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### IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

### IN RE: OSHA RULE ON COVID-19 VACCINATION AND TESTING, 86 FED. REG. 61402

On Petitions for Review

### PETITIONER BENTKEY SERVICES, LLC D/B/A THE DAILY WIRE'S OPPOSITION TO OSHA'S MOTION TO DISSOLVE STAY

(ECF # 69)

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To further its goal of controlling the American public's personal medical decisions, the federal government is making an unprecedented, pretextual use of a rare administrative procedure, the Emergency Temporary Standard, under the authority of the Occupational Safety and Health Administration ("OSHA"). See COVID-19 Vaccination and Testing: Emergency Temporary Standard, 86 Fed. Reg. 61402 (Nov. 5, 2021) ("ETS"). The ETS is just one part of the President's announced plan to impose a nationwide vaccine mandate after running out of "patience" with the unvaccinated, and while circumventing Constitutional restrictions prohibiting such a mandate. BST Holdings, L.L.C., 17 F.4th 604 (5th Cir. 2021) ("Order"), at 617-18; id. at nn. 11, 13. Courts have already blocked other parts of this plan, including vaccination mandates for federal contractors and health care workers, because the agencies exceeded their statutory authorities. See Georgia v. Biden, Civ. No. 1:21cv-163, slip op. at 18-19, 21 (S.D. Ga. Dec. 7, 2021) (federal contractor mandate); Kentucky v. Biden, No. 3:21-cv-00055-GFVT, 2021 U.S. Dist. LEXIS 228316 (E.D. Ky. Nov. 30, 2021) (same); Missouri v. Biden, -- F. Supp. 3d ---, \*8 (E.D. MO, Nov. 29, 2021) (healthcare worker mandate) (appeal filed).

As the Fifth Circuit held, "[e]xtraordinary power is delivered to [OSHA] under the emergency provisions of the Occupational Safety and Health Act," so "[t]hat power should be delicately exercised, and only in those emergency situations which require it." Order at 609 (citing *Fla. Peach Growers Ass'n v. U.S. Dep't of Lab.*, 489 F.2d 120, 129–30 (5th Cir. 1974)) (alterations in original). OSHA has issued ten ETSs in 50 years, six of which "were challenged in court," "most" of the challenged ETSs were stayed, and "only one survived." Order at 609; id. at n. 2.

The ETS's purpose, which circumvents federal administrative law's mandatory public notice and comment rulemaking, is to pressure nonhealthcare related private-sector employees into vaccination. It thus classifies tens of millions of American workers as workplace hazards subject to OSHA's control, solely based on their medical choices outside of work, for a disease that is not unique to the workplace or necessarily present in them or their workplace. Almost eighteen months after the current pandemic began, and six months after widespread COVID-19 vaccine availability, the President's command prompted OSHA to abruptly deem the virus a "grave danger" to justify one of the most sweeping exercises of federal government power in American history. Even worse, OSHA issued its belated ETS as COVID cases, hospitalizations, and deaths have significantly declined, and as the vaccination rate continues to climb.

The ETS would require employers to monitor their workers' COVID-19 vaccinations, track constant testing, enforce mask-wearing for vaccinated workers, invade employees' personal medical histories and religious choices, and fire noncompliant employees. The employers' compilation of confidential medical information would also complicate personnel decisions and create legal liability. The government, lacking legitimate power to impose a direct vaccination requirement on the public, is instead forcing businesses to do it for them and thereby risking liability to their employees under the Americans with Disability Act, anit-discrimination laws, and privacy rules.

The plethora of ETS citations showing that people have tested positive or died from COVID are irrelevant. OSHA must show substantial evidence that *workplace* COVID-19 exposures present a grave danger to workers, and that mandating employee vaccinations for companies with more than 100 workers is necessary to alleviate that

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danger. See Asbestos Information Ass'n/N. America v. OSHA, 727 F.2d 415, 427 (5th Cir. 1984).

OSHA's radical power grab is unconstitutional, not authorized by statute, and fails to satisfy the basic requirements for an ETS. OSHA's arguments are so outlandish, they can only be understood as *post hoc* excuses for a general vaccine mandate masquerading as a workplace safety rule. The Daily Wire is submitting three expert declarations that highlight the inconsistencies and inadequacies of OSHA's justifications.

The ETS's implementation should remain stayed. Here, The Daily Wire demonstrates the stay is necessary to maintain the status quo pending conclusive determination of the ETS's legality. *In re E.P.A.*, 803 F.3d 804, 806 (6th Cir. 2015). It can show: (1) the likelihood that it will prevail on the merits; (2) the prospect of irreparable harm absent relief; (3) the possibility of substantial harm to others if relief is granted; and (4) the strong public interest in favor of granting the stay. *Commonwealth v. Beshear*, 981 F.3d 505, 508 (6th Cir. 2020).

#### I. PETITIONERS ARE LIKELY TO PREVAIL ON THE MERITS.

The Fifth Circuit correctly concluded that "petitioners' challenges to the Mandate show a great likelihood of success on the merits, and this fact weighs critically in favor of a stay." Order at 618. The Daily Wire need only show "a sufficient probability of success on the merits." See *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 155 (6th Cir. 1991). Where constitutional rights are at stake, the "strength of the likelihood of success on the merits that needs to be demonstrated is inversely proportional to the amount of irreparable harm that will be suffered if a stay does not issue." *Baker v. Adams Cty. Ohio Valley Sch. Bd.*, 310 F.3d 927, 928 (6th Cir. 2002). This ETS offends both federalism and separation of powers. Long after COVID-19 has been relegated to history books, this ETS's damage to our constitutional government would endure.

### A. The Commerce Clause Does Not Empower OSHA to Mandate Vaccination or Testing for Private Employees.

The federal government is using the ETS to pressure Americans to receive a medical treatment the government prefers. As the Fifth Circuit held, however, the purpose of "[t]he Occupational Safety and Health Act, which created OSHA, was . . . to assure Americans 'safe and healthful working conditions and to preserve our human resources." Order at 611 (quoting 29 U.S.C. § 651). "It was not—and likely *could* not be, under the Commerce Clause and nondelegation doctrine—intended to authorize a workplace safety administration in the deep recesses of the federal bureaucracy to make sweeping pronouncements on matters of public health affecting every member of society in the profoundest of ways." Order at 611, citing *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2488–90 (2021) (per curiam).

The federal government's enumerated powers do not include "a plenary police power that would authorize enactment of every type of legislation." *United States v. Lopez*, 514 U.S. 549, 566 (1995); *see also* U.S. Const. Art. I, § 8 (list of Congressional powers). Vaccination requirements have been recognized as state police powers, *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), which Congress, and by extension OSHA, do not possess. "Any police power to regulate individuals as such, as opposed to their activities, remains vested in the States." *NFIB v. Sebelius*, 567 U.S. 519, 557 (2012).

The Fifth Circuit held the ETS exceeds the federal government's Commerce Clause authority because a "person's choice to remain unvaccinated and forgo regular testing is noneconomic activity." Order 617 (citing *NFIB*, 567 U.S. at 522 (2012) (Roberts, C.J., concurring); *see also id.* at 652–53 (Scalia, J., dissenting)). OSHA may only regulate commercial activity, NFIB, 567 U.S. at 550, which the Supreme Court has repeatedly found is not a limitless grant to prohibit disfavored conduct based on a tenuous link to commercial activity, or to regulate "classes of *individuals*, apart from any activity in which they are engaged." *Id.* at 556. Like those who choose not to purchase health insurance, those who choose not to vaccinate are "a class whose commercial inactivity rather than activity is its defining feature." *Id.* 

The federal government here utilizes OSHA's power to regulate workplace safety, an exercise of Congress's Commerce Clause power, as a pretext to regulate individuals based only on their choice *not* to be vaccinated. "Accepting the Government's theory would give Congress the same license to regulate what we *do not do*, fundamentally changing the relation between the citizen and the Federal Government." *Id.* at 554–55 (emphasis added). Even where people "fail to do things that would be good for them or good for society," the Commerce Clause does not authorize Congress "to compel citizens to act as the Government would have them act." *Id.* at 554.

The breadth of OSHA's attempted self-empowerment is illustrated by its inherent lack of a limiting principle: Anyone with a job—for that reason alone—could be subject to unrestricted OSHA regulation to protect them from their disfavored personal choices. If working means forfeiting the right to make personal *medical* choices to the federal government, there are *no choices or omissions* that remain free or reserved to the states' police powers. Fortunately, "[t]he Commerce Clause is not a general license to regulate an individual from cradle to grave, simply because he will predictably engage in particular transactions." *Id*.

OSHA likens the ETS to Congress's regulation of companies engaged in interstate commerce through Title VII and the Fair Labor Standards Act ("FLSA"), Resp's. Emergency Motion to Dissolve Stay ("Mot.") at 18. OSHA's reliance on *United States v. Darby*, 312 U.S. 100 (1941), which upheld challenged portions of the FLSA, is misplaced. The *Darby* Court found that Congress enacted the FLSA to "suppress[] . . .nationwide competition in interstate commerce by goods produced under substandard labor conditions[.]" *Darby*, 312 U.S. at 123. Congress, therefore, did not stray from regulating commercial transactions (the payment of wages) that affected interstate commerce. The Court did not, as OSHA suggests, hold that Congress could regulate *all* aspects of the employer-employee relationship, much less individual workers' medical decisions.

OSHA claims the ETS merely prescribes how to engage in commercial activity, Mot. at 20–22, but the ETS's vaccination and testing requirements do not even involve commercial activity. Instead, the ETS controls what workers do *outside* of work, and is transparently just one part of a national vaccination strategy. OSHA lists supposedly similar requirements—serving patrons regardless of race, filling out paperwork, establishing job qualifications, and *workplace* safety and health standards. Mot. at 19. But these have a direct bearing on transacting commerce. Even job qualifications, before OSHA promulgated the ETS, directly relate to a worker's job fitness and suitability. The ETS is markedly different because it regulates "noneconomic inactivity traditionally within the States' police power," Order at 617 (citations omitted), by barring the noncompliant from the workplace.

As the Fifth Circuit found, the ETS likely violates the separation of powers. The nondelegation doctrine "constrains Congress's ability to delegate its legislative authority to executive agencies." Order at 611 n.8 ("we have long insisted that 'the integrity and maintenance of the system of government ordered by the Constitution' [sic] mandate that Congress generally cannot delegate its legislative power to another Branch." (quoting *Mistretta v. United States*, 488 U.S. 361, 371–72 (1989). OSHA's answer that its power is "unambiguous and limited", Mot. at 22, is belied by the limitless power it asserts to control individual workers based solely on their presence in the workplace, to include their out-ofworkplace medical decisions.

Finally, the Fifth Circuit aptly noted that the ETS was both underand over-inclusive, Order at 615–16, which is detailed below within the context of OSHA's burden to establish the ETS is "necessary" and not arbitrary under the OSH Act and the Administrative Procedure Act ("APA"), respectively.

### B. The OSH Act Does Not Delegate Vaccine Mandate Authority to OSHA.

Even if the Commerce Clause allowed Congress to impose a national vaccination mandate (or a mandate that extends only to an arbitrary class of workers), Congress did not confer that authority on OSHA. The OSH Act empowered OSHA to protect employees from *workplace hazards*, not dictate workers' personal medical decisions outside the workplace. Indeed, until it submitted to political pressure to issue and defend this ETS, OSHA "conceded in the past that "[t]he OSH Act does not authorize OSHA to issue sweeping health standards to address entire classes of known and unknown infectious diseases on an emergency basis without notice and comment." Order at 612 n.14 (citing Department of Labor's Resp. to the Emergency Pet. for a Writ of Mandamus at 33–34, *In re AFL-CIO*, No. 20-1158 (D.C. Cir. May 29, 2020)).

The government's interpretation of its statutory power is "unreasonable [where] it would bring about an enormous and transformative expansion in [its] regulatory authority without clear congressional authorization." *Util. Air Regul. Grp.* (cleaned up) (citing *Brown & Williamson*, 529 U.S. at 159–60 (2000)). The Court "expect[s] Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Ala. Ass'n of Realtors*, 141 S. Ct. 2485, 2489 (2021) (cleaned up); *Util. Air Regul. Grp.*, 573 U.S. at 302; *see also Ala. Ass'n of Realtors*, 141 S. Ct. 2485, 2489 (2021) (CDC authority to prevent spread of communicable diseases did not authorize banning landlords from evicting 17 million tenants). Congress empowered OSHA to develop and promulgate "occupational safety and health standards," 29 U.S.C. § 651(b)(3), defined as "a standard which requires *conditions, or the adoption or use of one or more practices, means, methods, operations, or processes,* reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8) (emphasis added). It applies "with respect to employment performed *in a workplace.*" *Id.* § 653(a) (emphasis added). The statute was not intended to provide OSHA with the authority to issue broad, sweeping edicts with society-wide implications relating to public health outside the workplace. Order at 611. Yet, in enacting the ETS, OSHA did precisely that.

Thus, the Fifth Circuit rejected "OSHA's attempt to shoehorn an airborne virus that is both widely present in society (and thus not particular to any workplace) and non-life threatening to a vast majority of employees" into statutory authority to regulate "substances" and "agents" in the workplace. Order at 613. The OSH Act section upon which this ETS supposedly relies limits OSHA to regulating when "employees are exposed to grave danger from exposure to *substances or agents* determined to be toxic or physically harmful or from new hazards." 29 U.S.C. § 655(c)(1) (emphasis added). OSHA's ETS defines "the grave danger as workplace exposure to SARS–CoV–2, the virus that causes the development of COVID–19." ETS at 61,407 n. 3. Rather than regulate workers' potential virus exposure, however, the ETS regulates employees without reference to their workplace or actual exposure risk. But unvaccinated employees are not "toxic" "substances or agents" to which other unvaccinated "employees are exposed" under §655. And, of course, an unvaccinated employee is neither "exposed" to herself, nor "new," nor a "hazard[]."

OSHA's argument that it is merely promulgating regulations relating to viruses that also happen to exist outside the workplace, Mot. at 2, is unavailing. OSHA's refusal to require testing and masks for vaccinated workers, despite acknowledging that they too can contract and transmit COVID-19, reveals that the ETS is truly regulating people, not workplace hazards.

OSHA seeks to transform the OSH Act into something resembling federal police power. OSHA argues the Act's purpose was to ensure that workers could "work in a safe and healthy 'environment," including "the air we breath[e] at work," Mot. at 15–17 (cleaned up), and therefore OSHA can control workers' medical choices if they affect the air at their workplace. This tortured reading of the OSH Act would give OSHA virtually limitless authority to regulate workers rather than bona fide workplace conditions.

OSHA cites 29 U.S.C. § 669(a)(5) for the strained proposition that OSHA has the authority to "require 'immunization' . . . to protect employees from communicable diseases." Mot. at 16. OSHA's reading of § 669 is no more faithful than its reading of § 655. Section 669(a)(5) states that the Secretary of Health and Human Services, "in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents[.]" 29 U.S.C. § 669(a)(5) (emphasis added). The only reference to "immunization" in § 669 is a prohibition on "authoriz[ing] or requir[ing] medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health and safety of others." *Id.* This section must be read in parallel with the overall statutory scheme to address workplace and occupation hazards. Nothing in the

OSH Act comes close to authorizing OSHA to enact a vaccine mandate across all industries and workplaces (limited only by the arbitrary measure of number of employees).

The Fifth Circuit linked the Constitutional concerns, above, with OSHA's impermissibly expansive reading of its own power. "[E]even if the statutory language were susceptible to OSHA's broad reading—which it is not—these serious constitutional concerns would counsel this court's rejection of that reading." Order at 618 (citing *Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018)). As the Fifth Circuit put it, the ETS is "a monumental policy decision," and not a matter of "hard hats and safety goggles." Order at 617 n. 20. The Fifth Circuit therefore "[did] not infer" any "clear expression of congressional intent in § 655(c) to convey OSHA such broad authority" to promulgate the ETS. Order at 618. (Nor could it under the Commerce Clause, *see* p. 5, *supra*.).

## C. The ETS Is Not Supported by Substantial Evidence and OSHA Acted Arbitrarily and Capriciously.

The APA prohibits agency action that is unconstitutional, exceeds statutory authority, or is arbitrary, capricious, or an abuse of discretion. 5 U.S.C. §§ 705–06. Further, the ETS must be supported by "substantial evidence," requiring courts to take a "harder look" than even under the APA's arbitrary and capricious standard for reasoned decision-making. 29 U.S.C § 655(f); Asbestos Info. Ass'n/N. Am. v. Occupational Safety & Health Admin., 727 F.2d 415, 421 (5th Cir. 1984). Agencies must also provide reasons for changes in position and explain their rejection of alternatives. Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 140 S. Ct. 1891, 1910–15 (2020); Dep't of Commerce v. New York, 139 S. Ct. 2551, 2575 (2019). The substantial evidence standard requires that agency action be "reasonable under the state of the record before" the agency. Texas Indep. Ginners v. Marshall, 630 F.2d 398, 405 (5th Cir. 1980).

