L304) Program Chairman "A Night at the Museum: Inaugural Symposium of the Cardiorenal Society of America Transcending the Dinosaurs: Guiding AKI Prevention using next-gen biomarkers: Real World Experiences from modern practices" satellite Symposium at American Society of Nephrology Kidney Week, Field Museum, Chicago, IL, November 18, 2016

L305) "Pathobiologic Systems Involved in Cardiorenal Disease" 43rd Williamsburg Cardiovascular Conference, Williamsburg, VA, December 3-5, 2016

L306) "Cardiac Cachexia" Heart Failure University, MedReviews LLC, Los Angeles, CA, December 10, 2016

L307) "Is There a Role for Bariatric Surgery in Heart Failure Patients with Obesity?" Scientific Sessions 2017, American College of Cardiology , Washington, DC, March 18, 2017

L308) "Vascular and Cardiac Hypertrophy in Fabry Disease" 5th Annual Fabry Nephropathy Update, Mexico City, Mexico, April 26, 2017

L309) "Introduction to Cardiorenal Medicine" Cardiorenal University, Anaheim, CA, May 18, 2017

L310) "Sudden Death in End-Stage Renal Disease" Cardiorenal University, Anaheim, CA, May 18, 2017

L311) "Cardiorenal Syndromes and Heart Failure" Conference Chair, Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease, Athens, Greece, May 25-28, 2017

L312) "Vadadustat Does Not Prolong Corrected QT Interval In A Thorough QTC Study In Healthy Subjects" 54th ERA-EDTA Congress, Madrid, Spain, June 3-6, 2017

L313) "Cardiorenal Syndromes" 1st Annual Heart iN Diabetes: Where the Heart, Kidney, and Diabetes Meet in Clinical Practice, Philadelphia, PA, July 14-16, 2017

L314) "Cardiovascular Disease in Patients with Chronic Kidney Disease: A Serious Link" TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017

L315) "Statin Therapy to Prevent Onset and Progression of Vascular Disease" TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017

L316) "Keynote Address: Cardiorenal Society of America" 5th Annual Scientific Meeting of the Cardiorenal Society of America, Phoenix, AZ, October 6, 2017

L317) "Cardiovascular Benefits of Home Hemodialysis" Addressing Unmet Needs in Dialysis: Cardiovascular Care and Volume Control Symposium, Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017

L318) "CIEDs in ESRD Patients: What Are the Long-Term Data?" Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017

L319) "Cardiovascular Seminar Cardiorenal Syndrome: Who hurts who?" AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

L320) "Cardiac and Renal Fibrosis in CRS" AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

L321) Chair, Inaugural Cardiometabolic University and Nutrition Academy "The Skinny on Weight Loss: Practical Considerations for the Cardiovascular Specialist" MedReviews, Westlake, TX, December 1-3, 2017

L322) "Clinical Laboratory Advancements in Cardiometabolic Disease: Screening, Diagnosis, Prognosis, and Management" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2017

L323) "The Skinny on Weight Loss: Practical Approaches for the Cardiovascular Specialist" Cardiometabolic University 2017, Conference Chair, Dallas, TX , December 1-3, 2017

L324) "Diagnosis, Evaluation, and Role of Biomarkers in Heart Failure" Heart Failure University 2017, Conference Co-Chair, Los Angeles, CA, December 10-12, 2017

L325) "Biomarkers of Kidney Dysfunction and Cardiorenal Syndrome" University of California at San Diego 14th Annual Biomarkers in Heart Failure and Acute Coronary Syndromes: Diagnosis, Treatment and Devices, San Diego, CA, March 2, 2018

L326) "What do I do to Prevent Contrast Induced Renal Injury" 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018

L327) "AKI in the patient with Cancer" 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018.

L328) "CKD-Related Anemia and Cardiac Complications" NKF Spring Clinical Meetings, Austin, TX April 14, 2018

L329) "Principles of Distributive Shock" Cardiorenal Society of America National Grand Rounds Series, Boston, MA, April 30, 2018

L330) "Biomarkers with More Muscle: Moving Beyond Serum Creatinine to Define Cardiorenal Syndrome in HF" Heart Failure Society of American Annual Scientific Sessions, Nashville, TN, September 15, 2018

L331) "Heart Failure in Cardiorenal Syndrome: Updates on Biomarkers" Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

L332) "Novel Approaches in Lowering LDL-C" Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

L333) "What Do We Know About Cardiorenal Physiology? An Overview" American Society of Nephrology Kidney Week, San Diego, CA, October 26, 2018

L334) "Prevention of Heart Failure: The Next Frontier" Cardiometabolic Health Conference, Boston, MA, October 27, 2018

L335) "AKI and Heart Failure: How to Manage Compared to the General Population" Cardiometabolic Health Conference, Boston, MA, October 27, 2018

L336) "SGLT-2 Inhibitors and Cardio-renal Outcomes: Mechanistic Role and Rationale for Treatment of Heart Failure" American Heart Association Annual Scientific Sessions, Chicago, IL, November 10, 2018

L337) "Obesity and Heart Disease" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2018

L338) "Current Concepts in Hypertension Management" University of Texas Health Science Center, Tyler, TX, January 15, 2019

L339) "Managing the Heart Failure Patient with Worsening Renal Function (WRF)" 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019

L340) "Cardiorenal Syndrome: What Have We Learned?" 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019

L341) " Debate: Biomarker Guided Heart Failure Therapy: Con: Neuropeptides; ST2" 15th Annual USCD Biomarkers in Heart Failure and Acute Coronary Syndromes, Diagnosis, Treatment & Devices, La Jolla, CA March 1, 2019