The ETS glosses over the statistics showing that COVID-19 cases, deaths, and hospitalizations across the United States have plummeted. *See* ETS at 61, 4431. As a result, issuing the ETS at the same time the effects of the virus are dissipating, is not reasonable and not supported by substantial evidence or "reasonably necessary and appropriate to remedy a significant risk of material health impairment." *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Instit.*, 100 S. Ct. 2844, 2863 (1980). Generally, courts require that the administrative record contain "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229, 59 S.Ct. 206, 217, 83 L.Ed. 126 (1938). And "the extent to which the supporting evidence has survived public and scientific scrutiny, however, will affect the weight given to it by an inexpert judiciary." *Asbestos Information Ass'n/N. America v. Occupational Safety and Health Admin*. (5th Cir. 1984) 727 F.2d 415, 421. Courts have developed several exceptions countenancing use of extra-record evidence including:

(1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; (3) when an agency considered evidence which it failed to include in the record; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly; (5) in cases where evidence arising after the agency action shows whether the decision was correct or not; . . . (8) in cases where relief is at issue, especially at the preliminary injunction stage.

*Esch v. Yeutter*, 876 F.2d 976, 991-92 (D.C. Cir. 1989) (underscoring added).

Because OSHA sidestepped relevant factors, more evidence is needed to understand the issues, and new evidence shows OSHA's decision was not correct, the Court should consider the expert testimony included here.

### 1. OSHA failed to establish workplace exposure.

The Fifth Circuit concluded OSHA failed to meet a "threshold burden" of "show[ing] that employees covered by the ETS are in fact exposed to the dangerous substances, agents, or hazards at issue—here, COVID-19." Order at 613. Random information about workplace COVID-19 "clusters' and 'outbreaks' and other significant 'evidence of workplace transmission' and 'exposure" . . . misses the mark, as OSHA is required to make findings of exposure—or at least the presence of COVID-19—in all covered workplaces." Id. (quoting OSHA 5th Cir. Opp'n to Emergency Stay Mot. at 8). In fact, 98% of the ETS's 658 references are unrelated to COVID-19 workplace transmissions. (Kaufman Dec. ¶ 77, Exhibit "2"). For the few cases even slightly relevant to workplace transmissions, the authors warned about significant limitations in these studies which show that the ETS failed to prove that it was alleviating a grave risk to workers. (Kaufman ¶ 78).

### 2. OSHA failed to establish the gravity of potential workplace exposure.

The Fifth Circuit correctly noted that OSHA has not met its burden to establish the gravity of the workplace exposure COVID-19 risks, as the ETS concedes COVID-19 effects may range from "mild" to "critical." Order at 614. In addition, the gravity prong must also be considered alongside the fact that Americans over eighteen, who comprise nearly the entire workforce, are overwhelmingly vaccinated. *Id*. Currently 83.5%, and climbing, have received at least one vaccination dose. *See COVID Data Tracker*, Centers for Disease Control, *available at* https://covid.cdc.gov/covid-data-tracker/#vaccinations\_vacc-peopleonedose-pop-5yr (last accessed December 6, 2021).

OSHA failed to offer substantial evidence that SARSCoV-2 and COVID-19 pose a grave danger of a "serious or life threatening disease or condition" for all unvaccinated employees in non-medical workplaces. The risk of dying from COVID-19 varies widely based on age. (Bhattacharya Decl. ¶ 11-18, Exhibit "1"); (Lyons-Weiler Decl. ¶¶ 9, 25, Exhibit "3"); and (Kaufman Decl. ¶ 15, 34, 36-38, Exhibit ). Rather than account for employees of different ages and for widespread vaccination rates among adults, the ETS tracks numbers of employees in a company—not even the number in a given location. It also ignores the

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potential impact of treatment options, which are expanding.<sup>1</sup> (Lyons-Weiler Decl. ¶ 31-33); (Kaufman Decl. ¶ 16); *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1916 (2020) (agency failed to "provide a reasoned explanation for its action" by failing "to consider conspicuous issues", raising "doubts about whether the agency appreciated the scope of its discretion or exercised that discretion in a reasonable manner.").

# 3. OSHA failed to establish the need for the ETS because it is overbroad, underinclusive, and arbitrary.

As found by the Fifth Circuit, OSHA "reasonably determined' in June 2020 that an emergency temporary standard (ETS) was 'not necessary' to 'protect working people from occupational exposure to infectious disease, including COVID-19." Cir. Order at 609 (quoting *In re AFL-CIO*, 2020 WL 3125324, at \*1 (D.C. Cir. June 11, 2020)). The Fifth Circuit also correctly concluded "[t]he Mandate is staggeringly overbroad," because it "fails to consider what is perhaps the most salient

<sup>1</sup> See Brendan Morrow, Pfizer says effectiveness of COVID antiviral pill is 'beyond our wildest dreams', Yahoo News (Nov. 5, 2021). https://news.yahoo.com/pfizer-says-effectiveness-covid-antiviral-110635778.html?fr=sycsrp\_catchall fact of all: the ongoing threat of COVID-19 is more dangerous to *some* employees than to *other* employees. . . . [O]ne constant remains—the Mandate fails almost completely to address, or even respond to, much of this reality and common sense." Order at 615. Indeed, the Fifth Circuit noted that OSHA was previously opposed to a one-size-fits-all mandate for all workplaces, that could be "counterproductive," "inefficacious," and a "poorly-suited approach." *Id*.

It is a well-established scientific fact that natural COVID-19 immunity provides strong and long-lasting protection from subsequent infection without a vaccine. (Bhattacharya Decl. ¶ 7, 19, 22, 23, 25 & 26); (Kaufman Decl. ¶ 13, 56, 57, 59, 60, 61, 68, 69, 70 & 84); and (Lyons-Weiler Decl. ¶ 24). This ETS, however, makes no distinction between unvaccinated workers who have recovered from COVID and those who have never been exposed, which is arbitrary and capricious. *See Missouri* v. Biden, -- F. Supp. 3d ---, \*8 (E.D. MO. Nov. 29, 2021) (appeal filed) (arbitrary and capricious that CMS rejected alternatives to vaccine mandates for "those with natural immunity by a previous coronavirus infection."). The Fifth Circuit also doubted the need for the ETS based on its "underinclusive nature", which "implies that the Mandate's true purpose is not to enhance workplace safety, but instead to ramp up vaccine uptake by any means necessary." Order at 616. One key aspect of the ETS's underinclusiveness is that it "cannot prevent vaccinated employees from spreading the virus in the workplace, or prevent unvaccinated employees from spreading the virus in between weekly tests." Order at 616 n. 19. The coronavirus vaccine is only meant to decrease the length and severity of disease, but does not prevent infection and transmission. (Kaufman Decl. ¶¶ 40, 42, 50.) Both vaccinated and unvaccinated workers alike may become infected and transmit the virus. (Kaufman Decl. ¶¶ 13, 51.)

#### 4. The ETS is an impermissible stop-gap measure.

The Fifth Circuit also concluded the ETS was defective because it was being used as a mere "stop-gap measure." Order at 616 (citing *Asbestos Info.*, 727 F.2d at 422; ETS at 61,402, 61,434–35 (acknowledging that the ETS allows OSHA to "act as quickly as possible" while "[c]rafting a multi-layered standard that is comprehensive and feasible")).

5. The ETS's testing requirement undermines its alleged necessity.

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The ETS's testing requirement undermines the premise of its necessity, because COVID testing delivers both false positive and false negative results. (Lyons-Weiler Decl. ¶ 37). These errors are not harmless as false positives lead to unwarranted and costly workforce quarantining while allowing infectious individuals into the workplace. (Lyons-Weiler Decl. ¶¶ 14,15. False positive tests also lead to a higher fatality reporting rate. (Lyons-Weiler Decl. ¶¶ 13-18). The efficacy of testing in reducing the alleged grave danger is therefore unsupported.

### **II. II. THE BALANCE OF EQUITIES FAVORS A STAY**

OSHA argues that Petitioners "have not shown any injury that outweighs the injuries to the government and the public interest." (Motion p. 40). Yet OSHA glosses over the fact that 98% of the ETS's references have nothing to do with workplace transmission. (Kaufman Decl. ¶ 77). The few relevant cases have minimal, extremely weak evidence and are loaded with confounding variables. (Kaufman Decl. ¶ 79).

While OSHA argues that delaying the ETS would endanger thousands, the ETS has failed to consider a single study involving the known adverse vaccine side effects from sources like the Department of

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Health and Human Services Vaccine Adverse Event Reporting System. (Kaufman Decl. ¶ 80). While OSHA contends that there is extensive evidence of workplace transmission, a careful review of the ETS's 490 pages shows a complete lack of statistically significant references attributing risk to specific workplace environments. (Kaufman Decl. ¶ 81).

Similarly, OSHA contends, without a single scientific citation, that the ETS has proven that workers "are being hospitalized with COVID-19 every day, and many are dying. Pmbl.-61549." The ETS's few studies that even directly deal with worker COVID-19 infections fail to properly determine whether worker infection was due to a workplace or community transmission. (*See, e.g.,* Kaufman Decl. ¶ 78.b, 78.d, 78.j, and 78.l).

While the ETS fails to prove that there is a grave danger of workplace transmission, the ETS puts the Daily Wire in an untenable position. The Daily Wire employs over 100 people. (Declaration of Jeremy Boreing (Boreing Decl. at 38-54, Exhibit "4"). The ETS will force it to either (A) intrude on employees' private health decisions, undertake significant compliance costs, face increased liability to workers, and lose

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key employees; or (B) pay crushing fines for noncompliance. (Boreing Decl. at 39-54.) "As an employer, Bentkey Services is obligated to take extraordinary steps to protect employees' private health information." (Boreing Decl. at 43.) The ETS "exposes the company to danger of liability should any employee's information related to the vaccine or testing be exposed" and "opens the door to potential discrimination claims, including for example under the Americans with Disabilities Act and the Civil Rights Act." (*Id.*) By some estimates, administration costs could be millions of dollars a year.<sup>2</sup>

As the Fifth Circuit correctly concluded, companies such as The Daily Wire "seeking a stay in this case will also be irreparably harmed in the absence of a stay, whether by the business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, the diversion of resources necessitated by the Mandate, or by OSHA's plan to impose stiff financial penalties on companies that refuse to punish or test unwilling employees." Order at 618. "[C]omplying with a regulation later held invalid almost *always* 

<sup>&</sup>lt;sup>2</sup> Rebecca Rainey, Biden's Workplace Vaccine Mandate Faces Headwinds, Politico, *available at* https://www.politico.com/news/2021/09/13/biden-mandates-vaccines-reactions-511680 (last accessed December 5, 2021).

produces the irreparable harm of nonrecoverable compliance costs." *Id.* (citing *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016)); *see also Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and in the judgment).

The Fifth Circuit also correctly concluded that "a stay is firmly in the public interest" because of the "economic uncertainty" and "workplace strife" caused by "the mere specter of the Mandate" but, more importantly, "the principles at stake when it comes to the Mandate are not reducible to dollars and cents." Order at 618. "The public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals to make intensely personal decisions according to their own convictions—even, or perhaps *particularly*, when those decisions frustrate government officials." Order at 618–19.

### III. OSHA'S PROPOSED ALTERNATIVE RELIEF DOES NOT CURE OSHA'S LACK OF AUTHORITY OR EVIDENCE FOR THE ETS

If OSHA lacks the authority to issue an ETS imposing a general national vaccination mandate irrespective of workplace conditions or occupation, it has no such power to issue its proposed alternative—a general national testing and masking mandate. Even assuming arguendo

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it has any such power, the same statutory and evidentiary defects discussed above would remain.

### III. CONCLUSION

The Daily Wire asks the Court to deny OSHA's motion to dissolve the stay imposed by the Fifth Circuit based on the constitutional and statutory reasons found by that court. Further, as the Fifth Circuit held and as demonstrated above, OSHA has failed to show that COVID-19 exposures in the workplace present a grave danger to workers, and the record considered as a whole substantially fails to support OSHA's conclusion that an ETS mandating employee vaccines for employers with more than 100 workers is necessary to alleviate a grave risk to workers during the next six months.

Dated: December 7, 2021

Respectfully submitted,

<u>/s/ Harmeet K. Dhillon</u>

Ryan L. Bangert Ryan J. Tucker ALLIANCE DEFENDING FREEDOM 15100 N 90th Street Scottsdale, AZ 85260 (480) 444-0020 rbangert@ADFlegal.org rtucker@ADFlegal.org Harmeet K. Dhillon Ronald D. Coleman Mark P. Meuser Michael A. Columbo Stuart S. McCommas DHILLON LAW GROUP 177 Post Street, Suite 700 San Francisco, California 94108 (415) 433-1700 David A. Cortman John J. Bursch Matthew S. Bowman Frank H. Chang ALLIANCE DEFENDING FREEDOM 440 First Street, NW, Suite 600 Washington, DC 20001 (202) 393-8690 dcortman@ADFlegal.org jbursch@ADFlegal.org mbowman@ADFlegal.org fchang@ADFlegal.org harmeet@dhillonlaw.com rcoleman@dhillonlaw.com mmeuser@dhillonlaw.com mcolumbo@dhillonlaw.com smcommas@dhillonlaw.com (34 of 156)

Counsel for Bentkey Services, L.L.C. d/b/a The Daily Wire

### **CERTIFICATE OF COMPLIANCE**

1. This document complies with the type-volume limit of FED. R. APP. P. 27(d)(2)(A) because, excluding the parts of the document exempted by FED. R. APP. P. 32(f) and 6th Cir. R. 32(b), this document contains 5133 words according to the word count function of Microsoft Word 365.

2. This document complies with the typeface requirements of FED. R. APP. P. 32(a)(5) and the type-style requirements of FED. R. APP. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Century Schoolbook font.

/s/ Harmeet K. Dhillon Harmeet K. Dhillon

Date: December 7, 2021

### **CERTIFICATE OF SERVICE**

I hereby certify that on December 7, 2021, a true and accurate copy of the foregoing was electronically filed with the Court using the CM/ECF system. Service on counsel for all parties will be accomplished through the Court's electronic filing system.

> /s/ Harmeet K. Dhillon Harmeet K. Dhillon

Date: December 7, 2021
# EXHIBIT "1"

Lead Case No. 21-7000 (Member Case No. 21-4027/4028/4031/4032/4033/4080/4082/4083/ 4084/4085/4086/4087/4088/4080/4090/4091/4092/4093/4094/4095/4096/ 4097/4099/4100/4101/4102/4103/4108/4112/4114/4115/4117)

#### IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

#### IN RE: OSHA RULE ON COVID-19 VACCINATION AND TESTING, 86 FED. REG. 61402

On Petitions for Review

## DECLARATION OF JAY BHATTACHARYA, M.D., PH.D. IN SUPPORT OF PETITIONER BENTKEY SERVICES, LLC D/B/A THE DAILY WIRE'S OPPOSITION TO OSHA'S MOTION TO DISSOLVE STAY (ECF # 69)

#### **DECLARATION OF JAYANTA BHATTACHARYA, M.D., Ph.D.**

I, Jayanta Bhattacharya, M.D., Ph.D., declare as follows:

 I am an adult of sound mind and make this statement voluntarily, based upon my knowledge, education, and experience.

#### **EXPERIENCE & CREDENTIALS**

- 2. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine, and a research associate at the National Bureau of Economic Research. I am also Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 154 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed scientific literature more than 11,800 times.
- 3. I have dedicated my professional career to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions. I have studied extensively and commented publicly on the necessity and safety of

vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). I am intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

- 4. My assessment of vaccine immunity is based on studies related to the efficacy and safety of the one vaccine to receive full approval from the Food and Drug Administration (FDA) and the two vaccines for which the FDA has granted Emergency Use Authorization (EUA) for use in the United States. These include two mRNA-(manufactured by Pfizer-BioNTech and technology vaccines Moderna) and adenovirus-vector vaccine technology an (manufactured by Johnson & Johnson). Of those, the Pfizer vaccine, also known as Comirnaty, has full FDA approval.
- 5. I have not and will not receive any financial or other compensation to prepare this Declaration or to testify in this case, nor have I received compensation for preparing declarations or reports or for testifying in *any* other case related to the COVID-19 pandemic or any personal or research funding from any pharmaceutical

company. My participation here has been motivated solely by my commitment to public health, just as my involvement in other cases has been.

- 6. I have been asked to provide my opinion on several matters related to the Occupational Safety and Health Administration's recently enacted regulation, *COVID-19 Vaccination and Testing: Emergency Temporary Standard*.
  - Whether, based on the current medical and scientific knowledge, immunity after COVID recovery (sometimes referred to as natural immunity) is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;
  - Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity;
  - Whether there is scientific evidence to support OSHA's determination that immunity provided by COVID recovery

should not be considered as a reason to be excused from OSHA's vaccine mandate.

7. I can summarize my opinions briefly. The scientific evidence strongly indicates that the recovery from COVID disease provides strong and lasting protection against severe disease if reinfected, at least as good and likely better than the protection offered by the COVID vaccines. While the COVID vaccines are effective at protecting vaccinated individuals against severe disease, they provide only short-lasting and limited protection versus infection and disease transmission. Requiring vaccines for COVID recovered patients thus provides only a limited benefit while exposing them to the risks associated with the vaccination. Therefore, OSHA's emergency rule incorrectly does not provide an exclusion for naturally immune workers from its vaccination, masking, and testing requirements.

#### **OPINIONS**

## I. COVID-19 Infection Fatality Risk

8. SARS-CoV-2, the virus that causes COVID-19 infection, entered human circulation some time in 2019 in China. The virus itself is a

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member of the coronavirus family of viruses, several of which cause typically mild respiratory symptoms upon infection. The SARS-CoV-2 virus, by contrast, induces a wide range of clinical responses upon infection. These presentations range from entirely asymptomatic infection to mild upper respiratory disease with unusual symptoms like loss of sense of taste and smell, hypoxia, or a deadly viral pneumonia that is the primary cause of death due to SARS-CoV-2 infection.

9. The mortality danger from COVID-19 infection varies substantially by age and a few chronic disease indicators.<sup>1</sup> For most of the population, including the vast majority of children and young adults, COVID-19 infection poses less of a mortality risk than seasonal influenza. By contrast, for older people – especially those with severe comorbid chronic conditions – COVID-19 infection poses a high risk of mortality, on the order of a 5% infection fatality rate.

<sup>&</sup>lt;sup>1</sup> Public Health England (2020) Disparities in the Risk and Outcomes of COVID-19. August 2020.

 $https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908434/Disparities_in_the_risk_and_outcomes_of_COVID_August_2020_update.pdf$ 

- 10. The best evidence on the infection fatality rate from SARS-CoV-12 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people in a population who have specific antibodies against SARS-CoV-2 in their bloodstream. A seroprevalence study measures the fraction of a population who have antibodies that are produced specifically by people infected by the SARS-CoV-2 virus. The presence of specific antibodies in blood provides excellent evidence that an individual was previously infected.
- 11. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts. PCR tests are the most common type of test used to check whether a person currently has the virus or viral fragments in their body (typically in the nasopharynx). The PCR test should not be used to count the total number of people who have been infected to date in a population. Case reports and PCR test counts both miss infected people who are not identified by the public health

authorities or who do not volunteer for RT-PCR testing. That is, they miss people who were infected but recovered from the condition without coming to the attention of public health authorities. Because they ignore unreported infections, fatality rate estimates based on case reports or positive test counts are substantially biased toward reporting a higher fatality rate.

12. According to a meta-analysis<sup>2</sup> by Dr. John Ioannidis of every seroprevalence study conducted to date of publication with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate the inverse of the infection fatality rate—from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%. A separate metaanalysis<sup>3</sup> by other scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.

 <sup>&</sup>lt;sup>2</sup> John P.A. Ioannidis, *The Infection Fatality Rate of COVID- 19 Inferred from Seroprevalence Data*, Bulletin of the World Health Organization BLT 20.265892.
 <sup>3</sup> Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rate for COVID- 19: Meta-Analysis & Public Policy Implications* (Aug. 14,2020)MEDRXIV, <u>http://bit.ly/3gplolV</u>.

- 13.A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in *The Lancet*)<sup>4</sup> provides a detailed age breakdown of the infection survival rate in a preprint companion paper<sup>5</sup> 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65.
- 14.I estimated the age-specific infection fatality rates from the Santa Clara County seroprevalence study<sup>6</sup> data (for which I am the senior investigator). The infection survival rate is 100% among people between 0 and 19 years (there were no deaths in Santa Clara in that age range up to that date); 99.987% for people between 20 and 39 years; 99.84% for people between 40 and 69 years; and 98.7% for people above 70 years.

<sup>&</sup>lt;sup>4</sup> Silvia Stringhini, et al., Seroprevalence of Anti-SARS-CoV-2 lgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study (June 11, 2020) THE LANCET, <u>https://bit.ly/3187S13</u>.

<sup>&</sup>lt;sup>5</sup> Francisco Perez-Saez, et al. Serology- Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland (June 15,2020) OSF PREPRINTS, <u>http://osf.io/wdbpe/</u>.

<sup>&</sup>lt;sup>6</sup> Eran Bendavid, et al., COVID- 19 Antibody Seroprevalence in Santa Clara County, California (April 30,2020) MEDRXIV, <u>https://bit.ly/2EuLIFK</u>.

15. Those numbers are consistent with what the US CDC has reported.

A US CDC report<sup>7</sup> found between 6 and 24 times more SARS-CoV-2 infections than cases reported between March and May 2020. Correspondingly, the CDC's estimate of the infection fatality rate for people ages 0-19 years is 0.003%, meaning infected children have a 99.997% survivability rate. For people ages 20-49 years, it was 0.02%, meaning that young adults have a 99.98% survivability rate. For people age 50-69 years, it was 0.5%, meaning this age group has a 99.5% survivability rate. Finally, for people ages 70+ years, it was 5.4%, meaning seniors have a 94.6% survivability rate. <sup>8</sup> There is thus no substantial qualitative disagreement about the infection fatality rate reported by the CDC and other sources in the scientific literature. This should come as no surprise since they all rely on seroprevalence studies to estimate infection fatality rates.

16. It is helpful to provide some context for how large the mortality risk is posed by COVID infection relative to the risk posed by other

<sup>&</sup>lt;sup>7</sup> Fiona P. Havers, et al., Seroprevalence of Antibodies to SARS-CoV-2 in 10 Sites in the United States, March 23-May 12, 2020 (Jul. 21, 2020) JAMA INTERN MED., <u>https://bit.ly/3goZUgy</u>.

<sup>&</sup>lt;sup>8</sup> COVID- 19 Pandemic Planning Scenarios, Centers for Disease Control and Prevention, <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html</u>.

infectious diseases. Since seroprevalence-based mortality estimates are not readily available for every disease, in the figure immediately below, I plot case fatality rates, defined as the number of deaths due to the disease divided by the number of identified or diagnosed cases of that disease. The case fatality rate for SARS-CoV-2 is ~2% (though that number has decreased with the availability of vaccines and effective treatments). By contrast, the case fatality rate for SARS is over five times higher than that, and for MERS, it is 16 times higher than that.



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17. Perhaps the most important implication of these estimates is that they identify two distinct populations of people who face a very different risk from COVID infection. One segment – the elderly and others with severe chronic disease – faces a higher risk of mortality if infected (especially if unvaccinated). A second segment – typically non-elderly people – face a very low risk of mortality if infected and instead face much greater harm from lockdowns, school closures, and other non-pharmaceutical interventions than from COVID

infection itself. The right strategy, then, is focused protection of the vulnerable population by prioritizing them for vaccination while lifting lockdowns and other restrictions on activities for the rest since they cause harm without corresponding benefit for the nonvulnerable. The Great Barrington Declaration, of which I am a primary co-author, describes an alternate policy of focused protection. This policy would lead to fewer COVID-related deaths and fewer non-COVID-related deaths than universal lockdowns or a strategy that lets the virus rip through the population. My coauthors of this Declaration include Prof. Martin Kulldorff of Harvard University and Prof. Sunetra Gupta of Oxford University. Over 15,000 epidemiologists and public health professionals and 50,000 medical professionals have co-signed the Declaration.<sup>9</sup>

18. The infection fatality rate estimates presented in this section are drawn from data before widespread vaccination in the U.S. and elsewhere. The COVID-19 vaccines approved for use in the U.S. are very effective in substantially reducing the infection fatality rate.

 $<sup>^9</sup>$ Bhattacharya J, Gupta S, Kulldorff M (2020) Great Barrington Declaration. https://gbdeclaration.org

According to the US Centers for Disease Control, the mRNA vaccines were 94% effective against COVID-19 hospitalization for patients 65 and older.<sup>10</sup> So, the infection fatality rates that I provide above are overestimated by at least one order of magnitude. Fully vaccinated, non-elderly professors in classrooms face a vanishingly small risk of mortality even if the SARS-CoV-2 virus infects them.

## II. <u>Natural Immunity Provides Durable Protection Against</u> <u>Reinfection and Against Severe Outcomes If Reinfected;</u> <u>COVID-19 Vaccines Provide Limited Protection Against</u> <u>Infection but Durable Protection Against Severe Outcomes</u> <u>if Infected.</u>

19. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There is no reason to presume that vaccine immunity provides a higher level of protection than natural immunity. Since vaccines arrived one year after the disease, there is stronger evidence for long-lasting immunity from natural infection than from the vaccines.

20. Both types of immunity are based on the same basic immunological

 <sup>&</sup>lt;sup>10</sup> Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years
 — United States, January–March 2021. MMWR Morb Mortal Wkly Rep 2021;70:674–679. DOI: http://dx.doi.org/10.15585/mmwr.mm7018e1external icon

mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibody levels in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.<sup>11,12</sup> A Phase III trial showed 85% efficacy for the Johnson & Johnson adenovirus-based vaccine against severe disease.<sup>13</sup>

21. Immunologists have identified many immunological mechanisms of

<sup>12</sup> Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W. Jr., Hammitt, L. L., Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine*, 387(27), 2603-2615. doi: 10.1056/NEJMoa2034577

<sup>13</sup> Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P. A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K. L., Robb, M. L., Treanor, J., Barouch, D. H., Stoddard, J., Ryser, M. F., Marovich, M. A., Douoguih, M. for the ENSEMBLE Study Group. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *The New England Journal of Medicine*, *384*(23), 2187-2201. doi: 10.1056/NEJMoa2101544

<sup>&</sup>lt;sup>11</sup> Baden, L. R., El Sahly, H. M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S. A., Rouphael, N., Creech, C. B., McGettigan, J., Khetan, S., Segall, N., Solis, J., Brosz, A., Fierro, C., Schwartz, H., Neuzil, K., Corey, L., Zaks, T. for the COVE Study Group (2021). Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine*, *384*(5), 403-416. doi: 10.1056/NEJMoa2035389

immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells,<sup>14</sup> bone marrow plasma cells,<sup>15</sup> spike-specific neutralizing

<sup>15</sup> Turner, J. S., Kim, W., Kalaidina, E., Goss, C. W., Rauseo, A. M., Schmitz, A. J., Hansen, L., Haile, A., Klebert, M. K., Pusic, I., O'Halloran, J. A., Presti, R. M. & Ellebedy, A. H. (2021). SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. *Nature*, *595*(7867), 421-425. doi: 10.1038/s41586-021-03647-4 (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Callaway, E. (2021, May 26). Had COVID? You'll probably make antibodies for a lifetime. *Nature*. https://www.nature.com/articles/d41586-021-01442-

9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID %2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

<sup>&</sup>lt;sup>14</sup> Dan, J. M., Mateus, J., Kato, Y., Hastie, K. M., Yu, E. D., Faliti, C. E., Grifoni, A., Ramirez, S. I., Haupt, S., Frazier, A., Nakao, C., Rayaprolu, V., Rawlings, S. A., Peters, B., Krammer, F., Simon, V., Saphire, E. O., Smith, D. M., Weiskopf, D., Crotty, S. (2021). Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science*, *371*, 1-13. doi: 10.1126/science.abf4063 (finding that memory T and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility in most individuals").

antibodies,<sup>16</sup> and IgG+ memory B cells<sup>17</sup> following naturally acquired immunity.

22. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies overwhelmingly conclude that natural immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

<sup>17</sup> Cohen, K. W., Linderman, S. L., Moodie, Z., Czartoski, J., Lai, L., Mantus, G., Norwood, C., Nyhoff, L. E., Edara, V. V., Floyd, K., De Rosa, S. C., Ahmed, H., Whaley, R., Patel, S. N., Prigmore, B., Lemos, M. P., Davis, C. W., Furth, S., O'Keefe, J., McElrath, M. J. (2021). Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *medRxiv*, Preprint. (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

<sup>&</sup>lt;sup>16</sup> Ripperger, T. J., Uhrlaub, J. E., Watanabe, M., Wong, R., Castaneda, Y., Pizzato, H. A., Thompson, M. R., Bradshaw, C., Weinkauf, C. C., Bime, C., Erickson, H. L., Knox, K., Bixby, B., Parthasarathy, S., Chaudhary, S., Natt, B., Cristan, E., El Aini, T., Rischard, F., Bhattacharya, D. (2020). Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humor immunity. *Immunity*, *53*(5), 925-933. doi: 10.1016/j.immuni.2020.10.004 (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

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23. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19<sup>18</sup> and show that the vast majority

<sup>18</sup> Shrestha, N. K., Burke, P. C., Nowacki, A. S., Terpeluk, P. & Gordon, S. M. (2021). Necessity of COVID-19 vaccination in previously infected individuals. medRxiv, Preprint. doi: 10.1101/2021.06.01.21258176 ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study" and concluded that hose with natural immunity are "unlikely to benefit from COVID-19 vaccination"); Perez, G., Banon, T., Gazit, S., Moshe, S. B., Wortsman, J., Grupel, D., Peretz, A., Tov, A. B., Chodick, G., Mizrahi-Reuveni, M., & Patalon, T. (2021). A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: A preliminary report. *medRxiv*, Preprint. doi: 10.1101/2021.03.06.21253051 (Israeli study finding that approximately 1/1000 of participants were reinfected); Bertollini, R., Chemaitelly, H., Yassine, H. M., Al-Thani, M. H., Al-Khal, A., & Abu-Raddad, L. J. (2021). Associations of vaccination and of prior infection with positive PCR test results for SARS-CoV-2 in airline passengers arriving in Qatar. JAMA, 326(2), 185-188. doi: 10.1001/jama.2021.9970 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Pilz, S., Chakeri, A., Ioannidis, J. P. A., Richter, L., Theiler-Schwetz, V., Trummer, C., Krause, R., Allerberger, F. (2021). SARS-CoV-2 re-infection risk in Austria. European Journal of Clinical Investigation, 51(4), 1-7. doi: 10.1111/eci.13520 (previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Breathnach, A. S., Duncan, C. J. A., El Bouzidi, K., Hanrath, A. T., Payne, B. A. I., Randell, P. A., Habibi, M. S., Riley, P. A., Planche, T. D., Busby, J. S., Sudhanva, M., Pallett, S. J. C. & Kelleher, W. P. (2021). Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies. The Journal of Infection, 83(2), 237-279. doi: 10.1016/j.jinf.2021.05.024 (0.86% of previously infected population in London became reinfected); Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total CD4<sup>+</sup> and CD8<sup>+</sup> T cell reactivity in infected or vaccinated individuals, Cell Reports Medicine 2(7), 100355 (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of

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of reinfections are less severe than first-time infections.<sup>19</sup> For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided equivalent if not better protection than vaccine immunity in preventing COVID-19 infection, morbidity, and mortality.<sup>20</sup> Of the 187,549 unvaccinated

<sup>20</sup> Goldberg, Y., Mandel, M., Woodbridge, Y., Fluss, R., Novikov, I., Yaari, R., Ziv, A., Freedman, L., & Huppert, A. (2021). Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2.vaccine protection: A three-month

both recovered COVID patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

<sup>&</sup>lt;sup>19</sup> Abu-Raddad, L. J., Chemaitelly, H., Coyle, P., Malek, J. A., Ahmed, A. A., Mohamoud, Y. A., Younuskunju, S., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Butt, A. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Yassine, H. M., Al Kuwari, M. G., Al Romaihi, H. E., Al-Thani, M. H., Al Khal, A., Bertollini, R. (2021). SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. *EClinicalMedicine*, 35, 1-12. doi: 10.1016/j.eclinm.2021.100861 (finding that of 129) reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Hall, V. J., Foulkes, S., Charlett, A., Atti, A., Monk, E. J. M., Simmons, R., Wellington, E., Cole, M. J., Saei, A., Oguti, B., Munro, K., Wallace, S., Kirwan, P. D., Shroti, M., Vusirikala, A., Rokadiya, S., Kall, M., Zambon, M., Ramsay, M., Hopkins, S. (2021). SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study. *The Lancet*, 397(10283), 1459-1469. doi: 10.1016/S0140-6736(21)00675-9 (finding "a 93% lower risk of COVID-19 symptomatic infection... [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Hanrath, A. T., Payne, B., A., I., & Duncan, C. J. A. (2021). Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection. The Journal of Infection, 82(4), e29-e30. doi: 10.1016/j.jinf.2020.12.023 (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age. Another study, analyzing data from Italy found that only 0.31% of COVID-recovered patients experienced a reinfection within a year after the initial infection.<sup>21</sup>

24.Variants do not escape the immunity provided by prior infection with the pre-variant virus or vaccination.<sup>22, 23, 24</sup> This is true of the

nationwide experience from Israel. *medRxiv*, Preprint. doi: 10.1101/2021.04.20.21255670

<sup>22</sup> Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total CD4<sup>+</sup> and CD8<sup>+</sup> T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2*, 100355.