L342) "Cardiorenal Syndromes" Cardionephrology Congress, Rome, March 12 to 14, 2019

L343) "Iron and Heart Failure" Cardiometabolic Health Congress West meeting in Phoenix, AZ on Saturday, May 4, 2019

L344) "Up to Date Management of Arrhythmias in Dialysis Patients" National Kidney Foundation Spring Clinical Meetings, May 11, 2019

L345) "Lipids in Chronic Kidney Disease" National Kidney Foundation Spring Clinical Meetings, May 11, 2019

L346) "Cardiorenal Syndromes" Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston, MA, May 23, 2019

L347) "Chronic Kidney Disease as a Cardiovascular Risk State" Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston, MA, May 23, 2019

L348) "Biomarkers and Assessment of Cardiac Function In Fabry Cardiomyopathy" 6th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities, Prague, Czech Republic, May 26-28, 2019

L349) "Contrast-Induced Acute Kidney Injury" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L350) "Cardiac Biomarkers in AKI" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L351) "Risk Mitigation in the Cardiac Catheterization Laboratory" 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019

L352) "Pathophysiology and Current Concepts in Classification" Clinical Practice Clinical Science Track: Treatment of Cardiorenal Syndrome, American Heart Association Hypertension Scientific Sessions, New Orleans, LA, Sept 8, 2019

L353) "Cardiovascular Genetics" 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 9, 2019

L354) "Cardiorenal Syndromes" 17th World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC), Los Angeles, CA, December 4-7, 2019

L355) "Cardiorenal Syndromes" Internal Medicine Grand Rounds, Eastern Virginia College of Medicine, Norfolk, VA, February 19, 2020

L356) "Keynote Address: Prevention of Heart and Kidney Disease" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 6, 2020

L357) "Cardioprotective Effects of Antidiabetic Medications: Focus on Sodium-Glucose Transporter-2 Antagonists" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L358) "Fabry Disease: A Unique Cardiorenal Model" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L359) "Biomarkers in Heart and Kidney Disease: Practical Applications" Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

L360) "Expert Briefing from ADA 2020 Select Sessions: Update on Heart Failure for the Diabetologist & Cardiorenal–Metabolic Axis in Diabetes" American Diabetes Association, June 14, 2020

L361) "CKD, CHD and Hyperkalaemia: Clinical Outcomes, Morbidity and Mortality" American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020

L362) "RAASi Enabling in Cardiology Practice - Traditional vs New Potassium Binders; Potassium Binders for Treatment of Hyperkalaemia in HF" American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020

L363) "Optimizing Transitions from Hospital to Home: Best Practices for Reducing Readmissions in Heart Failure" Hospital Management Summit, October 3, 2020.

L364) "Assessment and Management of Hyperkalemia in the Hospital Setting: Optimizing Patient Outcomes" Hospital Management Summit, October 3, 2020.

L365) "Navigating the Challenges of Cardio-Renal Syndrome" 7th Annual Kansas Cardiovascular Symposium, October 10, 2020

L366) "Management Considerations for Heart Failure in CKD" American Society of Nephrology Kidney Week 2020, October 24, 2020

L367) "Pathophysiologic Basis and Rationale for Early Ambulatory Treatment of SARS-CoV-2 (COVID-19), SciInov, November 2, 2020

L368) "CV and Renal Benefits with new anti-diabetes medications: Potential Mechanisms" CReDO Conferences Middle East North Africa (MENA) 2020, November 6, 2020

L369) "Consequences of Withholding GDMT for Heart Failure in CKD: One Step Forward, Two Steps Back" AHA 2020 November 16, 2020

L370) "Early Ambulatory Treatment for SARS-CoV-2 (COVID-19)" Early Outpatient Treatment: An Essential Part of a COVID-19 Solution. US. Senate Committee on Homeland Security and Governmental Affairs, Washington DC November 19, 2020

L371) "Pathophysiological Basis & Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection" 18th Annual World Congress Insulin Resistance Diabetes & Cardiovascular Disease, December 3, 2020

L372) "Early Ambulatory Therapy for COVID-19 and Update on Vaccine Safety" Heritage Foundation, Washington DC, June 23, 2021

L373) "Pathophysiological Basis and Clinical Rationale for Early Ambulatory Treatment of COVID-19" Question Everything Conference Lockdowns – Is Now the Time for a Better Solution?, London, UK, July 17, 2021

L374) "Pathophysiological Basis and Clinical Rationale for Early Ambulatory Treatment of COVID-19 and Update on Vaccine Safety" American Academy of Anti-Aging Medicine, Ann Arbor, MI, July 18, 2021

L375) "Keynote: Winning the War Against Therapeutic Nihilism and the Rush to Replace Trusted Treatments with Untested Novel Therapies" Association of American Physicians and Surgeons, AAPS 78th Annual Meeting, Sept. 30 to Oct. 2, 2021 – Pittsburgh, PA, October 2, 2021

INTERNAL COMMITTEE POSITIONS

1) Member, Henry Ford Medical Group Hypertension Control Committee, 1998.

2) Ranking Member and Presenter, HFHS Institutional Review Board, 1998-2000.

3) Member, HFHS Teaching and Education Committee, Co-Chair of the Research Subcommittee, 1999-2000

4) Member, HFHS Graduate Medical Education Committee, 1999-2000.

5) Member, HFHS, Internal Medicine Residency Selection Committee, 1998-2000.

6) Chair, HFHS, Cardiovascular Diseases Fellowship Program Selection Committee, 1999-2000.

7) Co-Chair, HFHS, Information Technology and Medical Records Committee, 1999-2000.