<sup>23</sup> Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B.
E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K.
S., Seder, R. A. & Edwards, D. K. (2021). mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. *bioRxiv*, Preprint. doi: 10.1101/2021.01.25.427948

<sup>24</sup> Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T. C. & Tobian, A. A. (2021). CD8<sup>+</sup> T-cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants. *Open Forum Infectious Diseases 8*(7), ofab143.

<sup>&</sup>lt;sup>21</sup> Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

delta variant as well. In a study of a large population of patients in Israel, *vaccinated* people who had not been previously infected were 13 times higher odds of experiencing a breakthrough infection with the Delta variant than patients who had recovered from COVID but were never vaccinated.<sup>25</sup> They had 27 times higher odds of experiencing subsequent symptomatic COVID disease and 7 times higher odds of hospitalization. The design of this Israeli study was particularly strong – it tracked large cohorts of people over time from the time of vaccination or initial infection, and thus carefully distinguished the effect of time since initial exposure or vaccination in estimating its effect estimates. This is important because both vaccine-mediated and infection-mediated protection against subsequent infection diminish with time.

25.In summary, the overwhelming conclusion of the pertinent scientific literature is that natural immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

<sup>&</sup>lt;sup>25</sup> Gazit, S., Shlezinger, R., Perez, G., Lotan, R., Peretz, A., Ben-Tov, A., Cohen, D., Muhsen, K., Chodick, G. & Patalon, T. (2021). Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections. *medRxiv*, Preprint. doi: 10.1101/2021.08.24.21262415

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- 26. Furthermore, based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting. A survey article published on June 30, 2021, in the British Medical Journal concluded, "[t]here is reason to think that immunity could last for several months or a couple of years, at least, given what we know about other viruses and what we have seen so far in terms of antibodies in patients with COVID-19 and in people who have been vaccinated."26
- 27. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 (the virus that causes SARS) and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells 17 years after infection during the 2003 epidemic.<sup>27</sup> A Nature paper from 2008

<sup>&</sup>lt;sup>26</sup> Baraniuk, C. (2021). How long does covid-19 immunity last? *The British* Medical Journal, 373, 1-3. doi: 10.1136/bmj.n1605.

<sup>&</sup>lt;sup>27</sup> Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. Nature, 584, 457-462. doi: 10.1038/s41586-020-2550-z

found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.<sup>28</sup>

- 28. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, the researchers argue that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.<sup>29</sup>
- 29.A recent study from Qatar by Chemaitelly and colleagues, which tracked 927,321 individuals for six months after vaccination concluded that the Pfizer vaccine's "induced protection against infection appears to wane rapidly after its peak right after the

<sup>&</sup>lt;sup>28</sup> Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, 455, 532-536. doi: 10.1038/nature07231

<sup>&</sup>lt;sup>29</sup> Ledford, H. (2021). Six months of COVID vaccines: What 1.7 billion doses have taught scientists. *Nature*, *594*(7862), 164-167. doi: 10.1038/d41586-021-01505-x (study notes that "Six months is not much time to collect data on how durable vaccine responses will be. . . . In the meantime some researchers are looking to natural immunity as a guide.").

second dose, but it persists at a robust level against hospitalization and death for at least six months following the second dose."<sup>30</sup>

30. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine mediated protection against infection peaks at 72.1% zero to four weeks after the second dose, and then declines to 0%, 20 weeks after the second dose. According to this result, vaccines only protect against infection (and therefore disease spread) for a short period of time after the second dose of the mRNA vaccines.



<sup>&</sup>lt;sup>30</sup> Chemaitelly, H., Tang, P., Hasan, M. R., Al Mukdad, S., Yassine, H. M., Benslimane, F. M., Khatib, H. A. A., Coyle, P., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Kuwari, M. G. A., Romaihi, H. E. A., Abu-Raddad, L. J. (2021). Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar. *medRxiv*, Preprint. doi: 10.1101/2021.08.25.21262584

31. On the other hand, Panel B shows that protection versus severe

disease is long lasting after vaccination—even though the person



longer be fully protected against infection and, presumably, disease spread. At 20-24 weeks after the second dose, the vaccine remains 95.3% efficacious versus severe disease. While it appears to dip after 25 weeks to 71.5% efficacy, the confidence interval is so wide that it is consistent with no decrease whatsoever even after 25 weeks.



versus SARS-CoV-2 *infections*.<sup>31</sup> Though the drop in effectiveness is

<sup>&</sup>lt;sup>31</sup> Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, Frankland TB, Ogun OA, Zamparo JM, Gray S, Valluri SR, Pan K, Angulo FJ, Jodar L, McLaughlin JM. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *Lancet*. 2021 Oct 16;398(10309):1407-1416. doi: 10.1016/S0140-6736(21)02183-8. Epub 2021 Oct 4. PMID: 34619098; PMCID: PMC8489881.

not as steep as in the Qatari study, there is nevertheless a sharp drop. While in the first month, vaccine effectiveness is near 90% for all age-groups, by month 5, it drops to nearly 50% for all the groups. By contrast, **Panel B** plots vaccine efficacy versus *hospitalizations*. It remains high with no decline over time –near 90% throughout the period. The vaccine provides durable private protection versus severe disease, but declining protection versus infection (and hence transmission).

33. Another recent study tracked 620,000 vaccinated U.S. veterans to measure breakthrough infections for the three vaccines in common



use in the U.S.<sup>32</sup> Like the other studies, the authors of the study found a sharp decline in vaccine effectiveness versus infection. Five months after vaccination, the effectiveness of the J&J vaccine dropped from ~90% to less than 10%; the Pfizer vaccine dropped from ~90% to ~50%; and the Moderna dropped from ~90% to ~65%. The figure on this page tracks the decline in effectiveness of the vaccines against infection over time documented in this study. This study corroborates yet another study that documented declining vaccine efficacy in the first three months after vaccination against disease transmission in the era of the Delta variant.<sup>33</sup>

34.Yet another study conducted in Wisconsin confirmed that vaccinated individuals can shed infectious SARS-CoV-2 viral particles.<sup>34</sup> The authors analyzed nasopharyngeal samples to check

<sup>&</sup>lt;sup>32</sup> Cohn BA, Cirillo PM, Murphy CC, et al. Breakthrough SARS-CoV-2 Infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. medRxiv. October 14, 2021. https://doi.org/10.1101/2021.10.13.21264966;

<sup>&</sup>lt;sup>33</sup> Eyre, D. W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K. B., Walker, A. S. & Peto, T. E. A. (2021). The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *medRxiv*, Preprint. doi: 10.1101/2021.09.28.21264260

<sup>&</sup>lt;sup>34</sup> Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Halfmann, P. J., Segaloff, H. E., Kocharian, A., Florek, K. R., Westergaard, R., Bateman, A., Jeppson, G. E., Kawaoka, Y., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Shedding of infectious SARS-CoV-2 despite vaccination. *medRxiv*, Preprint. doi: 10.1101/2021.07.31.21261387

whether patients showed evidence of infectious viral particles. They found that vaccinated individuals were at least as likely as unvaccinated individuals to be shedding live virus. They concluded:

Combined with other studies these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons.

35.A recent study in the U.K. during its wave of delta COVID cases compared the likelihood of a vaccinated individual passing on the disease to someone within their same household relative to unvaccinated patients.<sup>35</sup> This study tracked these groups of patients over time to the point they tested positive for COVID. At that point, study investigators measured levels of the SARS-CoV-2 virus in the patients, and observed whether the patients passed on the disease to other household members. The authors find that while vaccination does reduce the fraction of time that a patient passes the disease on to household members from 38% [95%

<sup>&</sup>lt;sup>35</sup> Singanayagam A, Hakki S, Dunning J, et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study [published online ahead of print, 2021 Oct 29]. Lancet Infect Dis. 2021;doi:10.1016/S1473-3099(21)00648-4

confidence interval: 24-53] to 25% [95% confidence interval: 18-33], there was no statistically significant difference (p=0.17). They conclude:

Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts.

36. The CDC recognizes the importance of natural immunity in its updated science brief analyzing the difference in immunity from infection-induced and vaccine-induced immunity.<sup>36</sup> The CDC noted that "confirmed SARS-CoV-2 infection decreased risk of subsequent infection by 80–93% for at least 6–9 months," with some studies showing "slightly higher protective effects (89-93%)." It also noted that "researchers have predicted that the immune response following infection would continue to provide at least 50% protection against reinfection for 1–2 years following initial infection with SARS-CoV-2 or vaccination. This would be similar to

<sup>&</sup>lt;sup>36</sup> CDC, Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity (updated Oct. 29, 2021), https://www.cdc.gov/coronavirus/2019ncov/science/science-briefs/vaccine-induced-immunity.html#anchor\_1635539757101

what is observed with seasonal coronaviruses."

37. The CDC science brief does claim that vaccine-induced immunity is stronger than immunity from natural infection.<sup>37</sup> This study the CDC relies on to support this claim is not determinative for several reasons.<sup>38</sup> First, its result is contrary to the weight of other evidence, as set forth above. Second, the study compared hospitalization of those infected—and had natural immunity—90-225 days after their infection while against those who had completed their RNA vaccine regime 45-213 days before reinfection. Because immunity—regardless of how gained—wanes over time, the failure to adequately compare like periods means that the study's conclusions are biased in favor of vaccine-induced immunity. Indeed, the study admits this weakness. Third, the study design itself does not permit it to address the critical question of interest - whether COVID-recovery without vaccination or vaccination without COVID-recovery provides stronger protection

 $<sup>^{37}</sup>$  Id.

<sup>&</sup>lt;sup>38</sup> Bozio CH, Grannis SJ, Naleway AL, et al. Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January– September 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021.

against COVID-related hospitalization. The study analyzes only patients who are already in the hospital. To obtain an accurate answer to the question of interest, it would need to include and analyze patients before entering the hospital. As it is, the study implicitly and incorrectly assumes that the set of hospitalized patients with COVID-like symptoms is representative of the population at large, which is untrue.

- 38. In summary, the evidence to date strongly suggests that while vaccines—like natural immunity—protect against severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread. In short, there is no medical or scientific reason to believe that vaccine immunity will prove longer-lasting immunity than natural immunity, much less more durable immunity.
- III. <u>The CDC's Recommendation for Vaccination of Recovered</u> <u>COVID Patients Applies with Equal Force to Those Who</u> <u>Have Been Previously Vaccinated, Whose Protection</u> <u>Against Infection Wanes Within a Few Months After</u> <u>Vaccination.</u>

39. The CDC, in the Frequently Asked Questions (FAQ) section of its website encouraging vaccination, provides the following advice to previously recovered patients:39

Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

40. The text of this advice by the CDC does not address any of the scientific evidence included here about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that I do not know how long natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will last for years.<sup>40</sup> Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID-recovered patients from vaccination mandates, since the same can be said about vaccine mediated immunity. I do not know

<sup>&</sup>lt;sup>39</sup> Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2019 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

<sup>&</sup>lt;sup>40</sup> Patel, N. V. (2021, January 6). *Covid-19 immunity likely lasts for years*. MIT Technology Review.https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/

how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

- 41. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine breakthrough infections itself recognizes.<sup>41</sup> On the same CDC FAQ webpage I cite above,<sup>42</sup> the CDC writes about vaccine-mediated immunity, "We don't know how long protection lasts for those who are vaccinated."
- 42. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who *already* has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the

<sup>&</sup>lt;sup>41</sup> CDC COVID-19 Vaccine Breakthrough Case Investigations Team. (2021). COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. *Morbidity and Mortality Weekly Report* (*MMWR*), 70(21), 792-793. doi: <u>http://dx.doi.org/10.15585/mmwr.mm7021e3</u>

<sup>&</sup>lt;sup>42</sup> Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

CDC's statement in the FAQ is irrelevant. Here again, the possibility of reinfection does not alter the conclusion that, especially for those who have already recovered from COVID, accommodations can be allowed without threatening public safety.

### IV. OHSA's analysis of the Protection Provided by COVID-Recovery is Flawed

43.OSHA's analysis<sup>43</sup> of the effectiveness of COVID-recovery in providing protection versus future infection is deeply flawed. At the outset, I should note that the United States government is an outlier relative to other developed countries in its refusal to recognize the efficacy of natural immunity. For instance, the Netherlands recently extended the duration of its "natural immunity certificate," which can be used in lieu of a vaccine passport from 180 days to 365 days.<sup>44</sup> A similar exemption was

<sup>&</sup>lt;sup>43</sup> OSHA. COVID-19 Vaccination and Testing: Emergency Temporary Standard. Federal Register. Vol. 86 No. 212. Nov. 5, 2021. Rules and Regulations.

<sup>&</sup>lt;sup>44</sup> Block J. Vaccinating people who have had covid-19: why doesn't natural immunity count in the US? BMJ. 2021 Sep 13;374:n2101. doi: 10.1136/bmj.n2101. Erratum in: BMJ. 2021 Sep 15;374:n2272. PMID: 34518194.
made for natural immunity in vaccine passports in the U.K. when the country required them.<sup>45</sup>

44.OSHA's analysis rests on three arguments. First, OSHA asserts that immunogenicity depends on the severity of the initial COVID infection. They imply that people who experienced more severe COVID symptoms are more likely to be protected versus subsequent COVID reinfection than someone who experienced milder symptoms initially. However, the evidence that OSHA cites does not match the strength of the assertion. With the exception of the Cavanaugh et al. study, every other study that OSHA cites measures immunogenicity by reference to specific antibody levels. However, as I have described in Section II of this report, the protection provided by COVID-recovery includes immunological mechanisms, including cellular immunity that cannot be measured by antibody titers. So the studies cited to support OSHA's first argument do not address their point.

 $<sup>^{45}</sup>$  Diver T. Vaccine passports will show 'natural immunity' for people who have had Covid. MSN News. June 6, 2021.

45. The Cavanaugh et al. study is the exception in that it does not just measure antibody levels.<sup>46</sup> This study analyzes data from a sample of patients in Kentucky. The primary finding is that the odds of subsequent COVID infection for COVID-recovered patients who are not vaccinated are 2.3 times higher than COVID recovered patients who are vaccinated. The problem with this paper is that it does not provide an absolute risk reduction estimate from the vaccination of COVID recovered patients. However, we can estimate an upper bound on this number. While an odds ratio of 2.3 may appear large, recall the Vitale et al., referenced above, which measured the reinfection rate for the COVID recovered to be 0.3% at one year.<sup>47</sup> So the absolute reduction in COVID infection risk is negligible at one year - certainly less than 0.3%.

<sup>&</sup>lt;sup>46</sup> Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May– June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1081-1083. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7032e1</u>

<sup>&</sup>lt;sup>47</sup> Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

46. Furthermore, OSHA's argument implicitly assumes that there is no heterogeneity in the level of protection provided by vaccination; that is, vaccination may provide more complete protection for some patients than it does for others. That assumption is incorrect. For instance, Collier et al. document that antibody levels and other markers of immunogenicity are lower for older people after vaccination than for younger people.<sup>48</sup> Another article reports diminished immunogenicity in dialysis patients.<sup>49</sup> Yet another reported "small but significant" reduction in immunogenicity of the vaccines versus different variants.<sup>50</sup> Finally, some papers find

<sup>&</sup>lt;sup>48</sup> Collier DA, Ferreira IATM, Kotagiri P, Datir RP, Lim EY, Touizer E, Meng B, Abdullahi A; CITIID-NIHR BioResource COVID-19 Collaboration, Elmer A, Kingston N, Graves B, Le Gresley E, Caputo D, Bergamaschi L, Smith KGC, Bradley JR, Ceron-Gutierrez L, Cortes-Acevedo P, Barcenas-Morales G, Linterman MA, McCoy LE, Davis C, Thomson E, Lyons PA, McKinney E, Doffinger R, Wills M, Gupta RK. Age-related immune response heterogeneity to SARS-CoV-2 vaccine BNT162b2. Nature. 2021 Aug;596(7872):417-422. doi: 10.1038/s41586-021-03739-1. Epub 2021 Jun 30. PMID: 34192737; PMCID: PMC8373615.

<sup>&</sup>lt;sup>49</sup> Strengert M, Becker M, Ramos GM, Dulovic A, Gruber J, Juengling J, Lürken K, Beigel A, Wrenger E, Lonnemann G, Cossmann A, Stankov MV, Dopfer-Jablonka A, Kaiser PD, Traenkle B, Rothbauer U, Krause G, Schneiderhan-Marra N, Behrens GMN. Cellular and humoral immunogenicity of a SARS-CoV-2 mRNA vaccine in patients on haemodialysis. EBioMedicine. 2021 Aug;70:103524. doi: 10.1016/j.ebiom.2021.103524. Epub 2021 Aug 12. PMID: 34391096; PMCID: PMC8357427.

<sup>&</sup>lt;sup>50</sup> Wang Z, Schmidt F, Weisblum Y, Muecksch F, Barnes CO, Finkin S, Schaefer-Babajew D, Cipolla M, Gaebler C, Lieberman JA, Oliveira TY, Yang Z, Abernathy ME, Huey-Tubman KE, Hurley A, Turroja M, West KA, Gordon K, Millard KG, Ramos V, Da Silva J, Xu J, Colbert RA, Patel R, Dizon J, Unson-O'Brien C,

variation in the immune response to vaccination between patients with and without natural immunity due to COVID recovery.<sup>51</sup> So OSHA's argument about the heterogeneous immunological response to COVID-recovery applies with equal force to vaccinated patients.