8) Member, HFHS Department of Internal Medicine, Research Committee, 1999-2000.

9) Member, UMKC Adult Health Sciences Institutional Review Board, 2001-2002

10) Member, UMKC, Cardiovascular Diseases Fellowship Program Selection Committee, 2000-2002

11) Member, Truman Medical Center (TMC) Information Technology Steering Committee, 2001-2002.

12) Member, WBH Diabetes Research Center Steering Committee, 2002-2003

13) Chairperson, WBH Staff Privileges Appeals Committee, March 31, 2004

14) Chairperson, WBH Search Committee for Medical Director of Transplantation Medicine, 2005-2006

15) WBH Research Institute Board of Governors, board member, 2007-2010

16) Oakland University William Beaumont School of Medicine, Medical Student Committee (founding) for development of Liaison Committee on Medical Education (LCME) application, 2007-2010

17) St. John Providence Health System Graduate Medical Education Steering Committee (Chair), 2010 to 2013

18) St. John Providence Health System Research Leaders Committee, Chair, 2010 to 2012; Co-Chair 2012 to 2013

19) Ascension Michigan Research Affinity Group, Chair, 2010 to 2012; Co-Chair 2012 to 2013

20) St. John Providence Health System Executive Committee, 2011 to 2013

21) St. John Providence Health System Guidelines Committee, 2012 to 2013

22) St. John Providence Health System Presidents Council, 2012 to 2013

23) St. John Providence Health System Electronic Medical Record Meaningful Use Steering Committee, 2013

24) BUMC Graduate Medical Education Committee, 2014 to present

25) BUMC Internal Medicine Residency Program Clinical Competency Committee, 2014 to 2021

26) BUMC Clinical Cardiology Fellowship Program Clinical Competency Committee, 2014 to 2021

27) BUMC Founding Member, Department of Molecular Pathology and Medicine, 2016 to 2021

28) BUMC Precision Medicine Executive Committee, 2016 to 2021

29) BUMC COVID-19 Therapeutic Task Force 2020

EXTERNAL COMMITTEE POSITIONS

1) Member, AHA National Women's Heart Disease and Stroke Campaign, Healthcare Provider Sub-Group, Dallas, TX, 1998-1999

2) Member, AHA, Chronic Coronary Disease in the Elderly National Database Planning Committee, Dallas, TX, 1998-2000

3) Chair, Michigan Chapter of the American College of Cardiology, Annual Mini-Board Review, 1999-2000

4) Member, Michigan Chapter of the American College of Cardiology, Annual Meeting Planning Committee, 1999-2000

5) Member, National Kidney Disease Outcomes Quality Initiative (K/DOQI) Clinical Practice Guidelines Committee on Chronic Kidney Disease, Andrew S. Levey, MD, Chair, 2001-2002

6) Member, K/DOQI Learning System (KLS)™ Advisory Board, NKF, New York, NY, 2003 to 2010

7) Member, International EECP Patient Registry Working Group, 2003-2008.

8) Counselor at large, Michigan Chapter of the American College of Cardiology, 2004-2006

9) Member, Planning Committee, AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 26-28, 2006, Orlando, FL

10) Chair, Contrast-Induced Nephropathy (CIN) Working Group Consensus Panel, (international, multispecialty, consensus panel with published findings) 2004-2006. Published in *Am J Cardiol* 2006 Vol 98(6)

11) Workgroup Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Amsterdam, Netherlands, 2004, 2006

12) Member, Kidney Disease Improving Global Outcomes (KDIGO) Group for the development of Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease Related Mineral and Bone Disorders (CKD-MBD), Paris, France, 2007-2008

13) Board of Directors Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Brussels, Belgium, 2007-2010

14) Workgroup Member, The Sixth International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VI: Acute Kidney Injury in Cardiac Surgery, Vicenza, Italy May 27 – 28, 2007

15) Workgroup Leader, Prevention: The Seventh International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VII: Cardiorenal Syndrome, Venice, Italy, September 4-5, 2008, with publication n *Nephrology, Dialysis, and Transplantation*, 2010.

16) Chairman, Natriuretic Peptide Testing in Acute Coronary Syndromes Consensus Panel, with published findings in *Reviews in Cardiovascular Medicine* 2010, Dallas, TX, March 2, 2010

17) Scientific Advisory Board, NKF, New York, NY, 2010 to present

18) Scientific Advisory Board, Cardiorenal Society of America, Phoenix, AZ, 2012 to present

19) Workgroup Member, "Cardiovascular Disease in CKD: What is it and what can we do about it?" Kidney Disease Improving Global Outcomes (KDIGO), October 29-31, 2010, London, England.

20) Chairman, "Cardio-Renal Syndromes II: from pathophysiology to therapy" Eleventh Consensus Conference Cardio-Renal Syndromes II November 30 – December 2, 2012, Venice, Italy.

21) Conference Co-Chair: "Kidney Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease", Athens, Greece, May 25-28, 2017

22) Chairman, "Cardiometabolic University", Dallas, TX, December 3-4, 2017

23) Chair, American Heart Association Council on the Kidney in Cardiovascular Disease and Council on Clinical Cardiology. Cardiorenal Syndrome: Classification, Pathophysiology, Diagnosis, and Treatment Strategies: A Scientific Statement From the American Heart Association, 2019

24) Committee Member, American College of Cardiology, Navigating Treatment Decisions for Patients with ASCVD and Multiple Comorbidities Committee, 2019-2020

25) Chief Medical Advisor, Truth for Health Foundation, Tucson AZ, 2021 to present

26) Advisory Board Member, TrialSite News, 2021 to present

27) National and International Advisor/Reviewer/Presenter/Contributor for 4D Molecular Therapies, ABC News, Abbott Laboratories, AbbVie, Advanced Health Media, Aegerion, Affymax, Akceia, Akebia, Alere North America, AMAG, Amersham, Amgen, Amylin, AntiSeptiscope, Aralez, Ardian, Adelyx, Arra Hitech, Astellas, AstraZeneca, Astute Medical, Atherotech, Axio, BG Medicine, Avenue Therapeutics, Aventyn, Back Bay Lifescience Advisors, Bayer, Biocritique, Bioexpertise, Biomarin, Bionest Partners, Bioporto, Biosite, Biostar, BioZ, Boehringer Ingelheim, Braintree Laboratories, Broeker, Bristol Myer Squibb, Cardiokine, Cardiorentis, Chapman and Priest, Charles River Associates, Chelsea Therapeutics, Chiesi USA, ClearView Healthcare Partners, Clinipace, Complexa, Connected Research and Consulting, CorMedix, Cornerstone Therapeutics, Corvidia, Covance, Critical Diagnostics, Cromsource, Crossover Technologies, Chrysalis BioTherapeutics, Cytopheryx, Cytel, DaVita, Daws, DeMatteo Monness, Diadexus, Daiichi Sankyo, Decision Resources, ECG Healthcare, Edwards Life Sciences, Elsevier, Espirion, F. Hoffmann-La Roche Ltd, Fast Biomedical, Fish and Richardson, LLC, Fisher Scientific, FlowMedica Inc, Frictionless Digital, Fresenius Medical Care, General Electric, Genzyme, Gerson Lehrman, Gilead, GVI Clinical Development Solutions, Health Law Partners, Healthspan DX, HealthSTAR Communications, Hershey, Hikari, Hogan Lovells, Hudson Global, ICON, Huff, Powell, and Bailey, LLC, IMC Press, Imidex, Impact Education, Instrumentation Laboratories, Intercept Pharmaceuticals, Intrinsic Life Sciences, Ischemix Technologies, Janssen, Jannsen, Johnson and Johnson, Jordan, KAI Research, Keryx, Ketchum, Inc, Knowledge Point 360, Kowa, Eli Lilly, LabCorp, Lewis Brisbois, Liberty Dialysis, Ligand, Lipocine, Litchfield Cavo, Luitpold Pharmaceuticals, Lundbeck, Maxaccess Managed Markets, MannKind, MEDACorp, MedEd Group, Medevera, Medical Exchange International, Medical Package, Medicines Company, Medicure Pharma, Inc., MedReviews, Medscape, Medtronic, Merck, Meridian 361 International Law Group, Meso Scale Diagnostics, Miller Tanner Associates, Mitsubishi, Nanomix, Nanosphere, Nabi Biopharmaceuticals, Navigant, NephroGenix, Neumedicines, Noorik GmbH, Norman, Hanson, and Detroy, LLC, Novartis, NovoNordisk, NxStage, Ortho Clinical Diagnostics, Osprey, Otsuka, Overcome, P-value Communications, Parexel, Pharmapprove, Pfizer, Phoenix Holdings, Physicians World, PLC Medical, Praetego, PriMed, Progenabiome, Quidel Corporation, Qualidigm, Quintiles, Reata, Reliant Pharmaceuticals, Renew Research, Relypsa, Repros Therapeutics, Roche Diagnostics, Rock Creek, Saferox, Saghmos Therapeutics, Salix, Sanfit, Sankyo, Sanofi, Sarepta Therapeutics, Scarritt Group, Sentinel Investment, Sloan Law Firm, Sphingotec, Spectracell, St. Jude Medical, Strataca Systems, Statprobe, Sunshine Heart, Synageva, Takeda, Tasly, TheHill, Thrasos, TrialSiteNews, Trinity, Triptych Health Partners, US Medical Management, Vasomedical, Verrow, Vindico, Visiting Physicians Association, Vitalmetrix, Vivus, Watermark, WebMD, ZS Pharma, Inc.

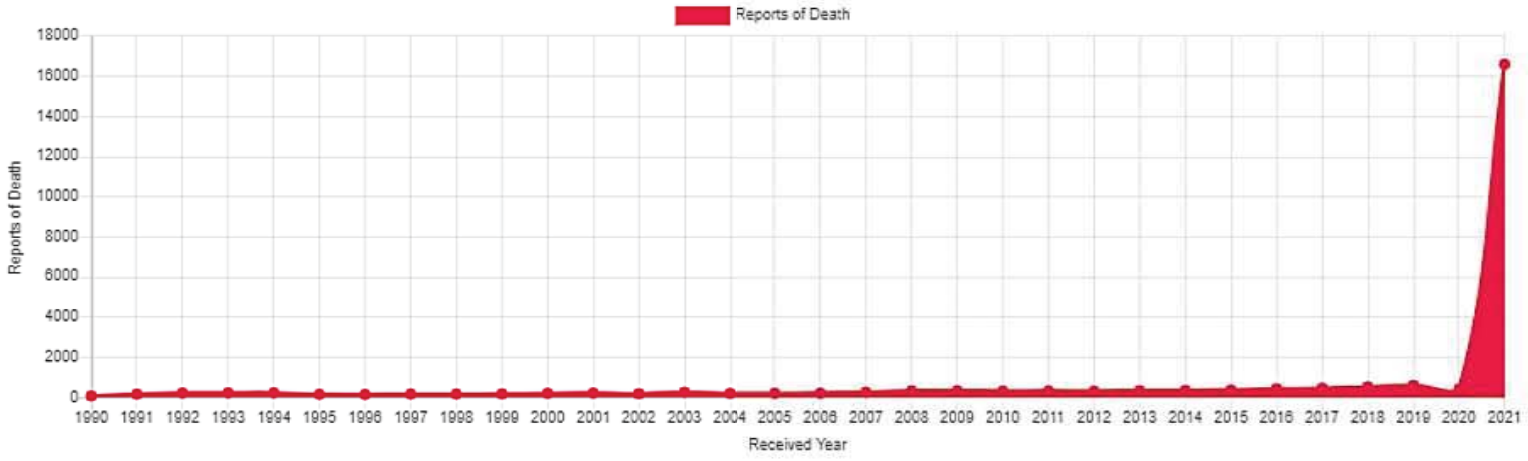
778,683 Reports
Through October 01, 2021