47. Second, OSHA argues that the studies measuring reinfection rates after COVID recovery are all flawed because of bias in who is selected for testing. They assert that people who are mildly ill are less likely to be tested and hence those studies underestimate the reinfection rate for the unvaccinated, COVID-recovered. The problem with this argument is that the same cohort study designs that provide the best evidence on vaccine efficacy over time (several of which I cite above) also depend on self-selected PCR testing to identify breakthrough cases. If this bias affects the studies of

Shimeliovich I, Gazumyan A, Caskey M, Bjorkman PJ, Casellas R, Hatziioannou T, Bieniasz PD, Nussenzweig MC. mRNA vaccine-elicited antibodies to SARS-CoV-2 and circulating variants. Nature. 2021 Apr;592(7855):616-622. doi: 10.1038/s41586-021-03324-6. Epub 2021 Feb 10. PMID: 33567448; PMCID: PMC8503938.

<sup>&</sup>lt;sup>51</sup> Tejedor Vaquero S, de Campos-Mata L, Ramada JM, Díaz P, Navarro-Barriuso J, Ribas-Llaurado C, Rodrigo Melero N, Carolis C, Cerutti A, Gimeno R, Magri G. The mRNA-1273 Vaccine Induces Cross-Variant Antibody Responses to SARS-CoV-2 With Distinct Profiles in Individuals With or Without Pre-Existing Immunity. Front Immunol. 2021 Sep 3;12:737083. doi: 10.3389/fimmu.2021.737083. PMID: 34539673; PMCID: PMC8446508.

natural immunity, it equally affects the studies on vaccine efficacy. At the same time, there is no reason to believe that the bias necessarily produces a tilt toward identifying patients with severe disease. Many localities worldwide have implemented mass testing programs of asymptomatic populations and contact tracing of asymptomatic individuals. Given the existence of these programs, these studies may be prone to selectively identify and include less severely ill individuals in their samples.

48. Finally, OSHA argues that there is no standardized testing protocol available to determine whether individual patients meet an (unspecified) confidence threshold that they are fully protected versus COVID infection. OSHA dismisses both antibody testing and a PCR-verified case as too error-prone to rely upon to establish natural immunity. Again, the problem with this argument is that it could be applied with equal force to the vaccinated population, who are also at risk of becoming infected and transmitting the disease. Vaccinated individuals have declining antibody levels over time and can become infected; if there is no testing protocol available for finding whether a COVID-recovered individual is protected versus reinfection, there is also no testing protocol available for finding whether a vaccinated individual is protected version a breakthrough infection. In both cases, we can rely on a past event (either COVID recovery or vaccination) to determine whether a person is relatively protected versus reinfection, with no certainty possible if OSHA's assertions about the lack of a standardized testing protocol is correct.

#### V. <u>Conclusion</u>

- 49. Based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable (or more) as that acquired through vaccination. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date.
- 50. Based on my analysis of the existing medical and scientific literature, any policy regarding vaccination that does not recognize natural immunity is irrational, arbitrary, and counterproductive to

community health.<sup>52</sup> This is certainly true of the OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard, which does not provide for an exemption for naturally immune individuals from its vaccination, testing, and masking mandates.

51. Indeed, now that every American adult, teenager, and child five and above has free access to the vaccines, the case for a vaccine mandate is weaker than it once was. Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero. At the same time, natural immunity provides benefits that are at least as strong and may well be stronger than those from vaccines.

<sup>52</sup> Bhattacharya, J., Gupta, S. & Kulldorff, M. (2021, June 4). *The beauty of vaccines and natural immunity*. Smerconish Newsletter. https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct.

Executed this 6th day of December, 2021, at Stanford, California.

Respectfully submitted,

DocuSigned by: 08C5AAE4B4174D0..

Jay Bhattacharya, MD, Ph.D. Professor of Health Policy Stanford University

## EXHIBIT "2"

Lead Case No. 21-7000 (Member Case No. 21-4027/4028/4031/4032/4033/4080/4082/4083/ 4084/4085/4086/4087/4088/4080/4090/4091/4092/4093/4094/4095/4096/ 4097/4099/4100/4101/4102/4103/4108/4112/4114/4115/4117)

#### IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

#### IN RE: OSHA RULE ON COVID-19 VACCINATION AND TESTING, 86 FED. REG. 61402

On Petitions for Review

### DECLARATION OF SEAN KAUFMAN IN SUPPORT OF PETITIONER BENTKEY SERVICES, LLC D/B/A THE DAILY WIRE'S OPPOSITION TO OSHA'S MOTION TO DISSOLVE STAY (ECF # 69)

#### DECLARATION OF SEAN KAUFMAN

I, Sean Kaufman, declare:

I have served as a public health professional for over 25-years. 1. I have a master's degree in Public Health (MPH), am Certified in Public Health (CPH) by the National Board of Public Health Examiners and am a Certified Professional in Biological Risk Management (IFBA CP BRM) from the International Federation of Biosafety Associations (IFBA). I am formally trained in health education, a specialty which translates scientific information for the public to understand, empowering individuals to make informed decisions for themselves and their families. During this time, I have served as a health education specialist specializing in infectious diseases and emergency response. My career in public health includes duties within the State of California, the Centers for Disease Control and Prevention (CDC), Emory University Rollins School of Public Health (RSPH), and presently at Safer Behaviors in Atlanta, Georgia. I make this declaration of personal, firsthand knowledge, and if called and sworn as a witness could and would testify competently thereto.

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2. My work in public health started during the HIV/AIDS epidemic, where I provided counseling for those who tested positive for HIV, managed HIV cases to an AIDS diagnosis, and worked with hospice in the attempt to reunite families which had been torn apart because of the stigma associated with HIV/AIDS. I transitioned to the Centers for Disease Control and Prevention (CDC) where I was awarded two Distinguish Service Awards from the Department of Health and Human Services for service to the postal employees in Trenton, New Jersey during the 2001 Anthrax Attacks and for serving the Los Angeles International Airport (LAX) quarantine office during the SARS epidemic in 2004.

3. I departed the CDC and accepted a director role at the RSPH where I taught several public health emergency preparedness and response courses. For a decade, I served as the Director of the Science and Safety Training Program which was funded by Dr. Anthony Fauci at the National Institute of Allergy and Infectious Diseases (NIAID). This program was responsible for training scientists from around the world to work safely in Biosafety Level-3 and Level-4 laboratory environments with dangerous infectious diseases. During my tenure at Emory

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University, I proudly served with the World Health Organization (WHO) in Mexico City, Mexico during the H1N1 pandemic. I also trained and managed the nurses and doctors who worked inside the Emory Healthcare Isolation Unit in 2014 who were responsible for treating the first two cases of Ebola in the United States of America. I then proudly served in Nigeria, Belgium, and Liberia throughout the remainder of the 2014 Ebola outbreak. I have tremendous pride in how I have served the profession of public health.

4. Following the Ebola outbreak, my small business focused its efforts on safer behaviors around infectious diseases. Since 2011, we have served scientists and public health professionals at the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the US Department of Agriculture (USDA).

5. In February of 2020, I published a book with the American Society of Microbiology (ASM) Press and Wiley titled *Prepare and* 

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Protect: Safer Behaviors in Laboratories and Clinical Containment Settings<sup>1</sup>.

6. I am recognized internationally as a leading global expert in behavior with and around infectious diseases.

## COVID-19 does not pose a grave danger to the United States Workforce.

7. Introduction. SARS-CoV-2 is the virus that causes the disease called 'COVID-19.' From a virology standpoint it is not new and from a virological point of view shares a similar identity to Severe Acute Respiratory Distress Syndrome Coronavirus from 2002 (SARS-CoV-1).<sup>2</sup> Scientists have been working with this coronavirus and many others including Middle East respiratory syndrome (MERS-CoV).

8. Coronaviruses are the cause of about 30% of 'common colds' each year, and most Americans have strong immunity against coronaviruses. SARS-CoV-2 looks like and behaves like SARS-CoV-1 and that is why it was classified and named as such. SARS CoV-2 has a similar genetic structure, uses the same host cell receptor to begin the

<sup>&</sup>lt;sup>1</sup> <u>https://www.wiley.com/en-</u> <u>us/Prepare+and+Protect%3A+Safer+Behaviors+in+Laboratories+and+Clinical+Con</u> <u>tainment+Settings-p-9781683670148</u>

<sup>&</sup>lt;sup>2</sup> https://www.frontiersin.org/articles/10.3389/fimmu.2020.552909/full

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infection cycle and causes the same types of symptoms and disease as SARS-CoV-1 in humans. SARS-CoV-2 has minor genetic modifications but is still remarkably similar to SARS-CoV-1.

9. As a single-stranded RNA virus, SARS-CoV-2 is a very unstable virus making infection of and replication in humans no easy task. Research scientists have studied SARS-CoV-1 for the last 17+ years. We can use what we have learned from the many years of indepth research on SARS-CoV-1 and apply it to SARS-CoV-2.

10. The premise of the OSHA ETS Vaccine Mandate for the US workforce is that COVID-19 presents a grave danger to only unvaccinated workers in the US. Specific to infectious diseases, grave danger is a risk that is more than significant when compared to existing risks within the same environment.

11. However, Dr. Anthony Fauci himself stated that influenza is a bigger risk in the US than coronavirus<sup>3</sup>. In an article that Dr. Fauci authored himself specific to the COVID-19 pandemic, he states "This suggests that the overall clinical consequences of COVID-19 may

<sup>&</sup>lt;sup>3</sup> <u>https://www.mynews13.com/fl/orlando/news/2020/02/15/disease-expert--flu-a-bigger-risk-in-the-us-than-coronavirus</u>

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ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively."<sup>4</sup> This does not minimize the serious threat COVID-19 continues to pose to the most vulnerable within our population.

12. The OSHA ETS Vaccine Mandate claims, "Further, unvaccinated workers are much more likely to contract and transmit COVID-19 in the workplace than vaccinated workers."

13. This is a gross misrepresentation of science, natural immunity and personal health characteristics (e.g., age, health status, current medications, social behaviors, etc.) which contribute to the contracting and transmission of disease.

> a. Those who have received the vaccine are not only capable of transmitting the virus but demonstrate the same amount of viral shedding as those who have not been vaccinated. In a recent study, scientists found no

<sup>&</sup>lt;sup>4</sup> <u>https://www.nejm.org/doi/full/10.1056/nejme2002387</u>

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significant differences in viral loads between the vaccinated and unvaccinated <sup>5</sup>.

- b. Both the 'vaccinated' and unvaccinated are equally capable of being infected and transmitting the virus. A study has shown that immunity after injection with COVID-19 'vaccines' wanes over a period of 3 to 10 weeks<sup>6</sup>.
- c. Since the COVID-19 'vaccination' only offers temporary short-term protection, as soon as immunity fades, the vaccinated themselves are also equally at risk of transmitting the disease and could experience more severe outcomes of the disease.
- d. COVID primarily affects people in older age groups (>65 years old), where the function of the immune system begins to decrease. This in addition with the development of chronic conditions like diabetes, cancer, heart and kidney diseases places them at higher risks

<sup>&</sup>lt;sup>5</sup> <u>https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1</u>

<sup>&</sup>lt;sup>6</sup> <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01642-</u> <u>1/fulltext</u>

for severe disease and deaths from not just COVID-19 but infectious disease threats.<sup>7</sup>

e. There are more than ninety studies showing that those that have had COVID infections have lasting and robust natural immunity to not only the original strain but also the variant strains of SARS-CoV-2<sup>8</sup>.

14. OSHA ETS states that "reported cases have increased to 44,857,861 and the number of deaths has increased to 723,205 (CDC, October 18, 2021– Cumulative US Cases; Cumulative US Deaths).

15. This statement is another gross misrepresentation of risk among those within the workplace.

a. As of November 3, 2021 - CDC reports that 75.4%
 (564,366) of the total deaths (748,164) occurred within those who were greater than 65 years old.<sup>9</sup>

<sup>&</sup>lt;sup>7</sup> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2265901/</u>

<sup>&</sup>lt;sup>8</sup> See Correlates of protection from SARS-CoV-2 infection. https://www.nature.com/articles/d41586-021-01442-9, and <u>https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-COVID-19-documented-linked-and-quoted/</u> <sup>9</sup> https://www.cdc.gov/nchs/covid19/mortality-overview.htm

- b. The CDC also states that only 5% of the deaths involving COVID-19 had COVID as the exclusive cause of death.<sup>10</sup>
- c. If we take into account the above CDC statements, we reduce 748,164 to 183,798 deaths by focusing solely on those who are of the working age of under 65.
- d. Furthermore, if only 5% of the deaths are attributed solely to COVID, the number is reduced even further to 9,189 deaths.
- e. These numbers are reported over a two-year period and have similar rates with an annual average death of approximately 4,600 (1% of the total number of deaths) workers who are under the age of 65 and whose death is attributed solely to COVID per year.

16. As demonstrated above, OSHA has misrepresented the overall risk of COVID-19 death to the US workforce. It should be noted that scientific and medical treatment advancement is allowing for earlier medical intervention, treatment with monoclonal antibodies, and

<sup>&</sup>lt;sup>10</sup> <u>https://www.cdc.gov/nchs/nvss/vsrr/COVID\_weekly/index.htm</u>

other repurposed drugs which is minimizing hospitalization and death associated with COVID-19 regardless of vaccine status.

17. OSHA has not demonstrated that a vaccinate mandate, weekly testing, and wearing of masks would adequately prevent deaths attributed to COVID-19 in workforce.

18. One problem with the OSHA vaccine mandate is that the definition of vaccine has changed several times over the last several years.

19. Prior to 2015, vaccinations were defined as "an injection of killed or weakened infectious organism in order to prevent disease."

20. In 2015, vaccinations were redefined as "the act of introducing a vaccine into the body to produce immunity to a specific disease".

21. This year, the CDC changed the definition of vaccination to, "the act of introducing a vaccine into the body to produce protection to a specific disease".<sup>11</sup>

<sup>&</sup>lt;sup>11</sup> <u>https://www.washingtonpost.com/politics/2021/09/09/vaccine-skeptics-claim-new-cdc-gotcha-moment-they-havent-got-much/</u>

22. The term vaccine was also updated from, "a product that stimulates a person's immune system to produce immunity to a specific disease" to "a preparation that is used to stimulate the body's immune response against diseases." These changes paint an accurate reflection of the COVID-19 vaccine.

23. Though the existing vaccine is "a preparation that is used to stimulate the body's immune response against" COVID-19 – the response is short-lived, does not prevent illness, or prevent transmission.

24. At one point in time, vaccines were viewed as a consumer product. In exchange for the risks one would accept as a result of vaccination, consumers were assured with the benefits gained as a result of the vaccine. At that time, vaccine assurances included evidence that the vaccine (1) was safe, (2) prevented disease, and (3) minimized the likelihood of transmission from one person to another.

25. Not only have the definitions of vaccine and vaccination changed, but the assurances of safety and effectiveness for the consumer have changed for the worse.

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# 26. Asymptomatic transmissions of COVID are too insignificant to warrant the vaccine mandate.

27. One concern discussed in the OSHA ETC is asymptomatic transmission in workplace.

28. However, researchers at Nature Communications<sup>12</sup> and the Journal of the American Medical Association (JAMA)<sup>13</sup> both found that asymptomatic transmissions of Coronavirus are less than one percent. The vaccine's main purpose is to prevent the spread of the disease to others, but that is already incredibly unlikely, not only due to natural herd immunity, but also because now, most people who have desired the vaccine have received it.

29. Low mortality of disease does not pose a grave danger to the workforce and therefore does not justify a vaccine mandate.

30. The particularly low mortality rate of the disease, but also its distribution by age, clearly denote that vaccination, whenever it becomes feasible, must be targeted.

<sup>&</sup>lt;sup>12</sup> <u>https://www.nature.com/articles/s41467-020-19802-w</u>)

<sup>&</sup>lt;sup>13</sup> <u>https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102</u>

31. This percentage is fictitiously over-evaluated for the time being (~2.5%): on the one hand, due to the over-representation of severely positive cases of the virus<sup>14</sup>, and on the other, given that the death toll from COVID has also included the deaths of cases found positive for COVID but with other, underlying diseases (not the SARS respiratory syndrome).

32. The Center for Disease Control (CDC) admits this, saying only 5% of deaths involving COVID-19 had COVID as the exclusive cause of death<sup>15</sup>.

33. Recent studies which have estimated the number of deaths in relation to the actual number of people exposed to the virus – based on serological tests (antibody tests) in a specific geographical area – have determined that this percentage is of the order of magnitude of seasonal flu (certainly <1%)<sup>16</sup>.

34. COVID affects people who are over the age of 65 and have one or more pre-existing medical conditions. The combination of age and these pre-existing conditions means the vaccine-induced active

<sup>&</sup>lt;sup>14</sup> <u>https://www.bmj.com/content/368/bmj.m1113.long</u>

<sup>&</sup>lt;sup>15</sup> <u>https://www.cdc.gov/nchs/nvss/vsrr/COVID\_weekly/index.htm</u>

<sup>&</sup>lt;sup>16</sup> <u>https://www.medrxiv.org/content/10.1101/2020.04.14.20062463v2</u>

immunity may not be capable of protecting the elderly, who are most vulnerable to the corona virus; hence, the finding of an anti-viral therapy should be a priority – assuming that the protection of the elderly is in fact what is desired. The healthy are affected very marginally, if not at all.

35. The nature of COVID-19 provides several opportunities to minimize severe disease and hospitalization as an alternative to the COVID-19 vaccination.

36. Most Americans are not at a meaningful risk for severe disease.

37. Statistically speaking, healthy adults under the age of forty are at  $\sim .0001\%$  risk for hospitalization or death from SARS-CoV-2.

38. We know what groups of people are at most risk for severe disease and complications after infection with SARS-CoV-2; the elderly, smokers, and those with MULTIPLE comorbid medical conditions (diabetes, hypertension, and obesity).

39. Given that the virus uses angiotensin-converting enzyme 2 (ACE2) to enter cells and initiate the infection cycle, levels of expression

of ACE2 are key for understanding those who would be at most risk of severe disease.

40. Knowing that the 'vaccines' are only meant to decrease the duration and severity of disease, it does not make sense to vaccinate every single person.

41. Genetics and demographic characteristics, lifestyle, comorbidities, and medication usage have an impact on ACE2 expression and activity in SARS-CoV-2 cellular infection. "It's expression level is high in Asian females and young people (Figure 1 and Table 1), those who are known to be less susceptible, and even less inflicted by severe or fatal outcome, while it is low in males, further decrease with age and T2D, those who are most susceptible to bad outcome (Figures 1 and 3), suggesting at a population level a negative correlation between ACE2 expression and COVID-19 severity and fatality"<sup>17</sup>.

42. The COVID-19 'vaccines' do not prevent infection with SARS-CoV-2, and they were never meant to prevent infection or transmission.

<sup>&</sup>lt;sup>17</sup> <u>https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/acel.13168</u>

43. The correlates of protection, the type of immune response needed to prevent infection with SARS-CoV-2, are still unknown. We do not know whether it is antibodies, what type of antibodies or what level is necessary to provide protection or whether cell-mediated immunity is an important measure of protection. There is also a significant difference between total antibodies and neutralizing antibodies. Neutralizing antibodies, antibodies that bind to the virus and prevent infection, cannot be measured with a point of care test.

44. In general, scientists study how infection programs the immune response after natural infection to inform the development of a vaccine that will mimic that same response.

45. A vaccine that provides sterilizing immunity prevents the vaccinated from being able to catch or transmit a virus.

46. The EUA COVID-19 'vaccines' were not designed to induce sterilizing immunity. They are merely a tool designed to teach the immune system to attack the spike protein, thereby priming the immune system to reduce the length and severity of infection.

47. Both CDC and Dr. Fauci have acknowledged this point and that is why they recommended that people should continue to follow

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because 'breakthrough' infections are expected.

48. There have been many reports of people having gotten 'vaccinated' and contracting COVID-19 not just in the United States but all over the world.

49. 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. As of May 1, 2021, CDC transitioned from publicly reporting the passive surveillance of all vaccine breakthrough cases on the website to focus on hospitalized or fatal vaccine breakthrough cases due to any cause.

50. As of September 13, 2021, 15,790 patients with COVID-19 'vaccine breakthrough' infections who have been hospitalized or died have been reported to the CDC from 49 U.S. states and territories. This supports the fact that the 'vaccines' are not preventing severe disease or hospitalizations.

51. Both the 'vaccinated' and unvaccinated are capable of being infected and transmitting the virus.<sup>18</sup>

 $<sup>^{18}\</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html$ 

52. A study has shown that immunity after injection with COVID-19 'vaccines' wanes over a period of 3 to 10 weeks<sup>19</sup>.

53. Because the Emergency Use Authorization (EUA) COVID-19 'vaccination' only offers temporary short-term protection, as soon as immunity fades, the vaccinated themselves may be at risk of more severe disease outcomes and/or unknown long-term side-effects.

54. Natural immunity is superior to COVID-19 vaccine in all studies indicating that there is no scientific rationale to vaccinating those already immune.

55. An issue that is being completely dismissed is natural immunity following a COVID-19 infection.

56. There are more than ninety studies showing that those that have had COVID infections have lasting and robust natural immunity to not only the original strain but also the variant strains of SARS-CoV-2<sup>20</sup>.

<sup>19</sup> <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01642-1/fulltext</u>

<sup>20</sup> See Correlates of protection from SARS-CoV-2 infection. https://www.nature.com/articles/d41586-021-01442-9, and <u>https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-COVID-19-documented-linked-and-quoted/</u> 57. A Cleveland Clinic study demonstrates that natural immunity acquired through prior infection with COVID-19 shows greater efficacy towards protection than any benefit conferred by the COVID vaccines<sup>21</sup>.

58. A study by Goldberg et al. noted that previously infected individuals had 96.4% efficacy towards protection from COVID, versus 94.4% in those injected with the vaccines.

59. These and other studies support that natural infection and the resulting antibodies generated provide better immunity towards COVID than any of the gene therapy vaccines currently utilized. One must ask themselves why natural immunity, which has been previously accepted for multiple other viral illnesses, is not being accepted for COVID despite clear data that shows its benefit far outweighs the vaccines.

60. Natural immunity to a virus is always more effective and longer lasting than a vaccine.

<sup>&</sup>lt;sup>21</sup> Shrestha, N., Burke, P., Nowacki, A., Terpeluk, P., Gordon, S. (2021), Necessity of COVID-19 Vaccination in Previously Infected Individuals. See <u>https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2</u>.

61. Active immunity (i.e., natural exposure and recovery) is always better and stronger than passive immunity (i.e., vaccines/gene therapies).

62. People who have a disease and recover will have broader and more robust immunity that is long-lasting. SARS-CoV-2 is no different in this regard.

63. Because SARS-CoV-2 is the same as SARS-CoV-1 we can use information from those who recovered from that virus in 2003 to inform us about lasting immunity.

64. A recent study showed that ".... patients (n = 23) who recovered from SARS (the disease associated with SARS-CoV-1 infection) possess long-lasting memory T cells that are reactive to the N-protein of SARS-CoV-1 17 years after the outbreak of SARS in 2003." "We also detected SARS-CoV-2-specific T cells in individuals with no history of SARS, COVID-19 or contact with individuals who had SARS and/or COVID-19 (n = 37)"<sup>22</sup>. What this tells us is that people who have had symptomatic COVID-19 will have lasting immunity after recovery. In addition, there are people who also have protection from infection

<sup>&</sup>lt;sup>22</sup> <u>https://www.nature.com/articles/s41586-020-2550-z</u>

with SARS-CoV-2 because they have been infected with other coronaviruses.

65. Research has shown that 90% of adults over the age of fifty have immunity to all four common human coronaviruses.

66. This cross protective immunity is why some people experience only mild symptoms upon exposure to SARS-CoV-2.

67. More studies are being published now showing that those who recovered from COVID-19 have more robust immunity than the immunity induced from the 'vaccines.'

68. Scientists have shown that immune memory to SARS-CoV-2 lasted up to at least 8 months after infection in 95% of those evaluated <sup>23</sup>. "This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity" <sup>24</sup>.

 $<sup>\</sup>frac{^{23} \text{ https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-COVID-19}{}$ 

<sup>&</sup>lt;sup>24</sup> <u>https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1</u>

69. <u>In my opinion, if someone has immunity from natural</u> <u>infection, under no circumstances would it make sense for them to get a</u> <u>vaccine</u>.

70. If natural immunity is strongly protective, as the evidence to date suggests it is, then vaccinating people who have had COVID-19 would seem to offer nothing or very little to benefit, logically leaving only harms—both the harms we already know about as well as those still unknown.<sup>25</sup>

71. The EUA COVID-19 vaccination strategy should be about mitigation of risk and protecting the most vulnerable, not about vaccinating the entire 'vaccine eligible' population of the US.

72. Even if 100% of the global population is vaccinated, SARS-CoV-2 will continue to spread.

73. Given the rate of transmission for the delta variant (R0=5), there is no way to stop it even with a 100% vaccination rate. The virus will continue to spread.

<sup>&</sup>lt;sup>25</sup> <u>https://www.bmj.com/content/374/bmj.n2101</u>

74. As with most viruses, as they interact more with a new host and mutate, they will invariably produce higher morbidity (make more people sick) but will have lower mortality (fewer people die).

75. "If a miraculous vaccine could be developed that could give us all 100% sterilizing immunity today. The length of time it takes to manufacture and ship eight billion doses (and then make vaccination appointments for eight billion people) ensures that by the time the last person gets their last dose, the never-ending conveyor belt of mutations will have already rendered the vaccine partially ineffective.

76. True sterilizing immunity simply will not ever happen with coronaviruses. It was 100% certain, from day one, that by the time the last dose is administered, the rapid evolution of the virus would ensure that it would already be time to start thinking about booster shots."<sup>26</sup>

#### OSHA has failed to prove that this ETS

#### is Necessary to Alleviate a Grave Risk of Worker Deaths

77. The OSHA COVID-19 Vaccination and Testing; Emergency Temporary Standard as published consists of 490 pages and utilizes 658

<sup>&</sup>lt;sup>26</sup> <u>https://www.juliusruechel.com/2021/09/the-snake-oil-salesmen-and-COVID-zero.html</u>

references (excluding the ETS itself.) After a thorough review of the 658 references, over 98% of the documents referenced are not related to COVID-19 workplace transmission.

78. Of the 15 references identified in the OSHA ETS that are relevant to workplace transmission, a closer look at these studies reveal that there are limitations to these studies that result in the fact that OSHA has failed to prove that this ETS is necessary to alleviate a grave risk of worker deaths:

a. Contreras et al, July 2021 is referenced in the ETS with the following statement. "A study of outbreaks in Los Angeles County found that the median number of employees in an establishment in which an outbreak occurred was 95, well above the 50 employee median for locations of employers covered by this rule, indicating that the rule will protect employees in the places where outbreaks are most likely to occur."
However, the author duly notes that the number of COVID-19 worksite outbreaks mirrored trends in community transmission. This limitation in the

study is evidence that workplace illness is an indicator of what is currently happening in the community.

- b. Gold et al., February 26, 2021 is referenced in the ETS concluding, "Approximately half of the schoolassociated cases involved two clusters that began with probable transmission between educators, followed by educator to student transmission." However, in the actual referenced paper, one of the limitations the author notes is "distinguishing in-school transmission from community transmission was challenging, particularly when the 7-day community incidence exceeded 150 cases per 100,000 persons and was increasing." The author states clearly that distinguishing in-school transmission from community transmission is a limitation of the conclusion being referenced in the ETS.
- c. Porter et al. (April 30, 2021) is used in the ETS to conclude, "that vaccination of these essential workers is important and requirements for COVID-19

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prevention were updated to include smaller quarantine groups, serial testing, and testing before transfers from one facility or vessel to another." The manner in which this reference is being used misrepresents the severe limitations noted by the author, "The findings in this report are subject to at least four limitations. First, case counts were based on surveillance data and might be subject to small discrepancies. Second, a comparison before and after implementation of the revised requirements was not possible because the initial set of required measures was issued early in the seafood processing season that took place during the summer months. Third, the lack of precise denominators restricted analysis of the overall rate of disease among seafood processing workers. Finally, quantifying the size of outbreaks was often challenging because testing strategies conducted after cases were identified

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### varied considerably among facilities, which likely affected case finding."

- d. Suhs et al., July 23, 2021 is referenced in the ETS and describes an outbreak associated with a fitness center where it is concluded that transmission occurred within the facility. However, the author notes several limitations with this conclusion including, "COVID-19 case interviews were voluntary and based on case recall; cases could choose not to respond to questions, such as fitness center attendance or close contacts." The sample size was >50, an assessment of secondary transmission was not conducted, and community infection rates were not considered at potential confounding causes of infections identified within the fitness center.
- e. Steinberg et al. (August 7, 2020) is referenced as concluding, "...that attack rates (i.e., the number of individuals who are infected in comparison to the total

number at risk) among production employees in the Cut (30.2%), Conversion (30.1%), and Harvest (29.4%) departments of a meat processing plant (where spacing between employees is less than 6 feet) were double that of salaried employees (14.8%) whose workstations had been modified to increase physical distancing from others." The author clearly states in the five limitations of this reference, "Finally, the location of virus acquisition (e.g., facility versus community) for individual employees could not be determined."

f. Ward et al. (June 2021) is referenced concluding,
"During that time period, COVID-19 cases in staff were
3 to 5 times higher compared to the U.S. population."
However, the authors acknowledges that,
"...worksite screenings may have prompted staff
to pursue higher rates of testing than the U.S.
population." This is a noted limitation by the author

because increased testing rates may also attribute to increased case rates within prison populations.

- **g.** Dougherty et al., July 16, 2021 is referenced as concluding that 47 people, including 3 of 11 staff members, 23 gymnasts, and 21 household contacts, contracted COVID-19 from an outbreak linked to an Oklahoma gymnastics facility." The author of the references fails to discuss community transmission rates, whether these individuals shared transportation, attended similar schools, or had contact outside the gymnastics facility. Additionally, the author concludes, "...vaccine effectiveness could not be calculated because of an inability to interview all persons associated with the outbreak and incomplete state immunization registry data."
- h. Kapoor et al., 2020 is referenced in the ETS and confirms that positive test rates in employees correlated with rates in New York State. As mentioned in previous limitations, disease acquisition and

transmission is more of a factor within the community than it is in the workplace. Furthermore, the author of this references concludes that vaccination is not needed to safely operate ambulatory care settings stating, "With stringent guidelines based on best available data in place as well as a robust strategy for testing and contact tracing—outpatient practices can remain open and safely provide care during this and future crises."

i. Hendrix et al., July 17, 2020 is referenced stating, "The study concluded that the strict use of face coverings likely mitigated the spread of COVID-19." However, the author notes the following limitation,
"Finally, the mode of interaction between stylist and client might have limited the potential for exposure to the virus. Services at salon A were limited to haircuts, facial hair trimmings, and perms. Most stylists cut hair while clients are

facing away from them, which might have also limited transmission." Limited services and policies could have been the contributing factor in minimizing disease transmission.

- j. Waltenburg et al. (January, 2021) is referenced in the ETS and concludes, "28,364 employees in those facilities were confirmed to have COVID-19 by laboratory testing and 132 died." However, the authors notes in the limitations section of reference, "Workers are members of their local communities; transmission of SARS-CoV-2 could have occurred both at the workplace and in the surrounding community and thus could be affected by levels of community transmission." There is no clear conclusion that transmission is occurring within the workplace.
- k. Miller et al. (April 30, 2021) is referenced in the ETS and discusses workplace transmission between farmers who were unable to practice social distancing. The

author notes in the limitation section the potential for bias specific to missing job role information, "missing job role information for some employees could bias the comparison of cumulative incidence and regression models." One cannot conclude transmission occurred as a result of spatial relations in the workplace if they do not have clear information about what and where an employee is working.

 Gunther T et al. (October 27, 2020) is listed as a reference but not used in the ETS. This reference discusses an outbreak investigation within a German Meat Processing Plant. In the limitations section, the author notes that employees share apartments and transportation. These behaviors indicate confounding factors as to where, how, and if transmission is occurring in the workplace.

- 79. The evidence of workplace transmission cited in the OSHA ETS is minimal, extremely weak, and loaded with confounding variables. In almost all cited references, the author notes limitations which would have a direct effect on the conclusions which are being used in the OSHA ETS to mandate vaccinations among the workforce. The ETS presents these references in a misleading and unethical manner in my professional opinion.
- 80. The attorneys for OSHA argue that delaying the ETS "would endanger many thousands of people and would likely cost many lives per day." However, in all 490 pages of this document, there is not one single mention of the Department of Health and Human Services Vaccine Adverse Event Reporting System. If this mandate is concerned with death, it should review the excessive death and injury this vaccine has caused in the United States and globally. These injuries are permanent and life ending among low risk populations within the workplace.

- 81. While the attorneys for OSHA contend in their motion that "there is extensive evidence of 'workplace transmission." It is my opinion that between the 490 pages of the OSHA ETS and over 600 references used, OSHA fails to provide statistically significant references attributing risk to specific workplace environments. In fact, on numerous references used by OSHA in the ETS – authors directly state that separating community and workplace transmission is a severe limitation.
- 82. While the attorneys for OSHA argue that the "reopening of workplaces" creates a "threat to workers" it is my opinion that the threat of infectious disease has been and will always be ongoing. The question is, will this threat "overwhelm"? Science has clearly identified that risk of severe disease falls primarily with the most vulnerable population and even among the most vulnerable population less than 1% succumb to this virus. The vaccine is only one of many strategies which can be used to fight this pandemic. Early intervention, mask wearing, social

distancing, identification and tracing have worked and will continue to work within the workplace. More and more people are recovering from this infection and acquiring natural immunity which exceeds the protection one gains from the COVID-19 vaccine.

83. While the attorneys for OSHA allege that workers "are being hospitalized with COVID-19 every day, and many are dying" this statement is not backed up by any citation to science. It is my opinion that a Majority of the hospitalizations and deaths are occurring among the most vulnerable populations and are no longer within the workforce. Death rates among the low-risk populations are equivalent to past influenza seasons.

### Conclusions

- 84. As discussed above:
  - a. Asymptomatic transmission represents less than one percent of all transmissions.<sup>9, 10</sup>
  - b. The CDC states that only 5% of the deaths involving
     COVID-19 had COVID as the exclusive cause of

death.<sup>13</sup> Additionally, CDC reports that 78% of those hospitalized for COVID suffered from obesity.

- c. Natural immunity is superior to the COVID-19 vaccine in all studies indicating no scientific rationale for vaccinating those already immune.
- 85. The OSHA Recommended Practices for Safety and Health Programs utilizes the Hierarchy of Controls<sup>27</sup>. This Hierarchy of Controls is designed by OSHA to protect workers from workplace hazards; help avoid illnesses, minimize or eliminate health risks, and help employers provide workers with healthful working conditions. There is no mention of vaccination within these controls.
- 86. The first control for creating a healthy work environment, which is noted as the most effective, is elimination of this risk. This can be accomplished by the sick worker staying at home and not leaving the house.
- 87. Though we cannot eliminate the risk of infectious disease in the workplace, we know that less than 1% of transmission

<sup>&</sup>lt;sup>27</sup> https://www.osha.gov/safety-management/hazard-prevention

is from asymptomatic cases. The development of policies which allow for staff to work remotely – substituting the need to be at work while sick (second control – substitution).

- 88. As noted in the influenza workplace transmission studies, "The "flu day" policy was even more effective: If one flu day was offered, workplace infections fell by an average of 25.33%; if two flu days were offered, infections dropped by 39.22%."<sup>28</sup>
- 89. The third control is engineering following by the fourth control of administration and final control of PPE.
- 90. Employers can drastically reduce transmissions of COVID-19 within the workplace by offering paid sick days and screening employees for COVID-19 symptoms, social distancing, masks, and proper ventilation of workplace sites.<sup>29</sup>
- 91. Risks of COVID-19 disease transmission within the workplace can be easily controlled through paid leave,

<sup>&</sup>lt;sup>28</sup> <u>https://journalistsresource.org/economics/impact-sick-days-workplace-influenza-infections/</u>

<sup>&</sup>lt;sup>29</sup> <u>https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1539-6924.2009.01232</u>.

workplace policies, and compliance to a set of public health procedures. Vaccination should remain a choice and not be mandated upon the workforce.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 7th day of December 2021, at Woodstock, Georgia.

Scan kaufman SEAN G. KAUFMAN

## EXHIBIT "3"

 $\begin{array}{c} \mbox{Lead Case No. $21$-7000} \\ (\mbox{Member Case No. $21$-4027/4028/4031/4032/4033/4080/4082/4083/ $4084/4085/4086/4087/4088/4080/4090/4091/4092/4093/4094/4095/4096/ $4097/4099/4100/4101/4102/4103/4108/4112/4114/4115/4117) \end{array}$ 

### IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

#### IN RE: OSHA RULE ON COVID-19 VACCINATION AND TESTING, 86 FED. REG. 61402

On Petitions for Review

## DECLARATION OF JAMES LYONS-WEILER IN SUPPORT OF PETITIONER BENTKEY SERVICES, LLC D/B/A THE DAILY WIRE'S OPPOSITION TO OSHA'S MOTION TO DISSOLVE STAY (ECF # 69)

James Lyons-Weiler declares,

1. My name is James Lyons-Weiler. I am a resident of Allison Park, Pennsylvania; I am over 18 years-old, and am otherwise competent to make this declaration.

2. I am currently CEO and Director of The Institute for Pure and Applied Knowledge in Pittsburgh, PA, a registered not-for-profit organization that conducts biomedical research in the public interest. I was formerly Senior Research Scientist at the University of Pittsburgh, where I served as the Scientific Director of the University of Pittsburgh's Bioinformatics Analysis Core. Prior to that, I had been faculty in the Departments of Pathology and Biomedical Informatics, where I conducted grant-funded research, taught courses and advised graduate students and medical and post-doctoral fellows. I have over 54 peerreviewed publications, and have served as Associate Editor and Editorin-Chief on two journals. I currently serve as the Founding Editor-in-Chief of the journal *Science, Public Health Policy & the Law*.

3. I have been asked to provide testimony on the new workplace vaccine mandate ruling issued by OSHA as Emergency Temporary

Standards (ETS) aka 29 CFR Parts 1910, 1915, 1917, 1918, 1926 and 1928 [Docket No. OSHA-2021-0007) (RIN 1218-AD42).

4. I currently conduct research on the molecular basis of disease in humans (e.g., Lyons-Weiler J. 2020) and on the safety and externalized costs of vaccines and vaccine programs (Lyons-Weiler & Thomas, 2021; Lyons-Weiler et al., 2020; McFarland et al., 2020, Lyons-Weiler & Ricketson, 2018). My research also includes consideration of the accuracy of molecular testing policies and the macroeconomic impacts of largescale testing strategies and policies that contributed to the perceived need for economically and psychologically devastating lock-downs (Lyons-Weiler, 2021).

5. I also currently teach courses in Public Health and research study design at IPAK-EDU, and have taught courses in research study design, attended by clinicians and residents at other universities. I was the Scientific Director of the Bioinformatics Analysis Core at the University of Pittsburgh, where I focused primarily on translational genetic, genomic and proteomic research (both basic (animal laboratory) and clinical studies). I designed and analyzed the data from over 100 research studies. As Senior Research Scientist, it was my responsibility to ensure that the scientific soundness and reproducibility of the studies I was involved in were secure. I helped bring in over \$27M in collaborative research funds in the first three years as a full faculty member in the University of Pittsburgh Cancer Center. I have served on numerous editorial boards as Associate Editor and twice (including currently) as Editor-in-Chief of scientific research and policy journals. I am routinely tasked as a peer reviewer by journals in the fields of biological science, cancer research, statistical analysis, mathematics, epidemiology, and public health. I founded the journal *Science, Public Health Policy & the Law*, which is an active peer-reviewed journal, and published studies and papers focused on the mismatch between public health policy, medical care, the law, and science.

6. I have used PCR and qRT-PCR in my own research and have taught the laboratory methodology and methods of analysis of PCR and RT-PCR in courses at multiple Universities. I am currently active in my research with new peer-reviewed publications as recent as 2021.

7. I will not and have not accepted any form of compensation for this testimony.

8. It is my opinion that the EST as implemented by OSHA is not based on solid facts backed by science, but is instead based upon flawed public health policies and positions that have been cobbled together using demonstrably incorrect knowledge claims.

9. The claim by OSHA that all unvaccinated workers face a grave danger is factually incorrect; a SARS-CoV-2 virus is only a risk to a minority of people, and therefore to a minority of unvaccinated workers.

10. The claim made by OSHA clearly requires two major assumptions:

- a. Assumption 1. OSHA assumes that everyone is at high risk of serious COVID-19 and death due to SARS-CoV-2 infection.
- b. Assumption 2. OSHA also assumes that COVID-19
   vaccines do not transmit the virus.

11. The counterevidence that shows that neither of these assumptions are correct includes:

a. Greater than 99.8% survival of COVID-19 cases in the period prior to the onset of vaccination;

- b. Over 78% of patients with serious COVID-19 had underlying autoimmunity health issues prior to infection whereas only 7% of patients with mild COVID-19 had prior autoimmunity issues;
- c. The number of cases and deaths provided by the CDC is overestimated due to the conflation of "PCR positive test result" with "COVID-19" and an unacceptably high false positive rate of RT-PCR as used in the diagnosis of COVID-19;
- d. Actual COVID-19 death rates are also tragically artificially inflated due to the widespread ignorance of the science demonstrating the efficacy of early treatment protocols.

12. One of the problems that the ETS does not address is the fact that unvaccinated workers might experience a false positive test result.

13. Over the last year and a half, there have been plenty of research that shows the problem with false positive test results.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> See e.g. "(E)vidence from external quality assessments and real-world data indicate enough a high enough false positive rate to make positive results highly unreliable over a broad range of scenarios. This has clinical and case management implications, and affects an array of

- 14. Researchers have found the following consequences to those individuals who have received a false positive test result:
  - a. Unnecessary isolation of individuals and quarantining of close contacts with financial and psychological strains;
  - b. Unnecessary contact tracing and testing;
  - c. Wasteful consumption of personal protective equipment;
  - d. Delays in surgical or other procedures;
  - e. Prolong hospital stays with wasteful consumption of PPE;
  - f. Potentially harboring uninfected individuals with infected individuals in hospitals and congregate living areas with possible nosocomial infection;
  - g. Possible exposure to inappropriate medical treatment;

epidemiological statistics, including the asymptomatic ratio, prevalence, and hospitalization and death rates, as well as epidemiologic models." Cohen et al

https://www.medrxiv.org/content/10.1101/2020.04.26.20080911v4 and SARS CoV 2 Mass Testing Endangers Residents of Long-Term Care Facilities

https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3656876; and False Positive Results With SARS-CoV-2 RT-PCR Tests and How to Evaluate a RT-PCR-Positive Test for the Possibility of a False Positive Result. Journal of Occupational and Environmental Medicine 63:e159-162 doi: 10.1097/JOM.00000000002138 <a href="https://journals.lww.com/joem/Fulltext/2021/03000/False\_Positive\_Results\_With\_SARS\_CoV\_2\_RT\_PCR.23.aspx">https://journals.lww.com/joem/Fulltext/2021/03000/False\_Positive\_Results\_With\_SARS\_CoV\_2\_RT\_PCR.23.aspx</a>

 h. Individual given false sense of security about immunity so may not follow public health guidelines or receive vaccination;

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- i. Impede correct diagnosis of patients with symptoms;
- j. Over diagnosis may distort epidemiologic statistics by including false-positives to estimate prevalence, hospitalization, and death rates as well as modeling (e.g., some individuals classified as asymptomatic carriers may actually had a false positive test).

15. I personally have explored these issues in a peer-reviewed analysis and I concluded that unless the full cost of the false positives are known, an appropriate balance of risk analysis cannot be conducted. The false assumption that false positives are harmless has already cost us one lock-down with all of the consequent job loss and permanent shuttering of hundreds of thousands of small business across the country and around the world.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> Lyons-Weiler, 2020a. Balance of Risk in COVID-19 Reveals the extreme cost of the false positives. Intern J Vacc Theor, Pract, Research 1(2):209-222.

The fact that the public health policy in the United States 16. presumes, by decree, that "PCR positive" determines SARS-CoV-2 infection, is scientifically unsound and has woefully misled the medical community. PCR tests are routinely conducted, and diagnosis of SARS-CoV-2 determined without regard for the false positive risk. It is well known in molecular diagnostic pathology and radiology that the use of tests to screen for conditions or even widespread indiscriminate testing can be seriously problematic for conditions with low prevalence if the tests have false positives, especially if there are risks and costs associated with a positive test result. For example, in cancer diagnostics, we do not routinely perform radiologic screening for solid tumors using Ct (computed tomography) because the follow-up step is usually biopsy, a procedure that has a risk of infection.

17. Researches have also estimated that the diagnosis rate for PCR testing is grossly exaggerated and that the FPR of the use of RT-PCR as implemented in the diagnosis of COVID-19 may be as high as 91%.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> Tartof SY, Slezak JM, Fischer H, et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA:

- 18. In layman's terms, this means:
  - a. The mortality rate estimates cited by OSHA are woefully incorrect; and
  - b. The efficacy of the vaccines is not well-determined given that the COVID-19 status in the trials have also been based on experimental use of RT-PCR with a fixed cycle threshold as a proxy diagnosis of COVID-19 under an Emergency Use Authorization.

19. Furthermore, it is my opinion that OSHA fails to cite the science showing a mass reduction in hospitalization and deaths due to early treatment protocols. They appear to be unaware, for example, of the efficacy of the SANOTIZE nitrous oxide nasal spray (ENOVID<sup>TM</sup>) which, in a series of clinical trials has been shown to clear the virus in 95% infected individuals in 24 hours, and in 99% of infected people within 72 hours (see <u>https://sanotize.com/press-releases/</u>).

20. The existence of such treatment options make the credibility of OSHA's claim of grave danger most dubious.

a retrospective cohort study. Lancet 2021; published online Oct 4. http://dx.doi.org/10.1016/S0140-6736(21)02183-8.

21. In reviewing OSHA's ETS, it is my opinion that the ETS is internally inconsistent on the reliability of testing for COVID-19.

22. The ETS states that given " scientific uncertainty and limitations in testing for infection and immunity, OSHA is concerned that it would be infeasible for employers to operationalize a standard that would permit or require an exception from vaccination or testing and face covering based on prior infection with COVID-19."<sup>4</sup>

23. However, in citing the limitations in testing for infection, OSHA should recognize that this uncertainly applies equally to the vaccinated, the unvaccinated, and the previously immune. This means the assessment of the efficacy of the vaccines in the clinical trials itself should be scrutinized closely. More importantly, OSHA should recognize that they cannot come to a determination of grave danger if the same testing methods used to determine the numbers of cases and deaths due to COVID-19, and to the estimates of the efficacy of the vaccines themselves, are unreliable, as OSHA has stated, and as published estimates demonstrating false positive rates such as the Lancet article revealed.

<sup>&</sup>lt;sup>4</sup> (Section 1.B.3):

24. Another internal inconsistency with OSHA's ETS is that OSHA wants the public and private sectors to have confidence in their assessment of "grave danger" based on the reported number of COVID-19 cases and deaths which are based on RT-PCR testing, but to not have confidence in the same RT-PCR testing used to determine long-lasting (durable) immunity in the previously infected (those with natural immunity). There are ample studies demonstrating durable immunity from natural infections which show that natural immunity is robust and durable<sup>5</sup>, while vaccination is now known to be extremely short-lived and is therefore not sterlizing.

25. OSHA defines the grave danger as "workplace exposure to SARS-CoV-2, the virus that causes the development of COVID-19". However, the vast majority of Americans are not at risk of serious COVID-19 or death from COVID-19 infection, and vaccination does not prevent transmission. OSHA should have considered that the "grave

<sup>&</sup>lt;sup>5</sup> Sekine T, Perez-Potti A, Rivera-Ballesteros O, Strålin K, Gorin JB, Olsson A, Llewellyn-Lacey S, Kamal H, Bogdanovic G, Muschiol S, Wullimann DJ, Kammann T, Emgård J, Parrot T, Folkesson E; Karolinska COVID-19 Study Group, Rooyackers O, Eriksson LI, Henter JI, Sönnerborg A, Allander T, Albert J, Nielsen M, Klingström J, Gredmark-Russ S, Björkström NK, Sandberg JK, Price DA, Ljunggren HG, Aleman S, Buggert M. Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19. Cell. 2020 Oct 1;183(1):158-168.e14. doi: 10.1016/j.cell.2020.08.017. Epub 2020 Aug 14. PMID: 32979941; PMCID: PMC7427556.

danger" they presume does not apply to the vast majority of people, including those in the following groups:

- a. Group A. Those who will become infected and survive without symptoms (estimated at 85%)<sup>6</sup>;
- b. Group B. Those will become infected and survive with minimal symptoms (estimated at >95%)<sup>7</sup>;
- c. Group C. Those who are previously immune due to past exposure to SARS-Cov-2 virus infection with moderate or severe COVID-19 (current estimate 45.6 million reported)<sup>8</sup>;

<sup>&</sup>lt;sup>6</sup> "Asymptomatic persons seem to account for approximately 40% to 45% of SARS-CoV-2 infections" <u>https://www.acpjournals.org/doi/10.7326/M20-3012</u>

<sup>&</sup>quot;Of 48 seropositive individuals with full symptom data, nine (19%) were fully asymptomatic, and 16 (27%) were asymptomatic for core COVID-19 symptoms: fever, cough or anosmia." <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7557299/</u>

<sup>&</sup>lt;sup>7</sup> "Approximately 5% of patients with COVID-19... experience severe symptoms necessitating intensive care." <u>https://pubmed.ncbi.nlm.nih.gov/32648899/</u>

<sup>&</sup>lt;sup>8</sup> Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19 <u>https://pubmed.ncbi.nlm.nih.gov/32979941/</u>

Paul Elias Alexander - 106 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted <u>https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/</u>

- d. Group D. Those who become infected who receive early treatment (very low due to systematic and pervasive disinformation from CDC, FDA, and NIAID)<sup>9</sup>; and
- e. Group E. Those who are previously immune due to past exposed to Coronaviruses other than SARS-CoV-2 (estimated at 21% of Americans, of 69.1 million Americans)<sup>10</sup>.

26. It is my opinion that given scientific uncertainty and limitations in knowledge of the safety in vaccination in each of these groups of people, OSHA's ETS will put millions of workers at unknown levels of risks of adverse reactions due to prior infection followed by vaccination.

<sup>&</sup>lt;sup>9</sup> "A total of 320/922 (34.7%) were treated resulting in 6/320 (1.9%) and 1/320 (0.3%) patients that were hospitalized and died, respectively." (Procter et al., 2020) <u>https://pubmed.ncbi.nlm.nih.gov/33388006/</u>

This means that widespread adoption of early treatment protocols could reduce the infection case fatality rate significantly. Dr. Pierre Kory estimates that as many as 85% of the deaths from COVID-19 were preventable by early treatment; the nitric oxide spray results suggest that 99% of hospitalization and deaths could be prevented.

<sup>&</sup>lt;sup>10</sup> "Recent reports have shown that SARS-CoV-2 cross-reactive memory T cells are detectable in  $\sim$ 28–50% of individuals not exposed to SARS-CoV-2" (Lipsitch et al., 2020) https://www.nature.com/articles/s41577-020-00460-4

27. One of the major issues with the OSHA ETS is that it relies on CDC reporting of the number of people who test positive for COVID. However, CDC's data is compromised as the CDC only reports cases of COVID-19 in vaccinated persons if they have a Ct < 28 and are hospitalized or dead whereas for the unvaccinated the CDC required a different standard of 40 - 45 cycles. The use of a Ct of 28 or less in ONLY the vaccinated results in up to a 90% reduction in the false positive rate among ONLY the vaccinated. This lowering of the Ct by the CDC skews results in favor of vaccination.

28. As a result of the CDC using the standard of 40-45 cycles between April 2020 until April 2021, the reliability of the positive COVID test rates is scientifically unreliable.

29. My organization, IPAK, published an important analysis that shows that CDC not only has exaggerated the number COVID-19 cases, but also the number of COVID-19 deaths, and that they failed to have the change in their diagnostic policy vetted by the appropriate committee review (Ealy et al., 2020).

30. The ETS Claims that SARS-CoV-2 is a "Grave Danger." To whit:

Yet by any measure, SARS–CoV–2 is a new hazard. Unlike any of the hazards addressed in previous ETSs, SARS–CoV–2 was not known to exist until January 2020. Since then, more than 3 million people have died worldwide and nearly 600,000 people have died in the U.S. alone (WHO, May 24, 2021; CDC, May 24, 2021b). This monumental tragedy is largely handled by healthcare employees who provide care for those who are ill and dying, leading to introduction of the virus not only in their daily lives in the community but also in their workplace, and more than a thousand healthcare workers have died from COVID–19. Clearly, exposure to SARS–CoV–2 is a new hazard that presents a grave danger to workers in the U.S.

31. This paragraph is factually incorrect. There is no standard of

care for people who are "ill" with COVID-19, only for those who are dying. The current standard of care treatment for people who test positive for SARS-CoV-2 via RT-PCR is no care at all - they are told to go home and return to the emergency room if they need emergency care. Further, ample studies show that early treatment - currently being denied to individuals who test positive via RT-PCR - can reduce mortality significantly. A study by Henry Ford Hospital found a reduction in mortality in COVID-19 patients by 66% in patients who received hydroxychloroquine, with a 71% reduction in patients who received both hydroxychloroquine and azithromycin - a result shrugged off by Dr. Anthony Fauci of the NIAID in testimony to the US Senate. This is in contradiction to the FDA's announcement of use of Real World Data and Real World Evidence, as well as the FDA's stated position on off-label use.

32. Subsequent to these initial studies, the scientific literature has exploded with studies that have shown efficacy of early treatment. The studies that do support early treatment are numerous and growing.

33. All of the US Government's position on the alleged Grave Danger of COVID-19 should be recast as "Grave Danger of Failure to Treat Apparent COVID-19 cases." They cite over 3 million deaths attributed globally and 600,000 deaths attributed in the US to "COVID-19"; in reality, most if not all of these deaths might have been prevented by a public health policy and medical standards of care that have now been established, empirically, by medical authorities on the matter such as Dr. Pierre Kory, Dr. Peter McCullough, Dr. Paul Marik, Dr. Jane Orient, Dr. Elizabeth Lee Vliet, and Dr. David Brownstein. Each of these treating physicians - doctors in the trenches, treating patients - have published treatment protocols backed by data that support that it is the mangled, unscientific, and arbitrary US public health policies that are leading the needless, preventable COVID-19 deaths.

34. Finally, it is my opinion that OSHA has failed to address many of the clinical concerns of researchers around the world. A summary of the many clinical concerns that researchers have to the current vaccines include<sup>11</sup>:

- a. Does the mRNA or adenoviral DNA that induce production of the Spike protein cause cell, tissue, or organ endothelial damage?
- b. What happens when the Spike protein circulates (body fluids, donated blood)?
- c. Why have there been no genotoxicity, teratogenicity, or oncogenicity studies?
- d. Does the report of ovarian accumulation of the Pfizer vaccine particle lead to long-term reproductive effects in vaccinated women?
- e. What of the reduced fertility study (Moderna, EMA)?
- f. Why was there no EAC, DSMB, Human Ethics Committee review of safety data?

<sup>&</sup>lt;sup>11</sup> Preprint by Bruno et al., (SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers)

- g. Why has there been no safety report card from the HHS to Congress?
- h. Why, in the vaccine roll-out, has there been no restriction of use of the vaccines on groups excluded from randomized clinical trials?
- i. Why did the CDC recommend vaccination for pregnant women, and women of childbearing potential, without appropriate safety studies on reproductive and fetal health?
- j. Why are COVID survivors and those previously immune subject to vaccination at all?
- k. Why has there been no effort to restrict vaccination according to risk for COVID-19 hospitalization and death?
- Why have there been no attempts to present or mitigate risks to public health given reports of myocarditis, clotting, and other serious adverse events?

35. One of my concerns over the current vaccines is that research scientists have found that there have been more deaths reported to

VAERS following COVID-19 vaccinations than all other vaccines combined over the entire history of VAERS (est. 1990).

36. In fact, Dr. Rose found a massive increase in reports of serious adverse events and deaths compared to prior years.<sup>12</sup>

Figure 1: Bar plots showing the number of VAERS reports (left) and reported deaths (right) per year for the past decade. (2021 is partial data set.)



37. The testing mandate component for unvaccinated workers as required by this ETS will not work due to inaccuracies of the test; the testing option poses a grave threat to economic harm due to a surge in false positives.

<sup>&</sup>lt;sup>12</sup> Rose, J. 2021. Critical appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a functioning pharmacovigilance system? Sci, Publ Health Pol & Law 3:100-129 (Independently Peer-Reviewed (Single-Blind, 2 reviewers)

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 8<sup>th</sup> day of November 2021.

DocuSigned by: BD741F8F055F40A...

James Lyons-Weiler, Ph.D.

# EXHIBIT "4"

### IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BENTKEY SERVICES, LLC D/B/A THE DAILY WIRE,	: : Case No.:	
Petitioner,	·	
	:	
v.	:	
	:	
OCCUPATIONAL SAFETY AND	:	
HEALTH ADMINISTRATION,	:	
DEPARTMENT OF LABOR,	:	
	:	
Respondent.	:	e
	:	

### **DECLARATION OF JEREMY BOREING**

Pursuant to 28 U.S.C. § 1746, I, Jeremy Boreing, hereby declare as follows:

### **Personal Background**

1. I am the Co-Chief Executive Officer of Bentkey Services,

LLC ("Bentkey Services"), which is under common ownership with and employs the staff of The Daily Wire, LLC.

2. I am also The Daily Wire's Manager, and this role entails providing a strategic vision and supervising The Daily Wire's executive team.
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3. I have personal knowledge regarding Bentkey Services' and The Daily Wire's strategic objectives, internal operations, personnel management, and finances.

## The Daily Wire's Mission and Operations

4. The Daily Wire is a media company with its primary office located in Nashville, Tennessee.

5. Bentkey Services employs the personnel and leadership who operate The Daily Wire.

6. Launched in 2015, The Daily Wire is one of America's fastest-growing conservative media companies and counter-cultural outlets for news, opinion, and entertainment. Ben Shapiro, Caleb Robinson, and I founded The Daily Wire with the vision of providing an alternative, conservative media platform.

7. The Daily Wire quickly became one of the leading and most popular online news sites and publishers available in the world.

8. The Daily Wire and its hosts also have vibrant and active social media presences and followings. In addition to utilizing its own website to distribute news and commentaries, The Daily Wire

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distributes its content on social media platforms such as YouTube, Facebook, Twitter, and Instagram.

9. The Daily Wire has seen a great success in reaching audiences via social media.

10. Some of The Daily Wire's hosts are extremely popular and reach millions of Americans. For example, Ben Shapiro has over 8 million Facebook followers; Candace Owens, over 5 million followers; Michael Knowles, over a million followers; and Andrew Klavan and Matt Walsh, each hundreds of thousands of followers.

11. The Daily Wire's articles and tweets are easily shared hundreds of thousands, if not millions, of times online; and its YouTube videos are regularly viewed by millions of users. It is often the most interactive media outlet account on Facebook in terms of likes, shares, and comments.

12. The Daily Wire's popularity is similarly widespread in the podcast world. Today, The Daily Wire's ongoing podcasts include *The Ben Shapiro Show, The Andrew Klavan Show, The Michael Knowles Show, The Matt Walsh Show, Candace, Daily Wire Backstage*, and

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*Morning Wire*. Many of these shows have dominated ratings on podcast platforms and ranked near the top of podcast charts.

13. The Daily Wire also is significantly engaged in the entertainment industry not only by providing reviews of books, TV shows, and movies, but also by distributing its own original movies.

14. In early 2021, The Daily Wire released *Run, Hide, Fight*, and currently has multiple other films and series in various stages of development.

15. The Daily Wire has also recently launched a book publishing division. One of its main goals in entering the book-publishing space is to give a voice to authors and writers who have been "canceled" by the mainstream publishers.

16. To support its media operations, Bentkey Services staffs The Daily Wire with talented and dedicated employees.

17. Because The Daily Wire's goal is to promote the freedom of speech and thought and to report the news to counterbalance the increasingly illiberal and one-sided mainstream media perspective, Bentkey Services has no political litmus test but carefully screens and

hires staff who understand and wish to be part of The Daily Wire's mission.

18. Furthermore, The Daily Wire's operations require specialized skill sets in numerous areas, including for example, digital content creation, social media outreach, news commentaries, and video production. Bentkey Services seeks out qualified employees for The Daily Wire who cannot be replaced easily.

19. As of October 31, 2021, Bentkey Services has a total of 135 employees who run The Daily Wire.

20. In the Nashville office, Bentkey Services has 105 employees for The Daily Wire who regularly report for work in person.

21. Bentkey Services also has 30 employees for The Daily Wire who work remotely.

22. Beyond the employees in Tennessee, Bentkey Services has Daily Wire employees who live in 13 other states.

## The Daily Wire's Stance on COVID-19 Vaccines

23. The Daily Wire's leadership and several of its hosts have been vocal *proponents* of COVID-19 vaccines, so long as individuals are free to make the decision whether or not to get vaccinated.

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24. I have publicly stated that I am personally pro-vaccine and believe that these vaccines are effective at mitigating the worst effects of the virus.

25. Throughout the pandemic, many of The Daily Wire hosts also called for the development of effective and safe COVID-19 vaccines to combat the disease.

26. For example, Ben Shapiro encouraged people via Twitter to get vaccinated by explaining that "[t]he vaccine is 95% effective in preventing you from getting the virus . . . and 99% of those who actually get covid-19 will survive." And, again, on July 20, 2021, Shapiro encouraged people to receive COVID-19 vaccines, tweeting: "Get vaxxed. I did. My wife did. My parents did."

27. Andrew Klavan similarly tweeted on February 1, 2021, that he received the vaccination.

28. However, The Daily Wire has always opposed mandatory vaccination against people's will or needs. Our leadership understands that the decision to inject one's body with substances is a personal choice.

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29. Bentkey Services has not required or requested employees for The Daily Wire to verify their vaccination status or to specifically request applicable exemptions.

30. However, based on current information, The Daily Wire's staff includes both vaccinated and unvaccinated individuals.

31. Some of our Bentkey Services employees have disclosed to us voluntarily and in confidence that they have refrained from receiving the COVID-19 vaccines for various reasons.

32. These reasons include: confirmed presence of natural immunity, presence of autoimmune conditions, and experience of prior adverse reactions to certain types of medicine.

33. Our leadership also appreciates that there may be additional employees with similar or additional reasons for refraining from the COVID-19 vaccines. These additional reasons may include religious objections or the fact that certain employees are young and maintain a healthy lifestyle.

34. In any event, The Daily Wire's leadership affirms that getting vaccinated is a personal choice, even though it encourages people to get vaccinated, if possible.

35. I am also well aware that, on September 9, 2021, President Joe Biden announced a sweeping COVID-19 vaccine mandate for private employers.

36. The Daily Wire's leadership has opposed this decree from the date of its announcement. The Daily Wire's leadership believes that the decision to receive COVID-19 vaccines should be left to free individuals. The ETS seeks to make our company the enforcement arm of a policy we oppose in contravention of our freedom of conscience.

37. Also, The Daily Wire's leadership firmly believes that the President, acting through an agency—let alone the federal government as a whole—lacks the constitutional or statutory authority to impose such a mandate on private employers.

## The Impact of OSHA's Unlawful Vaccine Mandate on The Daily Wire Staff

38. Bentkey Services employs over 100 in-person and full-time employees who operate The Daily Wire.

39. It is my understanding that the ETS will require private employers to ensure that their employees are either vaccinated or subjected to a weekly testing and/or masking.

40. If the ETS forces Bentkey Services to administer the federal mandate on its employees who staff The Daily Wire, it will cause significant and irreparable harm to Bentkey Services and its employees who staff The Daily Wire.

41. As an organization, The Daily Wire's leadership strongly believes in protecting employee privacy and autonomy. We would not intrude on our employees' private health choices regarding vaccination if we were not mandated to do so by the ETS. We also would not, on our own, require employees to get weekly tests or mask prior to coming to work.

42. If OSHA's regulatory requirements mandate us to keep records showing compliance with the ETS, this means that The Daily Wire staff will need to devote time and resources toward building and maintaining a safe and secure way to keep records of our employees' sensitive health information.

43. Furthermore, by requiring The Daily Wire staff to keep such records, the ETS exposes the company to potential liability. As an employer, Bentkey Services is obligated to take extraordinary steps to protect employees' private health information. Implementing vaccine,

testing, and/or masking requirements creates an entirely new workplace procedure which exposes the company to danger of liability should any employee's information related to the vaccine or testing be exposed. It also opens the door to potential discrimination claims, including for example under the Americans with Disabilities Act and the Civil Rights Act.

44. Discrimination against employees who do not receive the vaccine is likely to affect their social standing in the workplace as well. This opens the door to claims of discrimination, harassment, and retaliation.

45. The costs of these potential liabilities could be hundreds of thousands or millions of dollars.

46. Implementation of the ETS will require creation of policies and training employees and managers to implement them. We estimate this record-keeping requirement will be significant.

47. If the ETS requires Bentkey Services to provide paid time off for vaccination and recovery and to ensure employees' compliance with the weekly testing requirement, we estimate that the cost will be significant.

48. Additionally, if the federal mandate requires The Daily Wire staff to be tested weekly, it will take significant time and effort every week for Bentkey Services and its employees to comply with the mandated testing.

49. Also, The Daily Wire will need to devote personnel to ensure compliance with the ETS's masking mandate.

50. This loss of productivity and creativity of our employees is difficult to quantify at this point but would be substantial. Again, our employees work in a fast-paced media outlet that is engaged in protected speech. This effort will be irreparably harmed if our employees are required to lose work hours.

51. If the federal mandate coerces us to enforce it on our own employees, we fear that there may be employees who may simply leave The Daily Wire for another employer that has fewer than 100 employees and thus are not subject to the reach of the ETS. For example, Dave Rubin—the host of *The Rubin Report*—has stated on his September 10, 2021 tweet that his companies have fewer than 100 employees while expressing support for The Daily Wire leadership's decision to seek legal recourse. 52. Furthermore, OSHA's threat of punitive fines will force The Daily Wire to fire or remove from our office those employees who do not submit to its mandate.

53. The Daily Wire hired its staff with diligence and care for advancing the company's robust exercise of free speech. The fact that The Daily Wire will have to divert its resources from its normal media operations to administer the ETS will already hamper our free-speech activities.

54. The loss of any of its employees from this mandate will irreparably harm the company's expressive mission. Specifically, if the ETS requires Bentkey Services to comply, the loss of employees and the burdens of compliance with the ETS will mean that protected speech that otherwise would have been exercise will not be exercised.

I declare under penalty of perjury that the foregoing is correct.

Executed on this f day of November 2021.

Jaan Making