EXHIBIT 2

16,310 DEATHS	**75,605** HOSPITALIZATIONS	**87,814** URGENT CARE
121,305 DOCTOR OFFICE VISITS	**7,141** ANAPHYLAXIS	**9,446** BELL'S PALSY

2,415 Miscarriages	**7,868** Heart Attacks	**6,812** Myocarditis/Pericarditis	**20,789** Permanently Disabled
3,620 Thrombocytopenia/ Low Platelet	**17,619** Life Threatening	**28,168** Severe Allergic Reaction	**8,153** Shingles

All Deaths Reported to VAERS by Year



VAERS COVID Vaccine Reports of Deaths by Days to Onset-All Ages

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, United States Navy, NAVY SEAL 2, United States Navy, EOD OFFICER, United States Navy, SENIOR CHIEF PETTY OFFICER, United States Navy, CHAPLAIN, United States Navy, LIEUTENANT COLONEL 1, United States Marine Corps, LIEUTENANT COLONEL 2, United States Marine Corps, MAJOR, United States Marine Corps, SECOND LIEUTENANT, United States Marine Corps, CAPTAIN, United States Marine Corps, ARMY RANGER, United States Army, LANCE CORPORAL 1, United States Marine Corps, LANCE CORPORAL 2, United States Marine Corps, MAJOR, UNITED STATES AIR FORCE, NATIONAL GUARDSMAN, Virginia Army National Guard, COAST GUARD LIEUTENANT, United States Coast Guard, COLONEL, United States Army, TECHNICAL SERGEANT, United States Air Force, DEFENSE DEPARTMENT CONTRACTOR, United States Department of Defense, FEDERAL CIVILIAN ENGINEER CONTRACTOR, FEDERAL CIVILIAN CONTRACTOR EMPLOYER, FEDERAL NUCLEAR CONTRACTOR EMPLOYEE, DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH, for themselves and all others similarly situated, Plaintiffs, v. JOSEPH R. BIDEN, in his official capacity as President of the United States, LLOYD AUSTIN, in his official capacity as Secretary of the United States Department of Defense, and ALEJANDRO MAYORKAS, in his official capacity as Secretary of the Department of Homeland Security, Defendants.	Case No. _____

DECLARATION OF NAVY CHAPLAIN

I, Navy Chaplain, do hereby declare as follows:

1. I am over the age of 18 years, have personal knowledge of the matters set forth in this Declaration, and if called upon to testify to them, I would and could do so competently.

2. I am a Chaplain in the United States Navy.

3. I have served for over 18 years.

4. I am personally affected by the SECDEF's order for mandatory vaccinations.

5. I have recently returned from a extended deployment with a Navy Carrier Strike Group.

6. During this deployment, I have spoken with many Sailors who are anguished at the thought of a choice between the COVID shot, and their deeply-held, sincere religious beliefs that receiving the COVID shot would be a grave sin.

7. There have been many tears shed in my office by Sailors affected by the COVID shot mandates who have been in distress over their moral dilemma to follow orders or to follow their spiritual convictions and sincerely held religious beliefs.

8. I have spent well over 100 hours in counseling with these individuals over the course of 6 months talking through the issues individually and in groups.

Since 24 August 2021 it has been my primary counseling topic among all Sailors in my command.

9. I have observed that almost every Sailor who was faithful in attending chapel has also submitted religious accommodation requests regarding the COVID shot mandate, in order to maintain his or her sincere religious beliefs.

10. One Sailor in particular who ended up getting the shot wrestled day and night with the COVID shot order for two months, and was extremely conflicted between his other obligations, and his faith. He expressed that he was the sole breadwinner; has young children; desired to keep faith with the Navy and follow all lawful orders; and yet he felt that he was being unfaithful to God and coerced by the Navy. Ultimately, he felt he had to get the shot, notwithstanding his belief he was committing sin. He felt great fear of God's judgment for disobeying what he believed God wanted. He felt great fear for how his wife (who was adamantly opposed to him receiving the COVID shot) would react to the news, and the future of their marriage. He felt great shame for his weakness.

11. I personally observed and experienced tremendous amounts of coercion, bullying, censorship, and intimidation being brought forth by the command to bear against the personnel who expressed objections of any kind to the COVID shot mandates, including religious objections.

12. One coercion technique the Command used was telling the Sailors that if they got the COVID shot, they would be able to get liberty during deployment port visits.

13. However, when we arrived at each port, liberty was denied. The Sailors who had gotten the shots after this coercion felt resentful, angry, disillusioned, and distrustful of the command leadership. It was so bad that key words and phrases became so common that the Commanding Officer needed to specifically address the crew on two occasions in an effort to limit the use of the phrases.

14. Overall, Command Climate at our command has been very, very good in the past, but the "bait and switch" tactics throughout this ordeal has undermined trust in the Chain of Command.

15. As of September 24, 2021, it is reported that "52 troops have died from COVID-19 complications." "Their deaths bring the military's COVID-19 mortality rate to just over 0.00002, much lower than the roughly 2-percent rate nationwide," *See* Military Times, "Military COVID-19 deaths double in two months" *available at* https://www.militarytimes.com/news/pentagon-congress/2021/09/24/military-covid-19-deaths-double-in-two-months/ (last visited October 12, 2021).

16. DoD has expended vast resources on protecting the Force from the risks entailed by COVID-19, despite COVID's 99.98% survival rate amongst members of the U.S. Military.

17. **In contrast to 52 deaths attributed to COVID-19, Force-wide, since the pandemic was declared in January 2020**, in CY 2020, there were 384 suicide deaths in the Active Component of the DoD; 197 suicide deaths in the Reserve Component; and 120 suicide deaths in the National Guard, for **a total of 701 suicide deaths in Calendar Year 2020**. See *Department of Defense (DoD) Quarterly Suicide Report (QSR), 2nd Quarter, CY 2021* by Karin A. Orvis, Ph.D., Director, Defense Suicide Prevention Office (DSPO), *available at* https://www.dspo.mil/Portals/113/Documents/TAB%20A_20210929_OFR_Rpt_Q2%20CY%202021%20QSR.pdf?ver=7vDYCTnjJlZPN_qKR5pU9Q%3d%3d

18. As set forth by the DoD QSR Report, Calendar Year 2020 showed the highest number of suicides in recent years. Active Duty is the most directly affected by the mandates and restrictions placed on us in an "effort to reduce the spread of COVID." In 2020 the number of people committing suicide on Active Duty was 34 percent higher than in 2017, an increase of 97 personnel. This increase in suicide rate alone is nearly double the total COVID deaths.

19. In Quarter 1 of 2020, there were 90 suicide deaths in the Active Component of the DoD; 45 suicide deaths in the Reserve Component; and 25 suicide deaths in the National Guard, for a total of **160** suicide deaths in Q1 2020.

20. In Quarter 2 of 2021, there were 75 suicide deaths in the Active Component of the DoD; 43 suicide deaths in the Reserve Component; and 28 suicide deaths in the National Guard, for a total of **146** suicide deaths in Q1 2021.

21. **From January 2020, through June 30, 2021, there have been 1,012 suicide deaths DoD-wide**. In contrast, from January 2020, through September 2021, there had been **52 COVID-attributed military deaths DoD-wide**.

22. There have been countless COVID-19 memos, PowerPoints, briefings, meetings, and orders. Masking and social distancing has dehumanized our shipmates, cutting us off from camaraderie and the human connection necessary to life.

23. Clearly, the military has lost more lives to the increase in suicide from 2020-2021 (at least 1,012) than to all of COVID in 2 years (52), but suicide has not been a focus.

24. From 1 January to mid-October 2021 our command delivered approximately 20 minutes of "Suicide Prevention Training", during September 2021, "Suicide Prevention Month."

25. Prior to this training, since February 2020, the focus has been "Diversity, Equality, and Inclusion" ("DEI"), and "extremism" training.

26. The DEI training created a hostile environment on the ship and divided shipmates upon ideological and racial lines. The hostility was particularly focused

against white males. After the DEI training, every white male Sailor on our ship who was eligible for retirement submitted his retirement papers while females and other minorities eligible for retirement did not submit any requests for retirement.

27. The "extremism" training was also extremely divisive on the ship. It was entirely anti-Republican, anti-Conservative, anti-Christian, and anti-white male training. It created a hostile training environment and hostile work environment.

28. I do not recall the Commanding Officer speaking on suicide once during the deployment. He spoke approximately once per week on COVID. He spoke extensively about "Diversity, Equality and Inclusion" and "Extremism" and ensured he was present for every training session to emphasize how important the training was.

29. I have spoken with many Sailors who have expressed great stress and talked about the severe harm to their mental health, as a result of the SECDEF's COVID vaccination orders. Most of these Sailors caved to the pressure, despite their convictions; but many have not, and are faced with the prospect of punitive action if their religious exemption requests are denied.

30. In addition to these Sailors, and myself, I am concerned that many of my Chaplain colleagues will be forced to choose between their faith in God, as informed by their conscience and theologies, and the military service, which they also love.

31. Those who lose as result of this unnecessary choice will be these Chaplains, and all of the Sailors, Soldiers, Airmen and Marines whom these Chaplains would have continued to faithfully serve.

32. Chaplain recruiting has failed to meet annual recruiting goals in recent years and consequently the Navy Chaplain Corps is undermanned. The loss of more Chaplains will be especially profound, for those service members (and their loved ones) who will be unable to find the help they needed in the Chaplain Corps, because so many of the faithful Chaplains were driven out. Driven to despair, without hope and the loving help offered by faithful and caring Chaplains, we can expect a continued death toll from suicide that far exceeds any personnel tragically lost to "COVID-19."

I declare under penalty of perjury of the laws of the United States and the State of Florida that the foregoing statements are true and correct to the best of my knowledge.

Dated this 15th day of October, 2021

/s/ Navy Chaplain
NAVY CHAPLAIN

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, United States Navy, NAVY SEAL 2, United States Navy, EOD OFFICER, United States Navy, SENIOR CHIEF PETTY OFFICER, United States Navy, CHAPLAIN, United States Navy, LIEUTENANT COLONEL 1, United States Marine Corps, LIEUTENANT COLONEL 2, United States Marine Corps, MAJOR, United States Marine Corps, SECOND LIEUTENANT, United States Marine Corps, CAPTAIN, United States Marine Corps, ARMY RANGER, United States Army, LANCE CORPORAL 1, United States Marine Corps, LANCE CORPORAL 2, United States Marine Corps, MAJOR, UNITED STATES AIR FORCE, NATIONAL GUARDSMAN, Virginia Army National Guard, COAST GUARD LIEUTENANT, United States Coast Guard, COLONEL, United States Army, TECHNICAL SERGEANT, United States Air Force, DEFENSE DEPARTMENT CONTRACTOR, United States Department of Defense, FEDERAL CIVILIAN ENGINEER CONTRACTOR, FEDERAL CIVILIAN CONTRACTOR EMPLOYER, FEDERAL NUCLEAR CONTRACTOR EMPLOYEE, DEPARTMENT OF ENERGY CIVILIAN NUCLEAR TECH, for themselves and all others similarly situated, Plaintiffs, v. JOSEPH R. BIDEN, in his official capacity as President of the United States, LLOYD AUSTIN, in his official capacity as Secretary of the United States Department of Defense, and ALEJANDRO MAYORKAS, in his official capacity as Secretary of the Department of Homeland Security, Defendants.	Case No. _____

DECLARATION OF COAST GUARD LIEUTENANT

I, Coast Guard Lieutenant, do hereby declare as follows:

1. I am over the age of 18 years, have personal knowledge of the matters set forth in this Declaration, and if called upon to testify to them, I would and could do so competently.

2. I am a Lieutenant in the United States Coast Guard and a Florida resident.

3. I have submitted a request for a religious accommodation from the COVID shot mandates, based on my sincerely-held Presbyterian Christian religious beliefs.

4. I have submitted a request for medical accommodation based upon my status as a nursing mother, and based upon a known medical contraindication to multiple other shots, which were documented in the form of medical waivers permitting my accession to the Coast Guard.

5. However, myself and other mothers like me have been told that breastfeeding alone is not valid grounds for a temporary waiver, even though the insert to the approved Comirnaty states that there is no data on the effects to breastfeeding or our children or on the transfer of the vaccine through breast milk

6. I was present for a discussion by Rear Admiral Joanna Nunan during one of her Fall 2021 visits to Gulf Coast Units regarding the COVID shot mandates. I left that meeting feeling unsettled due to the admiral's statements.

7. Admiral Nunan is the Deputy Commandant for Personnel Readiness, meaning she is over all training and human resources, including the offices screening medical and religious exemption requests. The United States Coast Guard Academy Superintendent reports to her, as does the Commander of Force Readiness Command, and the Assistant Commandant for Human Resources.

8. Based on Admiral Nunan's statements about that religious and medical accommodations process, I left the meeting feeling the Coast Guard has little interest in screening those requests in good faith.

9. In regard to religious waivers: Admiral Nunan stated that "none of the major religions" (however she is defining that) "have come out against the vaccines." She stated that "the Pope had endorsed them," implying she (and the Coast Guard) saw no legitimacy for religious waiver requests, even though the actual policy and instruction bases those requests on a sincerely-held moral belief, not the actions of the Pope.

10. One of the questions addressed by Admiral Nunan was whether the Coast Guard expects the percentage of those with exemptions to this vaccine to pan

out in relationship to exemptions to other vaccines. Admiral Nunan could not answer as she did not know how many are even exempt from the other vaccines.

11. Admiral Nunan informed us that DOD is at 9% and Coast Guard is currently at 11% unvaccinated, indicating the Coast Guard was working to get more people vaccinated.

12. Admiral Nunan informed us that she expects very few people to have waivers of any kind, and that the only medical waivers she foresees medically are specific allergies to the vaccine. This appears to me to be a change from other medical waivers from Coast Guard-required vaccines, which, in my experience have taken the "better safe than sorry" approach (i.e. "do no harm"), and were issued by one's PCM, rather than Headquarters as they are being required now.

a. Medical seems to now be requiring a specific diagnosis of reaction to one of the ingredients, even though some have never been utilized in vaccines before. So, even if one has requested testing in the past, it wasn't something being screened for now.

b. I have asked to be medically screened for allergies multiple times in the past, as I react to other items that contain some of these ingredients, only to be told that testing wasn't necessary. Now that is backfiring, and even though they finally put in a request for me to get tested, I have been waiting over two months due to issues with issuing the referral.

13. Admiral Nunan spoke to the issue of our workforce, and how short staffed the Coast Guard was. Admiral Nunan brought up the example of being 500 non-rates short right now, with regard to just the most junior enlisted members. She then highlighted shortages in other fields, including inspections, cyber, aviation, and afloat. Immediately after this conversation, someone asked that given the shortages, if the Coast Guard could really afford to lose even 5% of the service over the vaccination issue, and incredibly, Admiral Nunan stated emphatically that we could.

14. Admiral Nunan informed us Coast Guard is working on what type of discharge members who decline the COVID vaccines will receive. She stated the Coast Guard was trying to find a way to strip those discharged over the vaccine of their benefits they earned under the 9-11 GI bill, as they are focusing on "incentives" to encourage people to get the shot rather than be discharged. Admiral Nunan stated that many more restrictive guidances for unvaccinated members would be forthcoming.

15. Another question presented to Admiral Nunan was if she had discussed how the Coast Guard was going to separate treatment (thinking specifically of those punitive actions such as negative Page 7's, Restriction of Movement, Denial of Leave) of those who had pending or approved medical/religious waivers (distinguishing from those who were just disobeying orders). She didn't have an answer.

16. Admiral Nunan further elaborated about those Page 7s and the potential for them to affect promotions and boards: those who had gotten the Counseling Form might not be allowed to take command positions in the future. She later emphasized that she wanted to push for more command positions to be available, and be a more important factor on promotion boards and selection panels.

17. While the military can be medically exclusive in its ascension within reason, to do this kind of thing to people already in the service and with valid requests would be a form of medical and religious discrimination.

18. On whether how vaccines were being treated at the accession sources (Boot Camp, OCS, and the Academy), Admiral Nunan informed the group that "my guidance will be 100% vaccinated. Period."

19. Admiral Nunan said "there are enough people who want those spots that I would exclude any who were not vaccinated." This was after she had just spoken about her primary focus being "diversity and inclusion." My impression after that conversation was that "diversity and inclusion" applies only to skin color, not a diversity of thought or religion.

20. Coast Guard Vice Admiral Thomas has since issued guidance (ALCOAST 352-21) limiting unvaccinated members (regardless of waiver status) to within 50 miles of their assigned units, while placing no such distance restrictions upon vaccinated members (despite vaccinated members' susceptibility to acquiring

and transmitting COVID). The guidance has also required cancellation of all training orders and ineligibility for training orders for any person not vaccinated, regardless of waiver status.

21. Thus, unvaccinated members are not permitted to go to training, harming their futures because they will be delinquent and deficient in their training, until they get vaccinated. I am aware of Petty Officers who lost their orders to A-School, because they were not vaccinated, despite their having submitted religious and/or medical exemption waiver requests.

22. In guidance ALCOAST 352-21, the Coast Guard further praised its readiness status, while stating the restrictions would remain in place until the "threat to mission readiness caused by COVID-19 was negligible." COVID-19's threat to mission readiness, with a survival rate of greater than 99.98% DoD-wide, is already "negligible." The Coast Guard, across its Civilian, Reserve, and Active components comprises "41,700 active-duty military; 7,800 reserve military part-time employees; 8,300 civilian full-time employees;" (see https://www.uscg.mil/seniorleadership/, last visited October 14, 2021). The total Coast Guard force of 57,800 persons has experienced eight (8) COVID-related fatalities. See ALCOAST 352-21, bullet one.

23. Admiral Nunan's statements, along with the above recent Coast Guard ALCOAST guidance lead me to conclude that my religious and medical exemption

requests are dead on arrival, absent court intervention, despite the COVID threat being "negligible."

I declare under penalty of perjury of the laws of the United States and the State of Florida that the foregoing statements are true and correct to the best of my knowledge.

Dated this 15th day of October, 2021

/s/ COAST GUARD LIEUTENANT
COAST GUARD LIEUTENANT

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

NAVY SEAL 1, et al., for themselves and all others similarly situated

(b) County of Residence of First Listed Plaintiff Hillsborough
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Roger K. Gannam, Liberty Counsel, PO Box 540774, Orlando FL 32854

DEFENDANTS

Jospeh R. Biden, in his official capacity as President of the United States, Lloyd Austin, in his official capacity as

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	**PERSONAL INJURY** ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Medical Malpractice **PERSONAL INJURY** ☐ 365 Personal Injury - Product Liability ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability **PERSONAL PROPERTY** ☐ 370 Other Fraud ☐ 371 Truth in Lending ☐ 380 Other Personal Property Damage ☐ 385 Property Damage Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881 ☐ 690 Other **LABOR** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Management Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Employee Retirement Income Security Act **IMMIGRATION** ☐ 462 Naturalization Application ☐ 465 Other Immigration Actions	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 **INTELLECTUAL PROPERTY RIGHTS** ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 840 Trademark ☐ 880 Defend Trade Secrets Act of 2016 **SOCIAL SECURITY** ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g)) **FEDERAL TAX SUITS** ☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 400 State Reapportionment ☐ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit (15 USC 1681 or 1692) ☐ 485 Telephone Consumer Protection Act ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities/ Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes

REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS
☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	☒ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/ Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	**Habeas Corpus:** ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty **Other:** ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
First Amendment to United States Constitution, 42 USC 2000bb, et seq., 21 USC 360bbb-3

Brief description of cause:
Constitutional and statutory challenge to mandatory COVID-19 vaccine policy for military, federal employees, and federal contractors

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
10/15/2021

SIGNATURE OF ATTORNEY OF RECORD
/s/ Roger K. Gannam

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

NAVY SEAL 1, et al., for themselves and all others similarly situated,

Plaintiff(s)

v.

JOSEPH R. BIDEN, in his official capacity as President of the United States, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* JOSEPH R. BIDEN
c/o Karin Hoppmann
Acting United States Attorney for Middle District of Florida
400 North Tampa Street
Suite 3200
Tampa, FL 33602

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roger K. Gannam
Liberty Counsel
PO Box 540774
Orlando, FL 32854

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

NAVY SEAL 1, et al., for themselves and all others similarly situated,

Plaintiff(s)

v.

JOSEPH R. BIDEN, in his official capacity as President of the United States, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* LLOYD AUSTIN
c/o Karin Hoppmann
Acting United States Attorney for Middle District of Florida
400 North Tampa Street
Suite 3200
Tampa, FL 33602

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roger K. Gannam
Liberty Counsel
PO Box 540774
Orlando, FL 32854

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

NAVY SEAL 1, et al., for themselves and all others similarly situated,

Plaintiff(s)

v.

JOSEPH R. BIDEN, in his official capacity as President of the United States, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ALEJANDRO MAYORKAS
c/o Karin Hoppmann
Acting United States Attorney for Middle District of Florida
400 North Tampa Street
Suite 3200
Tampa, FL 33602

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roger K. Gannam
Liberty Counsel
PO Box 540774
Orlando, FL 32854

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

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❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: