## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

PROFESSOR TODD ZYWICKI,	
Plaintiff,	)
v.	) ) CIVIL ACTION NO.
GREGORY WASHINGTON,	)
in his official capacity as President of	) COMPLAINT FOR DECLARATORY
George Mason University; JAMES W.	) JUDGMENT AND INJUNCTIVE
HAZEL, in his official capacity as Rector	) RELIEF
of the Board of Visitors;	)
HORACE BLACKMAN, in his official	) JURY TRIAL DEMANDED
capacity as Vice Rector of the Board of	
Visitors; SIMMI BHULLER, in her	
official capacity as Secretary of the	)
Board of Visitors; DAVID FARRIS, in	)
his official capacity as Executive Director,	)
Safety and Emergency Management;	)
JULIE ZOBEL, in her official capacity as	)
Assistant Vice President of Safety,	)
<b>Emergency, and Enterprise Risk</b>	)
Management; and ANJAN	
CHIMALADINNE, JUAN CARLOS	
ITURREGUI, MEHMOOD KAZMI,	
WENDY MARQUEZ, IGNACIA S.	)
MORENO, CAROLYN MOSS,	)
DOLLY OBEROI, JON PETERSON,	)
NANCY GIBSON PROWITT, PAUL	)
J. REAGAN, EDWARD J. RICE,	)
DENISE TURNER ROTH, and BOB	
WITECK, in their official capacities	)
as Members of the Board of Visitors,	)
Defendants.	)
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Plaintiff Todd Zywicki, by and through his attorneys at the New Civil Liberties Alliance, hereby complains and alleges the following:

#### **INTRODUCTORY STATEMENT**

- a. By the spring of 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, had spread across the globe. Since then, and because of the federal government's "Operation Warp Speed," three separate coronavirus vaccines have been developed and approved more swiftly than any other vaccine in our nation's history. The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-BioNTech COVID-19 Vaccine ("Pfizer Vaccine") on December 11, 2020. Just one week later, FDA issued a second EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine"). FDA issued its most recent EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine") on February 27, 2021 (the only EUA for a single-shot vaccine).
- b. The EUA statute, 21 U.S.C. § 360bbb-3, explicitly states that anyone to whom the product is administered must be informed of the option to accept or to refuse it, as well as the alternatives to the product and the risks and benefits of receiving it.
- c. On June 28, 2021, George Mason University ("GMU") announced a reopening policy (the "Policy") related to COVID-19 for the Fall 2021 semester. The Policy requires all unvaccinated faculty and staff members, including those who can demonstrate natural immunity from a prior COVID-19 infection, to wear masks on campus, physically distance, and undergo

<sup>&</sup>lt;sup>1</sup> Pfizer-BioNtech Vaccine FAQ, FDA, bit.ly/3i4Yb4e (last visited July 28, 2021).

<sup>&</sup>lt;sup>2</sup> Moderna, About Our Vaccine, bit.ly/2V14lUF (last visited July 28, 2021).

<sup>&</sup>lt;sup>3</sup> EUA for Third COVID-19 Vaccine, FDA, bit.ly/3xc4ebk (last visited July 28, 2021).

frequent COVID-19 testing. Additionally, the Policy strips unvaccinated employees of their eligibility for future merit-based pay increases because they cannot upload proof of vaccination. On July 22, GMU emailed students and employees about the policy and threatened disciplinary action—including termination of employment—against those who do not comply. This threat was reiterated on the university's website and in an August 2, 2021 email sent to Professor Zywicki.

- d. Professor Todd Zywicki has already contracted and fully recovered from COVID-19. As a result, he has acquired robust natural immunity, confirmed unequivocally by multiple positive SARS-CoV-2 antibody tests conducted over the past year. Professor Zywicki's immunologist, Dr. Hooman Noorchashm, has advised him that, based on his immunity status and personal medical history, it is *medically unnecessary* to undergo a vaccination procedure at this point (which fact also renders the procedure and any attendant risks medically unethical).
- e. Yet, if Professor Zywicki follows his doctor's advice and elects not to take the vaccine, that will diminish his efficacy in performing his professional responsibilities by hamstringing him in various ways, such as requiring him to wear a mask that has no public health value given his naturally acquired immunity. He will also face adverse disciplinary consequences. In short, the Policy is unmistakably coercive and cannot reasonably be considered anything other than an unlawful mandate. And even if the Policy is not deemed coercive, it still represents an unconstitutional condition being applied to Professor Zywicki's constitutional rights to bodily integrity and informed medical choice, respectively.
- f. Given the antibodies generated by his naturally acquired immunity, the Commonwealth of Virginia cannot claim a compelling governmental interest in overriding Professor Zywicki's personal autonomy and constitutional rights by forcing him, in essence, to either be vaccinated or to suffer adverse professional consequences. Natural immunity is at least

as robust and durable as that attained through the most effective vaccines, and is significantly more protective than some of the inferior vaccines that GMU accepts. Very recent studies are also establishing that natural immunity is significantly longer lasting. As a result, GMU's Policy is designed to force its way past informed consent and infringes upon Professor Zywicki's rights under the Ninth and Fourteenth Amendments to the United States Constitution.

- g. For similar reasons, the Policy constitutes an unconstitutional condition, because it is poorly calibrated to protect the public health, yet it poses disproportionate risks on some of its targets. That renders the Policy an unlawful condition insufficiently germane to its purported purpose. Furthermore, the disciplinary and other burdens that GMU is using to leverage ostensibly voluntary compliance with its Policy are not proportional to the purported public health aims.
- h. Even beyond its constitutional defects, GMU's unlawful Policy is irreconcilable with and frustrates the objectives of the statute governing administration of medical products authorized for emergency use only. Pursuant to the Supremacy Clause of the United States Constitution, federal law overrides conflicting state law and action by agents of the Commonwealth. Accordingly, the Policy is preempted by the EUA statute and must be enjoined.
- i. In a highly publicized opinion recently made public, the U.S. Department of Justice's Office of Legal Counsel ("OLC") argues that public and private entities can lawfully mandate that their employees receive one of the vaccines.<sup>4</sup> The opinion is silent on preemption, however, and thus cannot be read to prevent the EUA statute from having its ordinary preemptive effect, and this is especially true where OLC was assigned no role by Congress to administer the EUA statute. The OLC Opinion, as explained in detail in Count III below, is also deeply flawed on multiple additional legal grounds.

<sup>&</sup>lt;sup>4</sup> CNN story, https://cnn.it/3iWxH42, last visited (July 29, 2021).

j. In sum, the Policy violates *both* Professor Zywicki's constitutional *and* federal statutory rights because it undermines his bodily integrity and conditions his ability to perform his job effectively on his willingness to take a vaccine that his doctor has advised could harm him. And forcing him to take this vaccine will provide no discernible, let alone compelling, benefit either to Professor Zywicki or to the GMU community. The unconstitutional conditions doctrine exists precisely to prevent government actors from clothing unconstitutional objectives and policies in the garb of supposed voluntarism when those actors fully intend and expect that the pressure they are exerting will lead to the targets of such disguised regulation succumbing to the government's will. Professor Zywicki invokes this Court's Article III and inherent powers to insulate him from this pressure and to vindicate his constitutional and statutory rights.

#### **PARTIES**

- 1. Plaintiff Todd Zywicki (55 years old) is a GMU Foundation Professor of Law at the Antonin Scalia Law School, located in Arlington, Virginia. He resides in Falls Church, Virginia.
- 2. Defendant Gregory Washington is President of GMU, an administrative unit of the Commonwealth of Virginia located in Fairfax, Virginia. He is sued in his official capacity.
- 3. Defendant James W. Hazel is Rector of the Board of Visitors at GMU. He is sued in his official capacity.
- 4. Defendant Horace Blackman is Vice Rector of the Board of Visitors at GMU. He is sued in his official capacity.
- 5. Defendant Simmi Bhuller is Secretary of the Board of Visitors at GMU. She is sued in her official capacity.

- 6. Defendant David Farris is GMU's Executive Director of Safety and Emergency Management. He is sued in his official capacity.
- 7. Defendant Julie Zobel is GMU's Assistant Vice President of Safety, Emergency, and Enterprise Risk Management. She is sued in her official capacity.
- 8. Defendants Anjan Chimaladinne, Juan Carlos Iturregui, Mehmood Kazmi, Wendy Marquez, Ignacia S. Moreno, Carolyn Moss, Dolly Oberoi, Jon Peterson, Nancy Gibson Prowitt, Paul J. Reagan, Edward J. Rice, Denise Turner Roth, and Bob Witeck compromise the remainder of the Board of Visitors. They are sued in their official capacity.

#### STATUTORY AND NONSTATUTORY JURISDICTION AND VENUE

- 9. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3)-(4) (equitable relief), and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. That is because the claims here arise under the Constitution and statutes of the United States and because Professor Zywicki seeks prospective redress against state actors in their official capacity to end the deprivation, under state law, of his rights, privileges, and immunities secured by federal law.
- 10. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391 because Professor Zywicki resides in this judicial district and a substantial part of the events, actions, or omissions giving rise to the claim occurred in this judicial district, where GMU is principally located.
- 11. This Court's equitable powers permit it to issue nonstatutory injunctions to protect Professor Zywicki against wayward state actors engaged in unlawful conduct. *See Trump v. Vance*, 140 S. Ct. 2412, 2428-29 (2020) ("*Ex parte Young*, 209 U.S. 123, 155–156 (1908) (holding

that federal courts may enjoin state officials to conform their conduct to federal law).").<sup>5</sup> The only limitation is that a defendant subject to such an injunction must possess a connection to the establishment and enforcement of GMU's vaccine mandate. Each of the defendants in this action have the requisite connection. *See, e.g., Bostic v. Schaefer*, 760 F.3d 352, 371 n.3 (4th Cir. 2014) (Virginia's Registrar of Vital Records could be sued under *Ex parte Young* for unconstitutional actions related to marriage rights because he was charged with ensuring compliance with the Commonwealth's marriage laws). Defendants, respectively, run GMU, administer it, or as to some defendants, personally participated in formulating and issuing the Policy challenged here. *See generally Free Enter. Fund v. PCAOB*, 561 U.S. 477, 491 n.2 (2010) (collecting cases in the vein of *Bell v. Hood*, 327 U.S. 678, 684 (1946) ("[I]t is established practice for this Court to sustain the *jurisdiction* of federal courts to issue injunctions to protect rights safeguarded by the Constitution") (emphasis added)).

12. This Court may also issue declaratory relief pursuant to 28 U.S.C. § 2201. Additionally, "[f]urther necessary or proper relief based on a declaratory judgment may [also] be granted ...," including via injunction. *See Powell v. McCormack*, 395 U.S. 486, 499 (1969) ("A declaratory judgment can then be used as a predicate to further relief, including an injunction. 28 U.S.C. § 2202 ....").

<sup>&</sup>lt;sup>5</sup> See Erwin Chemerinsky, FEDERAL JURISDICTION, 8th ed. (2021) (Ex parte Young "has been heralded as 'one of the three most important decisions the Supreme Court of the United States has ever handed down.""), quoting Allied Artists Pictures Corp. v. Rhodes, 473 F. Supp. 560, 564 (E.D. Ohio 1979) (citations omitted).

#### **STATEMENT OF FACTS**

- I. BACKGROUND PERTAINING TO THE CORONAVIRUS PANDEMIC AND COVID-19 VACCINES
- 13. The novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, is a contagious virus spread mainly through person-to-person contact, including through the air.
- 14. It is well-settled that the coronavirus presents a significant risk primarily to individuals aged 70 or older and those with comorbidities such as obesity and diabetes. Bhattacharya and Kulldorff Joint Decl. ¶¶ 10-14 ("Joint Decl.") (Attachment A). See Smiriti Mallapaty, The Coronavirus Is Most Deadly If You Are Older and Male, NATURE (Aug. 28, 2020) (individuals under 50 face a negligible threat of a severe medical outcome from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car).
- 15. In fact, a meta-analysis published by the World Health Organization ("WHO") concluded that the survival rate for COVID-19 patients under 70 years of age was 99.95%. Joint Decl. ¶ 12.
- 16. CDC estimates that the survival rate for young adults between 20 and 49 is 99.95% and for people ages 50-64 is 99.4%. Joint Decl. ¶ 13.
- 17. A seroprevalence study of COVID-19 in Geneva, Switzerland, reached a similar conclusion, estimating a survival rate of approximately 99.4% for patients between 50 and 64 years old, and 99.95% for patients between 20 and 49. Joint Decl. ¶ 14.
- 18. To date, FDA has approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3.
  - a. FDA issued an EUA for the Pfizer Vaccine on December 11, 2020.
  - b. Just one week later, FDA issued an EUA for the Moderna Vaccine.
  - c. FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.

- 19. The vaccines' EUA status means that FDA has not yet approved the vaccines, but FDA permits their conditional use nevertheless due to exigent circumstances. *See* 21 U.S.C. § 360bbb-3.
  - 20. The standard for EUA approval is lower than that required for full FDA approval.
- 21. Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control. *See Vaccine Testing and the Approval Process*, CDC (May 1, 2014), *available at* https://bit.ly/3rGkG2s (last visited July 28, 2021).
- 22. The third phase typically takes place over years, because it can take that long for a new vaccine's side effects to manifest. *Id*.
- 23. The third phase must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. *Id*.
- 24. Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.
- 25. FDA must then determine, based on "substantial evidence," that the medical product is effective and that the benefits outweigh its risks when used according to the product's approved labeling. *See Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19*, CDC (Oct. 22, 2020), *available at* bit.ly/3x4vN6s (last visited July 28, 2021).
- 26. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current

- COVID-19 pandemic." *Emergency Use Authorization for Vaccines Explained*, FDA (Nov. 20, 2020), *available at* bit.ly/3x8wImn (last visited July 28, 2021).
- 27. EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for FDA approval or clearance. *See id.*
- 28. The EUA statute states that individuals to whom the product is administered must be informed: (1) that the Secretary has authorized emergency use of the product; (2) of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown; and (3) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).
- 29. Studies of immunizations outside of clinical-trial settings began in December 2020, following the first EUA for a COVID vaccine.
- 30. None of the three vaccines approved for emergency use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Noorchashm Declaration ("Noorchashm Decl.") ¶ 30 (Attachment B).
- 31. Indeed, trials conducted so far have *specifically excluded* survivors of previous COVID-19 infections. Noorchashm Decl. ¶ 30.
- 32. Recent research indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Noorchashm Decl. ¶¶ 22-26; Joint Decl. ¶ 27.
- 33. The heightened risk of adverse effects results from "preexisting immunity to SARS-Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic

reactions in previously immunized and predisposed individuals." Angeli et al., SARS-CoV-2 Vaccines: Lights and Shadows, 88 Eur. J. Internal Med. 1, 8 (2021).

## II. PRIOR INFECTION LEADS TO NATURALLY-ACQUIRED IMMUNITY TO COVID-19 AT LEAST AS ROBUST AS VACCINE-ACQUIRED IMMUNITY

- 34. Naturally acquired immunity developed after recovery from COVID-19 provides broad protection against severe disease from subsequent SARS-CoV-2 infection. Joint Decl. ¶ 15.
- 35. Multiple extensive, peer-reviewed studies comparing naturally acquired and vaccine acquired immunity have concluded overwhelmingly that the former provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna). Joint Decl. ¶ 18.
- 36. These studies confirm the efficacy of natural immunity against reinfection of COVID-19 and show that almost all reinfections are less severe than first-time infections and almost never require hospitalization. Joint Decl. ¶ 19.
- 37. A CDC/IDSA clinician call on July 29, 2021, summarized the current state of the knowledge regarding the comparative efficacy of natural and vaccine immunity. The presentation reviewed three studies that directly compared the efficacy of prior infection versus mRNA vaccine treatment and concluded "the protective effect of prior infection was similar to 2 doses of a COVID-19 vaccine."
- 38. Given that there is currently more data on the durability of natural immunity than there is for vaccine immunity, researchers rely on the expected durability of natural immunity to predict that of vaccine immunity. Joint Decl. ¶ 22.
- 39. Indeed, natural and vaccine immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response. Joint Decl. ¶ 16.

- 40. The level of antibodies in the blood of those who have natural immunity was initially the benchmark in clinical trials for determining the efficacy of vaccines. Joint Decl. ¶ 16.
- 41. Studies have demonstrated prolonged immunity with respect to memory T- and B-cells, bone marrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B-cells following a COVID-19 infection. Joint Decl. ¶ 17; Dr. Harvey Risch, Yale School of Medicine, interview ("Risch interview"), *Laura Ingraham Discusses How Medical Experts Are Increasing Vaccine Hesitancy* (July 26, 2021), *available at* https://bit.ly/3zOL6Sx (last visited July 27, 2021).
- 42. T-cells last "quite a while," but B-cells migrate to the bone marrow and last even longer. Risch interview.
- 43. New variants of COVID-19 resulting from the virus's mutation do not escape the natural immunity developed by prior infection from the original strain of the virus. Joint Decl. ¶ 29.
- 44. In fact, vaccine immunity only targets the spike-protein of the original Wuhan variant, whereas natural immunity recognizes the full complement of SARS-CoV-2 proteins and thus provides protection against a greater array of variants. Noorchashm Decl. ¶ 17.
- 45. The Janssen Vaccine provides immunity protection of somewhere between 66% and 85%, far below that conferred by natural immunity. Joint Decl. ¶ 16; Noorchashm Decl. ¶ 15.
- 46. The Chinese Sinovac Vaccine has been approved by WHO, which itself determined that this vaccine prevented *symptomatic* disease in just 51% of those who received it. *See WHO validates Sinovac COVID-19 vaccine for emergency use and issues interim policy recommendations*, WHO.INT (June 1, 2021), *available at* bit.ly/3yitIW7 (last visited Aug. 1, 2021).
- 47. Other clinical studies have found that the Sinovac Vaccine offers even lower levels of protection against infection, including a study of Brazilian healthcare workers

determining a mere 50.39% efficacy in preventing infection. See Elizabeth de Faria, et al.,

Performance of vaccination with CoronaVac in a cohort of healthcare workers (HCW)—

preliminary report, MEDRXIV (April 15, 2021), available at

https://www.medrxiv.org/content/10.1101/2021.04.12.21255308v1 (last visited Aug. 3, 2021).

- 48. Real-world evidence also suggests that the Sinovac Vaccine provides only minimal protection against the Delta variant. See Alexander Smith, China on 'high alert' as variant of Covid-19 spreads to 5 provinces, NBCNEWS.COM (July 30, 2021), nbcnews.to/2VcK3NB (last visited Aug. 1, 2021); Chao Deng, As Delta Variant Spreads, China Lacks Data on Its Covid-19 Vaccines, WALL St. J. (July 9, 2021), available at on.wsj.com/3rMjlXW (last visited Aug. 1, 2021); Matt D.T. Hitchings, et al., Effectiveness of CoronaVac in the setting of high SARS-Cov-2 P.1 variant transmission in Brazil: A test-negative case-control study, The LANCET (July 25, 2021), available at bit.ly/3C6F41J (last visited Aug. 1, 2021).
- 49. The Sinopharm Vaccine also is from China and is WHO-approved. Although its reported level of efficacy against symptomatic infection has been reported as fairly high (78%), real-world experience has generated severe doubts about the accuracy of that estimate. Because of the Sinopharm Vaccine's poor performance, several countries stopped using it. *See* Yaroslav Trofimov and Summer Said, Bahrain, *Facing a Covid Surge, Starts Giving Pfizer Boosters to Recipients of Chinese Vaccine*, WALL ST. J. (June 2, 2021), *available at* on.wsj.com/3ljM0lX (last visited Aug. 1, 2021).
- 50. The COVISHIELD vaccine, manufactured by the Serum Institute of India and South Korea's SK Bioscience Co., Ltd., is also WHO-approved and thus recognized as adequate to satisfy GMU's Policy. The WHO itself reported a mere 70.42% efficacy against *symptomatic* COVID-19 infection, which fell to 62.10% in individuals who received two standard doses. *See*

Recommendation on Emergency Use Listing on COVISHIELD submitted by SIIPL, WHO (Feb. 26, 2021), available at bit.ly/3rNjnPo (last visited Aug. 1, 2021); Recommendation for an Emergency Use Listing of AZD1222 Submitted by AstraZeneca AB and manufactured by SK Bioscience Co. Ltd., WHO (Feb. 23, 2021), available at bit.ly/3yiQD3s (last visited Aug. 1, 2021). These vaccines have not been approved by the FDA for use in the United States.

- 51. Recent Israeli data found that those who had received the Pfizer Vaccine were 6.72 times *more likely* to suffer a subsequent infection than those with naturally acquired immunity. David Rosenberg, *Natural Infection vs Vaccination: Which Gives More Protection?* ISRAELNATIONALNEWS.COM (Jul. 13, 2021), *available at* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited Aug. 1, 2021).
- 52. Israeli data also indicates that the protection Pfizer grants against infection is short-lived compared to natural immunity and degrades significantly faster. In fact, as of July 2021, vaccine recipients from January 2021 exhibited only 16% effectiveness against infection and 16% protection against symptomatic infection, increasing linearly until reaching a level of 75% for those vaccinated in April. See Nathan Jeffay, Israeli, UK data offer mixed signals on vaccine's potency against delta strain, The TIMES OF ISRAEL (July 22, 2021), available at bit.ly/3xg3uCg (last visited Aug. 1, 2021).
- 53. Those who received a second dose of the Pfizer Vaccine between January and April of this year were determined to have 39% protection against infection and 41% protection against symptomatic infection. This further suggests that the large number of breakthrough infections was the result of waning vaccine protection as opposed to the spread of the Delta variant. See Carl Zimmer, Israeli Data Suggests Possible Waning Infection in Effectiveness of Pfizer Vaccine, THE

NEW YORK TIMES (July 23, 2021); Kristen Monaco, *Pfizer Vax Efficacy Dips at 6 Months*, MEDPAGE TODAY (July 29, 2021), *available at* https://bit.ly/2VheBxw (last visited Aug. 1, 2021).

- 54. Early data also suggests that naturally acquired immunity may provide greater protection against both the Delta and Gamma variants than vaccine-induced immunity. A recent analysis of an outbreak among a small group of mine workers in French Guiana found that 60% of fully vaccinated miners suffered breakthrough infections compared to *zero* among those with natural immunity. Nicolas Vignier, et al., *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinated Gold Miners, French Guiana, 2021*, 27(10) EMERG. INFECT. DIS. (Oct. 2021), available at bit.ly/2Vmjx43 (last visited Aug. 3, 2021).
- 55. In this vein, a mere few days ago, the CDC reported that "new scientific data" indicated that vaccinated people who experienced breakthrough infections carried similar viral loads to the unvaccinated (but not naturally immune), leading the CDC to infer that vaccinated people transmit the virus at concerning levels. *See CDC reversal on indoor masking prompts* experts to ask, "Where's the data?", WASHINGTON POST (July 28, 2021), available at wapo.st/2THpmIQ (last visited July 30, 2021).
- 56. Around three-quarters of cases in a Cape Cod outbreak occurred in vaccinated individuals, again demonstrating that the vaccines are inferior to natural immunity when it comes to preventing infection. *See* Molly Walker, *CDC Alarmed: 74% of Cases in Cape Cod Cluster Were Among the Vaxxed*, MEDPAGE TODAY (July 30, 2021), *available at* bit.ly/2V6X3UP (last visited July 30, 2021).
- 57. Many experts believe that the solution to "breakthrough" cases (individuals who become infected after vaccination or reinfection) is treating patients with a therapeutic intervention—not mandating vaccines for everyone, which will not entirely solve the problem for

the reasons discussed above. The availability and effectiveness of therapeutics thus bear on the validity of state actors' claims that a vaccine mandate is necessary to protect the public health. *See* Risch interview.

58. As Drs. Bhattacharya and Kulldorff have explained, there is no legitimate public-health rationale for GMU to require proof of vaccination to participate in activities that do not involve care for high-risk individuals:

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 and natural immunity, which provides benefits that are at least as strong[.] At the same time, the requirement for . . . proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice.

Joint Decl. ¶¶ 45-46.

## III. COVID-19 VACCINES CAN CAUSE SIDE EFFECTS, INCLUDING SEVERE ADVERSE EFFECTS

- 59. Though the COVID-19 vaccines appear to be relatively safe at a population level, like all medical interventions, they carry a risk of side effects. Those include common, temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and nausea. More rarely, they can cause serious side effects that result in hospitalization or death. Joint Decl. ¶¶ 24-25.
- 60. The vaccines could cause other side effects that remain unknown at this time given the preliminary, emergency stage of the vaccines' approval process. Joint Decl.¶ 27.

61. Put differently, as a matter of simple logic, one cannot be certain about the long-term effects of a vaccine that has existed only for approximately a year, and thus cannot have been studied over a substantial period of time. *See* Joint Decl. ¶ 26.

#### IV. PROFESSOR ZYWICKI HAS ROBUST NATURALLY ACQUIRED IMMUNITY TO COVID-19

- 62. Todd J. Zywicki is a GMU Foundation Professor of Law at the Antonin Scalia Law School.
- 63. He has been employed at GMU since August 1998, except for occasional service as a visiting professor at other law schools (including Georgetown University Law Center, Vanderbilt University Law School, and Boston College Law School) as well as high-level service in the United States government.
- 64. He is one of the law school's most frequently cited and influential scholars and has been an exemplary leader in service to GMU and the community.
- 65. In early March 2020, Professor Zywicki fell ill with symptoms consistent with a COVID-19 infection, including chills, night sweats, fatigue, and mental fogginess.
- 66. At that time, COVID-19 tests were scarce and required a doctor's prescription, so Professor Zywicki could not obtain one.
- 67. Professor Zywicki has subsequently tested positive for SARS-CoV-2 antibodies on several occasions when donating blood at the American Red Cross.
- 68. Professor Zywicki requested these tests because he had volunteered to teach in person beginning in the Fall 2020 semester and wanted to reassure students of his immunity status.
- 69. He received an unbroken string of positive COVID-19 antibody tests on July 25, September 29, and December 16, 2020, and February 9 and May 25, 2021.

- 70. On June 1, 2021, Professor Zywicki consulted with Dr. Hooman Noorchashm, an immunologist.
- 71. Dr. Noorchashm prescribed Professor Zywicki a full COVID-19 serological screening, which LabCorp. conducted a few days later. Noorchashm Decl. ¶ 7.
- 72. Just as Dr. Noorchashm expected, the screening confirmed that Professor Zywicki had previously recovered from SARS-CoV-2 and had a positive IgG Spike Antibody assay and a positive SARS-CoV-2 Nucleocapsid result. Noorchashm Decl. ¶ 7.
- 73. Professor Zywicki's semiquantitative antibody reading measured 715.6 U/ml—approximately 900 times higher than the baseline level of <0.8 and comparable to that possessed by vaccinated persons who share his age and health profile. Noorchashm Decl. ¶ 7.
- 74. Drs. Noorchashm and Bhattacharya have no doubt that Professor Zywicki has natural immunity because of his antibody levels. Noorchashm Decl. ¶ 7. See also Joint Decl. ¶ 40.
- 75. Professor Zywicki's antibodies and immune protection provide sufficient and durable protection against reinfection and transmission of COVID-19. Noorchashm Decl. ¶ 7.
- 76. Medical necessity is a fundamental tenet of medical ethics. This principle requires that public health agents utilize "the least intrusive" means possible to achieve a given end, because every medical procedure carries some risk. Noorchashm Decl. ¶ 10; *see also* Joint Decl. ¶ 39.
- 77. Based on his analysis of Professor Zywicki's antibodies screening test and overall medical history, Dr. Noorchashm concluded that *it is not medically necessary* for Professor Zywicki to undergo a full-course vaccination procedure to protect himself or the community from infection. Noorchashm Decl. ¶¶ 12-34.

- 78. Dr. Noorchashm also determined that a full-course vaccination procedure would expose Professor Zywicki to a heightened risk of adverse side effects that would exceed any speculative benefit the vaccine could confer on someone already protected with antibodies. Noorchashm Decl. ¶¶ 12-34.
- 79. Existing clinical reports and studies indicate that individuals with a prior infection and naturally acquired immunity face an *elevated* risk of adverse effects from the vaccine, compared to those who have never contracted COVID-19. Noorchashm Decl. ¶¶ 21-28.
- 80. This is consistent with understandings of immunology generally, which recognize that "vaccinating a person who is recently or concurrently infected [with any virus] can reactivate, or exacerbate, a harmful inflammatory response to the virus. This is NOT a theoretical concern[.]" Noorchashm Decl. ¶ 28.
- 81. Given these potential side effects, and the fact that Professor Zywicki possesses naturally acquired immunity that makes the vaccine medically unnecessary, Dr. Noorchashm concluded, in his expert medical opinion, that subjecting Professor Zywicki to a full vaccine course would pose a risk of undue harm and thereby violate a fundamental tenet of medical ethics. Noorchashm Decl. ¶¶ 19-30.
- 82. Professor Zywicki has real, substantial, and legitimate concerns about taking the vaccines in light of his naturally acquired immunity and the potential for short- and long-term side effects from the vaccines themselves.

## V. GMU'S IMPOSITION OF A BLANKET VACCINE REQUIREMENT AS PART OF ITS REOPENING POLICY AND PROFESSOR ZYWICKI'S EXEMPTION REQUEST

- 83. GMU is a public research university located in Fairfax (Fairfax County), Virginia, that offers a variety of undergraduate and graduate programs, including several courses of legal studies at the Antonin Scalia Law School (GMU's law school) in Arlington, Virginia. *See* George Mason University, *Wikipedia, available at* https://bit.ly/2TFxqtC (last visited July 28, 2021).
- 84. In 2019, the average age of the law student entering class averaged 25 years. George Mason University, *Profile of the Fall 2019 Entering Class*, available at bit.ly/3l6vGVF (last visited July 28, 2021).
- 85. On June 28, 2021, GMU announced via email its "campus reopening and vaccine requirements" for the Fall 2021 term. (Attachment C).
- 86. Another email addressing the Policy was distributed on July 22, 2021, to both employees and students (Attachment D), and a similar statement posted on GMU's website (Attachment E). *See* George Mason University, "COVID-19 Public Health and Safety Precautions Immunization (July 30, 2021), *available at* bit.ly/37irKJ6 (last visited Aug. 3, 2021).
- 87. According to GMU's Policy, all employees are "strongly encouraged to get vaccinated, and required to share their vaccination status[.]" (Attachment D).
- 88. The Policy requires "[a]ll George Mason University employees ... to submit proof of COVID-19 vaccination no later than August 1, 2021 or receive one dose of a World Health Organization (WHO) approved vaccine by August 15, 2021." (Attachment D).
- 89. Employees must "share vaccination status through Mason COVID Health Check and, if vaccinated, [their] documentation through the Health Service portal." (Attachment D).
- 90. Employees may seek a medical examination at their own cost, a religious exemption, or a 100%-remote-work exemption from their manager. (Attachment D).

- 91. Unvaccinated employees who do not obtain a work-from-home exemption must "wear masks while on campus, physically distance, and undergo frequent COVID-19 testing." (Attachment C).
- 92. Under the Policy, disclosure of vaccination status is also "a prerequisite for eligibility for any merit pay increases." (Attachment C).
- 93. Employees who "fail to receive an exemption and do not disclose their status and receive the vaccine" face "disciplinary action" that includes "unpaid leave or possible loss of employment." (Attachments D & E); *See* George Mason University, "COVID-19 Public Health and Safety Precautions Immunization."
- 94. GMU's Policy does not exempt faculty and staff with naturally-acquired immunity to COVID-19 acquired through recovery from prior infection. (Attachments C, D, E & I).
- 95. Based on personal information and correspondence, and without prejudice to what discovery may otherwise reveal, Defendants Farris and Zobel led the GMU Policy.
- 96. According to their publicly available biographies, neither Mr. Farris nor Ms. Zobel has any medical credentials.
- 97. Mr. Farris earned an undergraduate degree in Biology, a master's degree in Business Administration, and a Ph.D. in Education; he began employment at GMU as "Chemical Hygiene Officer" and subsequently was also tasked with fire-safety management responsibilities.
- 98. Ms. Zobel holds a bachelor's degree in Hazardous Materials/Environmental Management and Civil Engineering, a master's degree in Civil Engineering, and a Ph.D. in Biodefense.
- 99. On July 21, 2021, Professor Zywicki, through his counsel at NCLA, the undersigned, sent a letter to GMU representatives demanding that his naturally acquired immunity

be recognized as equivalent to vaccine immunity and that the University respond by July 28, 2021, due to the tight timetable. (Attachment G).

- 100. Through his physician, Dr. Noorchashm, Professor Zywicki requested an exemption on medical grounds, submitted July 23, 2021. Dr. Noorchashm stated that a vaccine posed a risk of harm to Professor Zywicki as a result of his naturally acquired immunity. (Attachment H).
- 101. GMU responded to NCLA's letter on July 30, 2021 and denied Professor Zywicki's request. It would not allow him a medical exemption on the grounds cited and did not recognize the validity of his legal arguments and contention that he should be treated as though he were vaccinated. (Attachment I).
- 102. Citing two CDC webpages, the letter states that "Mason is not currently exempting individuals who previously had COVID-19 from the vaccination requirement as such an exemption is not consistent with the guidance issued by the CDC." (Attachment I).
- 103. This guidance which underpinned GMU's denial of Professor Zywicki's request itself states that reinfection from COVID-19, "although rare," is possible. *See Frequently Asked Questions about COVID-19 Vaccination*, CDC (June 15, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (last viewed Aug. 3, 2021).
- 104. Likewise, the same webpage acknowledges that "[e]xperts are still learning more about how long vaccines protect against COVID-19" and that "[w]e don't know how long protection lasts for those who are vaccinated." *Id*.
- 105. According to Drs. Bhattacharya and Kulldorff, the CDC guidance is inapposite, as it does not address the extensive scientific literature contained in their declaration. Joint Decl. ¶ 36.

- 106. Furthermore, "[u]ncertainty 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. We do not know 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." Joint Decl. ¶ 36.
- 107. The doctors also note that "the immunological evidence to date suggests that protection against disease will last for years" and that "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." Joint Decl. ¶ 36.
- 108. Bhattacharya and Kulldorff also point out that "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." Joint Decl. ¶ 37. In fact, the CDC FAQ webpage upon which GMU relies states "[w]e don't know how long protection lasts for those who are vaccinated." *Id*.
- 109. The question that the CDC is addressing here is not even the one in contention, they go on to explain. Joint Decl. ¶ 38. The CDC is attempting 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 CDC's statement in the FAQ is non-responsive, and ignores the scientific evidence." Joint Decl. ¶ 38.
- 110. On August 2, 2021, GMU sent Professor Zywicki an email noting that he had not yet uploaded proof of vaccination into the online portal, and that if he does not do so, he will "be

out of compliance with this requirement and subject to disciplinary action, which can lead to being placed on unpaid administrative leave or eventual termination of employment." (Attachment J).

# VI. PROFESSOR ZYWICKI HAS EXPERIENCED, AND WILL CONTINUE TO EXPERIENCE, CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF GMU'S VACCINE POLICY

- 111. To remain unvaccinated without facing disciplinary action, Professor Zywicki must obtain an exemption to work at home. Otherwise, he must comply with punitive masking, testing, and social-distancing requirements, while facing the prospect of disciplinary action, including termination of employment and lost eligibility for merit pay raises. Under any of these scenarios, Professor Zywicki's personal autonomy and ability to perform his professional duties is being infringed upon.
- 112. Professor Zywicki is slated to teach 61 students in a first-year contracts course and 15 students in his public choice and public law seminar. These students enrolled in the course with the expectation of in-person instruction.
- 113. Masking requirements hinder Professor Zywicki's ability to communicate with students in a lecture environment.
- 114. The social distancing mandate prevents him from holding office hours or having lunches with students, participating in faculty workshops and meetings, and attending various academic events.
- 115. Likewise, frequent testing is burdensome, invasive, painful, and carries its own risk of physical injury.
- 116. Obviously, exercising a remote teaching option deprives students of the learning experience they signed up for, since presence in a classroom is crucial to effective instruction.

- 117. By imposing such impediments, the Policy prevents Professor Zywicki from carrying out his responsibilities as successfully as his vaccinated colleagues, jeopardizing his teaching evaluations, future student enrollment, opportunities for academic collaboration, reputational standing, pay raises, and other professional opportunities.
- 118. The Policy further damages Professor Zywicki by making disclosure of vaccination status a prerequisite for merit-based pay increases and threatening disciplinary action—including forced unpaid leave and termination of employment—if he does not obtain an exemption (religious or medical) or a COVID-19 vaccine. (Attachments C, D, & E).
- 119. Thus, although the Policy purports not to require vaccination, in reality and in effect it exerts such an enormous amount of pressure on Professor Zywicki to subject himself to receiving the vaccine (to avoid being professionally handicapped and facing loss of employment) that it amounts to an ineluctable mandate. It is obviously designed for that purpose and to have that impact.
- 120. By threatening adverse professional and personal consequences, GMU's Policy not only directly and palpably harms Professor Zywicki's bodily autonomy and dignity, but it forces him to endure the stress and anxiety of choosing between his teaching career and his health.
- 121. The risk-avoidance benefits that the Policy provides, compared to the restrictions and intrusive options offered to Professor Zywicki are disproportionate. Similarly, given that naturally acquired immunity confers equal or greater protection than that provided by the vaccines (especially with respect to some of the WHO-approved vaccines GMU considers adequate to fulfill the Policy's requirements), the Policy is arbitrary and irrational. There is no indication that the Policy is tailored to account for its impact on those who have acquired natural immunity.

122. Professor Zywicki requires relief on a tight timeline because GMU did not send the final email about its policy until a mere three weeks before the deadline it set for employees to receive the vaccine. (Attachments D & E). Any school's academic calendar may include minor deviations from year to year but typically includes Fall, Spring, and Summer semesters or programs. It has thus been foreseeable to GMU for months that Fall Semester law school classes would begin in August 2021.

#### **CLAIMS FOR RELIEF**

## COUNT I: VIOLATION OF THE RIGHT TO REFUSE UNWANTED AND MEDICALLY UNNECESSARY MEDICAL CARE

- 1. Plaintiff realleges and incorporates by reference the foregoing allegations as if fully set forth herein.
- 2. GMU's coercive Policy requires Professor Zywicki to take a vaccine without his consent—and against the expert medical advice of his immunologist—thereby depriving him of his ability to refuse unwanted medical care.
- 3. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" *Washington v. Harper*, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. *See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261, 278 (1990) ("At common law, even the touching of one person by another without consent and without legal justification was a battery"). *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984).); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) ('Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and

a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.').

- 4. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." *Cruzan*, 497 U.S. at 278; *King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).
- 5. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." *Washington v. Glucksberg*, 521 U.S. 702, 722 n.17 (1997).
- 6. The Court has explained that the right to refuse medical care derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco v. Quill*, 521 U.S. 793, 807 (1997).
- 7. Coercing employees to receive an EUA vaccine for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others, because those employees already possess natural immunity to the virus, violates the liberty and privacy interests that the Ninth and Fourteenth Amendments protect.
- 8. When a state policy implicates a fundamental right, through coercion or otherwise, the strict scrutiny standard "applies[;] a law will not be upheld unless the government demonstrates that the law is necessary to further a compelling governmental interest and has been narrowly tailored to achieve that interest." *Mohamed v. Holder*, 266 F. Supp. 3d 868, 877 (E.D. Va. 2017).
- 9. Defendants cannot show that they have a compelling interest in coercing Professor Zywicki into taking a COVID-19 vaccine, because GMU has no compelling interest in treating employees with natural immunity any differently from employees who obtained immunity from a vaccine.

- 10. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Noorchashm Decl. ¶ 16-17; Joint Decl. at ¶ 15-23); Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination In Previously Infected Individuals*, MEDRXIV (June 5th, 2021), *available at* https://bit.ly/2TFBGcA (last visited Aug. 1, 2021); *see also* Yair Goldberg, et al., *Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience From Israel*, MEDRXIV (Apr. 20, 2021), *available at* https://bit.ly/3zMV2fb (last visited Aug. 1, 2021); Smerconish, *Should Covid Survivors and the Vaccinated Be Treated the Same?*: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), *available at* https://cnn.it/2WDurDn (last visited Aug. 1, 2021); Marty Makary, *The Power of Natural Immunity*, WALL STREET JOURNAL (June 8, 2021), *available at* https://on.wsj.com/3yeu1Rx (last visited Aug. 1, 2021).
- 11. In recognition of the highly protective character of natural immunity, the European Union has recognized "a record of previous infection" as a substitute for any vaccine passport requirements. Noorchashm Decl. ¶ 27. Even France's controversial new restrictive mandate on the ability to participate in daily life focuses on a person's immunity rather than their vaccine status—treating natural immunity and vaccine immunity equally. *See, e.g.*, Clea Callcutt, *France forced to soften rules after coronavirus green pass backlash*, POLITICO (July 20, 2021), *available at* https://politi.co/3f9AZzS (last visited July 29, 2021).
- 12. Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Documentation of recovery suffices as a substitute, although proof of vaccination does not. See Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving

in the United States, CDC (July 6, 2021), available at https://bit.ly/3yfcJDM (last visited July 28, 2021).

- 13. Indeed, the CDC recently acknowledged that vaccinated individuals appear to be spreading COVID-19 at rates similar to unvaccinated (but not naturally immune) people. That further underscores the arbitrary nature of GMU's policy. *Where's the data*?, WASHINGTON POST (July 28, 2021), *available at* wapo.st/2THpmIQ (last visited July 30, 2021).
- 14. Likewise, recent data from Israel suggest that individuals who receive the Pfizer Vaccine can pass the virus onto others a mere few months after receiving it.
- 15. The Commonwealth of Virginia's public policy has also traditionally reflected that it lacks any interest in vaccinating persons for a disease to which they carry antibodies. For instance, the law mandating vaccination of school children for measles, mumps, rubella, and varicella (chickenpox) *explicitly exempts* from the requirements those who can demonstrate existing immunity through serological testing that measures protective antibodies. 12 Va. Admin. Code § 5-110-80 (2021).
- 16. GMU simply has no compelling interest in departing from the Commonwealth's typical public policy in this case. There is no question that Professor Zywicki has natural immunity, given his recent antibodies screening test demonstrating ongoing and robust immune protection as confirmed by his immunologist and Dr. Bhattacharya. Noorchashm Decl. ¶ 7; Joint Decl. ¶ 36.
- 17. In addition to GMU's lack of interest in requiring that already immune employees get vaccinated, Defendants cannot show that the Policy is narrowly tailored to any compelling governmental interest.

- 18. Any interest that GMU may have in promoting immunity on campus does not extend to those employees who already have natural immunity—particularly those who can demonstrate such immunity through antibody screenings.
- 19. Similarly, the much lower effectiveness of the Janssen, Sinovac, and Sinopharm vaccines in preventing infection, compared to natural immunity, renders Professor Zywicki far less likely to contract or spread the virus than his colleagues who have been immunized with these inferior vaccines. Yet having taken any of them would leave an otherwise similarly situated colleague at the law school free of GMU's restrictive Policy.
- 20. By failing to tailor its Policy to only those employees who lack immunity, GMU's Policy forces employees like Professor Zywicki, who have robust natural immunity, to choose between their health, their personal autonomy, and their careers.
- 21. Professor Zywicki has suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Professor Zywicki for the deprivation of his constitutional rights. He will suffer irreparable harm unless this Court enjoins Defendants from enforcing their Policy.
- 22. Professor Zywicki is entitled to a judgment declaring that the Policy violates his constitutional right to refuse medical treatment and an injunction restraining Defendants' enforcement of the Policy.

## COUNT II: VIOLATION OF THE UNCONSTITUTIONAL CONDITIONS DOCTRINE AND THE FOURTEENTH AMENDMENT'S RIGHT TO DUE PROCESS

- 23. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.
- 24. Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, GMU cannot impair Professor Zywicki's right to refuse medical care through subtle forms of coercion any more than it could through an explicit mandate. *See, e.g., Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"); *Memorial Hosp. v. Maricopa Cty.*, 415 U.S. 250 (1974) ("[An] overarching principle, known as the unconstitutional conditions doctrine ... vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up").
- 25. The Due Process Clause of the Fourteenth Amendment provides: "nor shall any state deprive any person of life, liberty, or property, without due process of law ...." U.S. Const., amend. XIV, sec. 1.
- 26. Professor Zywicki possesses both a liberty interest in his bodily integrity and, as a tenured professor, a property interest in his teaching career.
- 27. It is less appreciated in legal circles that, to prevail, unconstitutional conditions claims do not need to establish that a challenged government policy amounts to coercion. Instead, it is sufficient that the state policy burden a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right. In other words, the presence of some remaining voluntarism after new conditions are imposed on the exercise of a constitutional right does not stand as a barrier to establishing a successful unconstitutional

conditions claim. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder.

- 28. For example, in *Speiser v. Randall*, 357 U.S. 513 (1958), the Court invalidated a loyalty oath imposed as a condition for veterans to obtain a state property tax exemption, even though (a) California citizens were not required to own real property, of course; (b) California veterans could freely opt not to seek the exemption and simply pay the unadorned tax; and (c) California was not even obligated to provide veterans with the exemption but rather the exemption was a mere privilege.
- 29. The *Speiser* Court deemed the oath condition unconstitutional in part because the burden to establish qualification for the exemption was placed on applicants. *See id.* at 522. The question the Supreme Court saw itself deciding was "whether this allocation of the burden of proof, on an issue concerning freedom of speech, falls short of the requirements of due process." *Id.* at 523.
  - 30. The Court addressed this question by stating the guiding principle that

Where one party has at stake an interest of transcending value—as a criminal defendant his liberty—this margin of error is reduced as to him by the process of placing on the other party the burden of producing a sufficiency of proof in the first instance .... [But] Due process commands that no man shall lose his liberty unless the Government has borne the burden of producing the evidence and convincing the factfinder of his guilt.

*Id.* at 525-26.

31. Here, the analogue of the criminal defendant rights of "transcending value" referenced in *Speiser* are the liberty rights of all persons to be free of unconsented-to bodily intrusions and medical interventions. This means that unconstitutional conditions doctrine and due process rights *combine* to invalidate the Policy. That result occurs because GMU has not and

cannot show that the school's forcing Professor Zywicki to take the vaccine reduces any risk that he will become infected with and spread the virus to GMU students and personnel. *See also Lawrence v. Texas*, 539 U.S. 558, 562 (2003) (The Due Process Clause protects "liberty of the person both in its spatial and in its more transcendent dimensions").

- 32. Similar to the California law in *Speiser* "creat[ing] the danger that ... legitimate utterance will be penalized," 357 U.S. at 526, the process GMU has established in relation to taking COVID-19 vaccines poses dangers to Professor Zywicki's health (and thus to his liberty interests) as well as threatening him with various forms of penalties and other detriments.
- 33. Indeed, more so than in *Speiser*, the factual issues involved in this case are complex. "How can a claimant ... possibly sustain the burden of proving the negative of these complex factual elements? In practical operation, therefore, this procedural device must necessarily produce a result which the State could not command directly." *Id.* There is perhaps no better encapsulation by the Supreme Court of how unconstitutional conditions doctrine and Due Process can and do intersect and reinforce one another. *See also id.* at 529 ("The State clearly has no such compelling interest at stake as to justify a short-cut procedure which must inevitably result in suppressing protected speech."). The Commonwealth of Virginia's GMU similarly possesses no compelling interest that could justify its defective Policy that will inevitably result in at least some unwarranted medical intrusions into the bodies of members of the GMU community.
- 34. For these reasons, GMU cannot by means of its Policy effectively flip the burden of proof and require Professor Zywicki to prove that it is safe for him to teach without being vaccinated. And setting up such a process, which is what GMU's Policy does, thereby represents

a concurrent *procedural* due process violation and an unconstitutional condition burdening his liberty interests to be free of unwanted medical interventions.

- 35. Speiser also rests on the mismatch between the loyalty oath California required and the grant of a property tax exemption to veterans. "[T]he State is powerless to erase the service which the veteran has rendered his country; though he be denied a tax exemption, he remains a veteran." *Id.* at 528.
- 36. In this situation, there is an equally jarring logical incongruity. GMU's Policy is terse. It offers no justifications for why the penalties and other restrictions it establishes are appropriate and tailored to members of the University community that have acquired robust natural immunity. Whatever GMU is trying to decree through its unconstitutional-conditions sleight of hand, Professor Zywicki remains a University community member with natural immunity as a matter of pre-Policy fact (just as the *Speiser* veterans remained veterans as a matter of pre-tax law fact), and the existence of such immunity fully serves the supposed purposes of the public-health protection that GMU says that it is pursuing.
- 37. The proportionality of the Policy is also deficient because the Policy does not seek to assess the current antibody levels of its targets, something that is it is now feasible for medical science to test.<sup>6</sup> For the Policy is not a mere presumption that vaccination is superior to natural immunity (a contention that would have to be borne out by the science in any event or else GMU had no business adopting its Policy) that Professor Zywicki can try to overcome. No, the Policy

<sup>&</sup>lt;sup>6</sup> Such antibody testing was not feasible more than a century ago when *United States v. Jacobson* was decided, as diagnostic antibody testing was not invented until the 1970's. 197 U.S. 11 (1905) (upholding a city regulation fining individuals \$5 if they refused to take Smallpox vaccine). *See The history of ELISA from creation to COVID-19 research*, MOLECULAR DEVICES, *available at* https://www.moleculardevices.com/lab-notes/microplate-readers/the-history-of-elisa (last visited Aug. 1, 2021).

is, in essence, *a conclusive presumption* that vaccination (even as to vaccines of far-lesser efficacy) is required unless the risks of the vaccine to a particular recipient warrant a special exception. But what if Professor Zywicki and others with natural immunity possess *higher* levels of antibodies than at least many of those who took one or more of the various inferior vaccines? And why has GMU deemed all vaccines to be equally protective in the fictitious presumption it has established? Finally, is there any scientific basis for the presumptions GMU has built into its Policy? The Policy answers none of these questions. It does not even try.

For these reasons, the *de facto* presumptions the Policy establishes also become another part of GMU's procedural due process violations that also run afoul of unconstitutional conditions doctrine. In short, allocating burden of proof responsibility to those with natural immunity like Professor Zywicki, coupled with GMU's stacking the process with presumptions Plaintiff will show are scientifically unwarranted, contravene the Due Process Clause. *See Perry v. Sinderman*, 408 U.S. 592, 597 (1972) (holding that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"); *Wieman v. Updegraff*, 344 U.S. 183, 192 (1952) ("We need not pause to consider whether an abstract right to public employment exists. It is sufficient to say that constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory").

38. "Since the entire statutory procedure, by placing the burden of proof on the claimants, violated the requirements of due process, appellants were not obliged to take the first step in such a procedure." *Id.* at 529. Just so here. GMU's Policy makes a mockery of due process. As a result, Professor Zywicki was not even obligated to take the first step in the Policy to gain an exception from its terms. Nevertheless, Professor Zywicki went above and beyond and applied for a medical exemption anyway. But the Policy's burden-shifting and erroneous

embedded presumptions worked just as GMU designed them, leading unsurprisingly to the predictable *ex ante* outcome that Professor Zywicki was going to be denied a medical exemption. Professor Zywicki gave the deficient process set out in the Policy more than the benefit of the doubt, but it has now become apparent that it is as flawed in practice as it appears on its face.

#### **COUNT III—VIOLATION OF THE SUPREMACY CLAUSE**

- 39. Plaintiff realleges and incorporates by reference all the foregoing allegations as though fully set forth herein.
- 40. Defendants' Policy requires Professor Zywicki to receive a vaccine in order to teach effectively without regard to his natural immunity or the health risks he faces.
- 41. He also must divulge personal medical information by uploading it into an online portal and is threatened with disciplinary action if he declines to comply with these arbitrary mandates.
- 42. The Policy thus coerces or, at the very least, unduly pressures Professor Zywicki into getting a vaccine that FDA approved only for emergency use.
- 43. The United States Constitution and federal laws are the "Supreme Law of the Land" and supersede the constitutions and laws of any state. U.S. Const. art. VI, cl. 2.
- 44. "State law is pre-empted to the extent that it actually conflicts with federal law." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (internal citations and quotation marks omitted).
- 45. Federal law need not contain an express statement of intent to preempt state law for a court to find any conflicting state action invalid under the Supremacy Clause. *See Geier v. American Honda*, 520 U.S. 861, 867-68 (2000).

- 46. Rather, federal law preempts any state law that creates "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399-400 (2012).
- 47. The EUA statute mandates informed and voluntary consent. *See John Doe No. 1* v. *Rumsfeld*, No. Civ. A. 03-707(EGS), 2005 WL 1124589, \*1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA "on a *voluntary* basis"). *See also* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).
- 48. It expressly states that recipients of products approved for use under it be informed of the "option to accept or refuse administration," and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id.*
- 49. Since GMU's Policy (a state program) coerces Professor Zywicki by making enjoyment of his constitutionally and statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute. *See* 21 U.S.C. § 360bbb-3.
- 50. The conflict between the Policy and the EUA statute is particularly stark given that the statute's informed consent language requires that recipients be given the "option to refuse" the EUA product. That is at odds with the Policy's forcing Professor Zywicki to sustain significant injury to his career if he does not want to take the vaccine (in light of masking, frequent testing, social distancing, and looming disciplinary action).
- 51. Put differently, the Policy frustrates the objectives of the EUA process. *See Geier*, 520 U.S. at 873 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

- 52. As noted above, OLC made a memorandum available to the public on July 27, 2021 (dated July 6, 2021) opining that the EUA status of a medical product does not preclude vaccine mandates that might be imposed by either the public or private sectors. See "Memorandum Opinion for the Deputy Counsel to the President," Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization (July 6, 2021) (OLC Op.) at 7-13, available at https://www.justice.gov/olc/file/1415446/download (last visited Aug.1, 2021).
- 53. Of course, the separation of powers dictates that this Court is not bound by the OLC Opinion—an advisory opinion written by the Executive Branch for the Executive Branch. *See Citizens for Responsibility & Ethics in Wash. v. Office of Admin.*, 249 F.R.D. 1 (D.C. Cir. 2008) ("OLC opinions are not binding on the courts[; though] they are binding on the executive branch until withdrawn by the Attorney General or overruled by the courts[.]") (cleaned up).
- 54. Relatedly, the Justice Department until only days ago took a very different approach. See Attorney General Memorandum, Balancing Public Safety with the Preservation of Rights 27, 2020), available https://www.justice.gov/opa/page/ Civil (Apr. at file/1271456/download (last visited Aug. 1, 2021, 2021) ("If a state or local ordinance crosses the line from an appropriate exercise of authority to stop the spread of COVID-19 into an overbearing infringement of constitutional and statutory protections, the Department of Justice may have an obligation to address that overreach in federal court."). See also Kevin Liptak, CNN, Biden Jumps Into Vaccine Mandate Debate as VA Requires Health Workers to Get Vaccinated (July 26, 2021) ("The [new OLC] opinion marks a reversal from the previous administration. Last year, Attorney General William Barr used the Justice Department's legal power to try to fight certain Covid

restrictions, including joining some businesses that sought to overturn state mask mandates."), available at cnn.it/37bwAbl (last visited Aug. 1, 2021).

- 55. Moreover, the OLC Opinion is entirely silent on the issue of preemption. As such, it cannot be read even as offering a potentially persuasive legal view on whether the GMU Policy is preempted by the EUA statute or not. In light of what this Count pleads, the OLC opinion is a legal *non sequitur*.
- 56. The OLC Opinion is also premised on faulty reasoning. While recognizing that EUA products have "not yet been generally approved as safe and effective," and that recipients must be given "the option to accept or refuse administration of the product," the Opinion nevertheless maintains that the EUA vaccines can be mandated. OLC Op. at 3-4, 7.
- 57. According to OLC, the requirement that recipients be "informed" of their right to refuse the product does not mean that an administrator is precluded from mandating the vaccine. All that an administrator must do, in OLC's view, is tell the recipient they have the *option* to refuse the vaccine. *Id.* at 7-13.<sup>7</sup> That facile interpretation sidesteps the fact that the Policy's employment consequences effectively coerce or at least unconstitutionally leverage the GMU community into taking the vaccine, reducing to nothingness both the constitutional and statutory rights of informed consent. This approach of stating the obvious but ignoring competing arguments is likely why the Opinion remained mum on the doctrine of preemption.

<sup>&</sup>lt;sup>7</sup> The OLC opinion is as irrelevant to the constitutional questions in this case posed by Counts I and II as it is to the preemption questions in Count III. For it was no answer in *Speiser* to the due process and unconstitutional conditions problems created by California's property tax exemption and oath system to quickly breathe a sigh of relief because California tax authorities could simply tell veterans applying for the tax exemption that they could just go away and forgo the tax exemption. The Constitution and the text of congressional statutes cannot be so easily dodged.

- 58. Recognizing the illogic of the Opinion and its inability to square its construction with the text of the EUA statute, OLC admits that its "reading ... does not fully explain why Congress created a scheme in which potential users of the product would be informed that they have 'the option to accept or refuse' the product." *Id.* at 10. This understatement would be droll but for the serious rights at stake, especially given that the elephant in the room—which the OLC Opinion ignores—is the Supremacy Clause and the preemption doctrine that Clause powers. In truth, Congress called for potential users to be informed precisely so that they could refuse to receive an EUA product. OLC's obtuse reading of the statute blinks reality.
- 59. In other words, nothing in the OLC Opinion addresses the fact that if it were taken as a blanket authorization for state and local governments to impose vaccine mandates, a vital portion of the EUA statute's text would be rendered superfluous. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") (cleaned up).
- 60. Yet, OLC turns around and claims that Congress would have explicitly stated if it intended to prohibit mandates for EUA products. *Id.* at 8-9. But Congress *did* say so. The plain language states that the recipient of an EUA vaccine must be informed "of the option to accept or refuse the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Especially when read against the backdrop of what the Constitution requires *and* against the common law rules from which the constitutional protections for informed consent arose, Congress's intent to protect informed consent is pellucid. And Congress "is understood to legislate against a background of commonlaw ... principles," *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991).

- 61. The EUA statute's prohibition on mandating EUA products is reinforced by a corresponding provision that allows the President, in writing, to waive the option of those in the U.S. military to accept or refuse an EUA product if national security so requires. 10 U.S.C. § 1107a(a)(1). That provision would be redundant if consent could be circumvented merely by telling a vaccine recipient that he or she is free to refuse the vaccine but would nonetheless encounter various adverse consequences that violated unconstitutional conditions doctrine.
- 62. To circumvent the statutory text about the military waiver, OLC spins out a tortured argument under which the President's waiver would merely deprive military members of their rights to *know* that they can refuse the EUA product—rather than waiving their rights to actually refuse the product. OLC Op. at 14-15.
- 63. Unsurprisingly, OLC's strained reading runs counter the Department of Defense's understanding of this statutory provision. As the OLC Opinion acknowledges, "DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a." *Id.* at 16 (citing DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008)).
- 64. OLC even acknowledges that its opinion is belied by the congressional conference report, which also contemplated that 10 U.S.C. § 1107a(a)(1) "would authorize the President to waive the right of service members to refuse administration of a product if the President determines, in writing, that affording service members the right to refuse a product is not feasible[.]" *Id.* (quoting H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.)).

- 65. Unlike OLC, this Court must not ignore the plain statutory prohibition on mandating EUA products. Though released to much fanfare in the media, the Court should discount the severely flawed OLC Opinion in its entirety, affording it no weight in this litigation.
- 66. Just as Congress prohibited the federal government from mandating EUA products, the state governments cannot do so, for the Supremacy Clause dictates that the EUA statute must prevail over conflicting state law or policy.
- 67. Defendants' Policy is thus preempted by federal law. *See* U.S. Const. art. VI, cl. 2; *see also Kindred Nursing Ctrs. Ltd P'ship v. Clark*, 137 S. Ct. 1421 (2017) (holding that Federal Arbitration Act preempted incompatible state rule); *Hughes v. Talen Energy Marketing, LLC*, 136 S. Ct. 1288, 1297 (2016) ("federal law preempts contrary state law," so "where, under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" the state law cannot survive).
- 68. Defendants' Policy is invalid pursuant to Article VI, Cl. 2 of the United States Constitution, and must be enjoined and set aside.

#### ADDITIONAL LEGAL CLAIMS

- 69. Professor Zywicki has suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Professor Zywicki for the deprivation of his constitutional or statutory rights. He will suffer irreparable harm unless this Court enjoins Defendants from enforcing their Policy.
- 70. 42 U.S.C. § 1983 provides a civil right of action for deprivations of constitutional protections taken under color of law.

- 71. Professor Zywicki is entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 because he is being deprived of "rights, privileges, or immunities secured by the Constitution and laws." Section 1983 thus supports both Professor Zywicki's constitutional and statutory causes of action against the GMU defendants because Section 1983 protects rights "secured by the Constitution *and* laws." 42 U.S.C. § 1983 (emphasis added).
- 72. Likewise, Professor Zywicki is entitled to injunctive relief pursuant to *Ex parte Young*'s nonstatutory equitable right of action. *See Verizon Md., Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 648 (2002) ("We conclude that 28 U.S.C. § 1331 provides a basis for jurisdiction over Verizon's claim that the Commission's order requiring reciprocal compensation for ISP-bound calls is pre-empted by federal law. We also conclude that the doctrine of *Ex parte Young* permits Verizon's suit to go forward against the state commissioners in their official capacities.").
- 73. In sum, Professor Zywicki is entitled to a judgment declaring that the Policy violates the Supremacy Clause and an injunction restraining Defendants' enforcement of the Policy, since it is preempted by federal law.

#### RELIEF REQUESTED

**WHEREFORE,** Plaintiff respectfully requests that the Court find the Defendants have committed the violations alleged and described above, and issue in response the following:

- A. A declaratory judgment that GMU's Policy infringes upon Plaintiff's constitutionally protected rights to protect his bodily integrity and to refuse unnecessary medical treatment.
- B. A declaratory judgment that GMU's Policy represents an unconstitutional condition, especially in light of a set of explicit and implicit procedures established in the Policy that violates the Due Process Clause of the Fourteenth Amendment.

C. A declaratory judgment that GMU's Policy violates the Supremacy Clause of the United States Constitution because the Policy, a state program, conflicts with the federal EUA Statute;

**AND** 

D. Injunctive relief restraining and enjoining Defendants, their officers, agents, servants, employees, attorneys, and all persons in active concert or participation with them (*see* Fed. R. Civ. P. 65(d)(2)), and each of them, from enforcing coercive or otherwise pressuring policies or conditions similar to those in the Policy that act to compel or try to exert leverage on GMU employees with natural immunity to get a COVID-19 vaccine.

#### **JURY DEMAND**

Plaintiff herein demands a trial by jury of any triable issues in the present matter.

August 3, 2021

Respectfully submitted,

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Local Counsel for the Plaintiff

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Pro hac vice application forthcoming

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Attorney for Plaintiff

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JS 44 (Rev. 04/21)

#### **CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet.

(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

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(c) Attorneys (Firm Name, Address, and Telephone Number) Jenin Younes, NCLA; 1225 19th Street NW, Washing				Attorneys (If Known)							
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### **ATTACHMENT A**

#### Joint Declaration of Dr. Jayanta Bhattacharya and Dr. Martin Kulldoff

We, Drs. Jayanta ("Jay") Bhattacharya and Martin Kulldorff provide the following Joint Declaration:

#### **Background**

- 1. Dr. Jay Bhattacharya is a Professor of Medicine at Stanford University and a research associate at the National Bureau of Economic Research. He is also Director of Stanford's Center for Demography and Economics of Health and Aging. He holds an M.D. and Ph.D. from Stanford University. He has published 152 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. His research has been cited in the peer-reviewed scientific literature more than 11,000 times.
- 2. Dr. Martin Kulldorff is a Professor of Medicine at Harvard Medical School, and he is a biostatistician and epidemiologist at Brigham and Women's Hospital. He holds a Ph.D. from Cornell University. He is the author of 237 published articles in leading medical, epidemiological, statistics, and science journals, cited over 25,000 times in peer-reviewed scientific journals. Dr. Kulldorff is recognized internationally for his foundational research on the monitoring of vaccines and other medical health and safety issues. His methods are routinely used by the Centers for Disease Control and Prevention ("CDC") and other public health agencies around the world.
- 3. Both of us have dedicated our professional careers to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions.
- 4. We have both 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"). We are 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.

- 5. Our assessment of vaccine immunity is based on studies related to the efficacy and safety of the three vaccines that have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) for use in the United States. These include two mRNA technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus vector vaccine technology (manufactured by Johnson & Johnson).
- 6. Neither of us has received any financial or other compensation to prepare this Declaration. Nor have we ever received any personal or research funding from any pharmaceutical company. In writing this, we are motivated solely by our commitment to public health.
  - 7. Neither of us has an existing doctor-patient relationship with Professor Zywicki.
- 8. We have been asked to provide our opinion on several matters related to George Mason University's (GMU or University) vaccine policy for faculty and staff (the "mandatory vaccination" policy), including the following:
  - a. Whether, based on the current medical and scientific knowledge, 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; and

- c. An assessment of the comparative safety to recipients of administering vaccines to those who have natural immunity relative to immunologically naïve recipients with no prior history of COVID infection.
- 9. Our opinions are summarized in a recent article we published and which we reaffirm here: "[R]ecovered COVID patients have strong, long-lasting protection against severe disease if reinfected, and evidence about protective immunity after natural infection is at least as good as from the vaccines. Hence, it makes no sense to require vaccines for recovered patients. For them, it simply adds a risk, however small, without any benefit."

### Mortality Risk from COVID-19 Infection and Corresponding Marginal Benefit From Vaccination Varies By Orders of Magnitude Based on Age

10. The mortality risk posed by COVID infection is a fundamental parameter necessary to understand the lack of net public health benefits from vaccine mandates and passports. The best evidence on the infection fatality rate from SARS-CoV-2 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 within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or a positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts; these both miss infected people who are not identified by the public health authorities or do not volunteer for RT-PCR testing. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports or positive test counts are substantially biased upwards. According to a meta-analysis (published by the World Health Organization) by Dr. John Ioannidis of every seroprevalence study

<sup>&</sup>lt;sup>1</sup> Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

conducted with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival 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%.<sup>2</sup> A newly released meta-analysis by scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.<sup>3</sup>

- 11. The mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at higher risk of death if infected, while younger patients face a vanishingly small risk.<sup>4</sup> The same is true for hospitalization risk, which is similarly age-dependent. The best evidence on age-specific infection fatality rates comes again from seroprevalence studies.
- 12. The CDC's best estimate of the infection fatality ratio for people ages 0-19 years is 0.00002, meaning infected children have a 99.998% infection survivability rate.<sup>5</sup> The CDC's best estimate of the infection fatality rate for people ages 20-49 years is 0.0005, meaning that young adults have a 99.95% survivability rate. The CDC's best estimate of the infection fatality rate for people age 50-64 years is 0.006, meaning this age group has a 99.4% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 65+ years is .09, meaning seniors have a 91.0% survivability rate.
- 13. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the *Lancet*)<sup>6</sup> provides a detailed age breakdown of the infection survival rate in a preprint

<sup>&</sup>lt;sup>2</sup> Ioannidis JPA, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, Bull World Health Organ (Jan 1, 2021).

<sup>&</sup>lt;sup>3</sup> Andrew T. Levin, et al., Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications, MEDRXIV (Aug. 14, 2020), https://bit.ly/3gpIoIV.

<sup>&</sup>lt;sup>4</sup> Kulldorff M., *COVID-19 Counter Measures Should Be Age-Specific*, LINKEDIN (Apr. 10, 2020), https://www.linkedin.com/pulse/covid-19-counter-measures-should-age-specific-martin-kulldorff/.

<sup>&</sup>lt;sup>5</sup> Centers for Disease Control and Prevention, *COVID-19 Pandemic Planning Scenarios*, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

<sup>&</sup>lt;sup>6</sup> Silvia Stringhini, et al., Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study, THE LANCET (June 11, 2020), https://bit.ly/3187S13.

companion paper<sup>7</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 years old.

14. In summary, the mortality risk posed by COVID infection in the young is vanishingly small, while the threat posed to the elderly is orders of magnitude higher. One direct corollary of this point is that the corresponding personal benefit from vaccination, at least as far as mortality risk is concerned, is orders of magnitude lower for the young relative to the elderly.

### **Both Vaccine Immunity and Natural Immunity Provide Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected**

- 15. 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.
- 16. Both types are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibodies level 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>8,9</sup> A Phase III trial

<sup>&</sup>lt;sup>7</sup> Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland*, OSF PREPRINTS (June 15, 2020), https://osf.io/wdbpe/.

<sup>&</sup>lt;sup>8</sup> Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T., *COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, N ENGL J MED (Feb. 4, 2021).

<sup>&</sup>lt;sup>9</sup> Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL,

showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.<sup>10</sup>

- 17. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells<sup>11</sup>, bone marrow plasma cells<sup>12</sup>, spike-specific neutralizing antibodies <sup>13</sup>, and IgG+ memory B cells<sup>14</sup> following naturally acquired immunity.
- 18. 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).

Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC, Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine, N ENGL J MED. (Dec. 31, 2020).

<sup>&</sup>lt;sup>10</sup> Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, Goepfert PA, Truyers C, Fennema H, Spiessens B, Offergeld K, Scheper G, Taylor KL, Robb ML, Treanor J, Barouch DH, Stoddard J, Ryser MF, Marovich MA, Neuzil KM, Corey L, Cauwenberghs N, Tanner T, Hardt K, Ruiz-Guiñazú J, Le Gars M, Schuitemaker H, Van Hoof J, Struyf F, Douoguih M, Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19, N ENGL J MED (June 10, 2021), 2187-2201.

<sup>&</sup>lt;sup>11</sup> Jennifer M. Dan, et al., *Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection*, SCIENCE (Feb. 5, 2021) (finding that memory T and B and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility for most individuals").

<sup>12</sup> Jackson S. Turner, et al., *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, NATURE (May 24, 2021) (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"); Ewen Callaway, *Had COVID? You'll probably make antibodies for a lifetime*, NATURE (May 26, 2021), 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>13</sup> Tyler J. Ripperger, et al., *Orthogonal SARS-Cov-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humor Immunity*, 53 IMMUNITY, Issue 5, pp. 925-933 E4 (Nov. 17, 2020) (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

<sup>&</sup>lt;sup>14</sup> Kristen W. Cohen, et al., Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells, MEDRXIV (Apr. 27, 2021), https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v1 (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").

19. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19<sup>15</sup> and show that the vast majority of reinfections are less severe than first-time infections. <sup>16</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>17</sup> Of the 187,549 unvaccinated 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

<sup>&</sup>lt;sup>15</sup> Nabin K. Shrestha, et al., *Necessity of COVID-19 vaccination in previously infected individuals*, MEDRXIV (preprint),

https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3. ("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 those with natural immunity are "unlikely to benefit from covid-19 vaccination"); Galit Perez, et al., A 1 to 1000 SARS-CoV-2 reinfection proporation in members of a large healthcare provider in Israel: a preliminary report, MEDRXIV (Mar. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1 (Israeli study finding that approximately 1/1000 of participants were reinfected); Roberto Bertollini, et al., Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar, JAMA (June 9, 2021), https://jamanetwork.com/journals/jama/fullarticle/2781112?resultClick=1 (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); Stefan Pilz, et al., SARS-CoV-2 re-infection risk in Austria, Eur. J. CLIN. INVEST. (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988582/(previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Aodhan Sean Breathnach, et al., Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies, 82 J. OF INFECTION e11-e12 (2021) https://doi.org/10.1016/j.jinf.2021.05.024 (.0.86% of previously infected population in London became reinfected); Alison Tarke, Negligible impact of SARSOCoV-2 variants on CD4 and CD8 T cell reactivity in COVID-19 exposed donors and vaccines, BIORXIV (Mar. 1, 2021), https://www.biorxiv.org/content/10.1101/2021.02.27.433180v1 (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 both recovered Covid patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

<sup>&</sup>lt;sup>16</sup> Laith J. Abu-Raddad, et al., SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals followed for up to 35 weeks, MEDRXIV (Feb. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.01.15.21249731v2 (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); Victoria Jane Hall, et al., SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study, 397 LANCET: 1459-69 (Apr. 9, 2021), https://pubmed.ncbi.nlm.nih.gov/33844963/ (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"); Aidan T. Hanrah, et al., Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection, **JOURNAL** OF INFECTION, Issue 4. E29-E30 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832116/ (Apr. 1, 2021) (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).

<sup>&</sup>lt;sup>17</sup> Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2. vaccine protection: A three-month nationwide experience from Israel*, MEDRXIV (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

over 80 years of age. 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.

- 20. 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."<sup>18</sup>
- 21. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 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. A *Nature* paper from 2008 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>20</sup>
- 22. 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>21</sup>

<sup>&</sup>lt;sup>18</sup> Chris Baranjuk, How long does covid-19 immunity last? 373 BMJ (2021) (emphasis added).

<sup>&</sup>lt;sup>19</sup> Nina Le Bert, SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control, NATURE (Aug. 2020).

 $<sup>^{20}</sup>$  Xiaocong Yu, et al., *Neutralizing antibodies derived form the B cells of 1918 influenze pandemic survivors*, NATURE (2008).

<sup>&</sup>lt;sup>21</sup> Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses hove taught scientists*, 594 NATURE 164 (June 10, 2021), https://www.nature.com/articles/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.").

23. In short, there is no medical or scientific reason to believe that vaccine immunity will prove longer-lasting than natural immunity, much less that all currently approved vaccines will be expected to prove more durable than natural immunity despite their different technological foundations and dosing protocols.

#### Vaccine Side Effects Do Occur, Including Rare But Deadly Side Effects

- 24. Though the COVID vaccines are safe by the standards of many other vaccines approved for use in the population, like all medical interventions, they have side effects. In summarizing the evidence on vaccine side effects, the CDC lists both common side effects, at least one of which occurs in over half of all people who receive the vaccines, as well as deadly side effects that occur rarely in demographic subsets of the vaccinated population.
- 25. The common side effects include pain and swelling at the vaccination site and fatigue, headache, muscle pain, fever, and nausea for a limited time after vaccination.<sup>22</sup> Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur immediately after vaccination, which can typically be treated with an epinephrine injection if it occurs.<sup>23</sup> Finally, the CDC's vaccine safety committee has identified rare but deadly side effects, including a heightened risk of clotting abnormalities<sup>24</sup> in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis<sup>25</sup> in young people but especially young men after mRNA vaccination, and higher risk of

<sup>&</sup>lt;sup>22</sup> Centers for Disease Control, *Possible Side Effects After Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.

<sup>&</sup>lt;sup>23</sup> Centers for Disease Control, *What to Do If You Have an Allergic Reaction after Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.

<sup>&</sup>lt;sup>24</sup> Martin Kulldorff, *The Dangers of Pausing the J&J Vaccine*, THE HILL (April 17, 2021), https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine.

<sup>&</sup>lt;sup>25</sup> Centers for Disease Control, *Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults* (May 28, 2021), https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.

Guillane-Barre Syndrome<sup>26</sup> after the J&J vaccine. There is still the possibility of severe side effects that have yet to be identified as the vaccines have been in use in human populations for less than a year. Active investigation to check for safety problems is still ongoing.

- 26. Though the CDC<sup>27</sup> still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts<sup>28</sup> have objected to overly rosy assumptions made in the CDC analysis about vaccine side effects. They suggest that the recommendation is fragile to minor perturbation in their assumptions. The critical point for our analysis undisputed in the scientific literature is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known at this point in time.
- 27. Some clinical evidence indicates that those who have recovered from COVID-19 could have a *heightened* risk of adverse effects compared with those who have never had the virus.<sup>29 30</sup> This may be because vaccaine reactogenicity after the first dose is higher among those with prior immunity.<sup>31</sup>

<sup>&</sup>lt;sup>26</sup> LaFranier and Weiland, *FDA Attaches Warning of Rare Nerve Syndrome to Johnson & Johnson Vaccine*, NEW YORK TIMES (July 12, 2021), https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html.

<sup>&</sup>lt;sup>27</sup> Walensky, *CDC Director Statement on Pfizer's Use of COVID-19 Vaccine in Adolescents Age 12 and Older* (May 12, 2021), https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html.

<sup>&</sup>lt;sup>28</sup> Pegden, Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses (June 24, 2021), https://medium.com/@wpegden?p=d7d6b3df7cfb.

<sup>&</sup>lt;sup>29</sup> Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).

<sup>&</sup>lt;sup>30</sup> Cristina Menni, *Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study*, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021) (finding that "Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 [i.e., AstraZeneca vaccine] and 2.9 times after the first dose of BNT162b2 [i.e., Pfizer/BioNTech vaccine]) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2).").

<sup>&</sup>lt;sup>31</sup> Florian Krammer, et al., *Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a singe dose of SARS-CoV-2 mRNA vaccine*, MEDRXIV (Feb. 1, 2021), https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1 (concluding that "vaccine reactogenicity after the first dose is substantially more pronounced in individuals with pre-existing immunity." The authors note that "quantitative serological assays that measure antibodies to the spike protein could be used to screen individuals prior to vaccination," which would "limit the reactogenicity experienced by COVID-19 survivors.).

#### Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

- 28. Since its spread through the human population, the SARS-CoV-2 virus an RNA virus—has been mutating, including some forms that are likely more transmissible than the original wild-type virus that emerged from Wuhan, China, in 2019. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that a vaccine mandate for young people is unwarranted.
- 29. First, the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination. Although reinfection can occur, people who have been previously infected by the wild-type (non-variant) virus are unlikely to have a severe outcome (hospitalization or death) after exposure to a variant virus. A variant circulating in the population thus poses little additional risk of hospital overcrowding or excess mortality due to viral infection.
- 30. Second, theoretical work suggests that lockdowns place selective pressure that promotes the development and establishment of more deadly variants. This, in part, may explain why the most concerning variants have emerged in places like the U.K., South Africa, and California, where severe lockdowns have been imposed for extended periods.<sup>35</sup> While this hypothesis awaits a definitive empirical test, it is consistent with the *prima facie* evidence on mutant variants' development.

<sup>&</sup>lt;sup>32</sup> Alison Tarke, A., Sidney, J., Methot, N., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., da Silva Antunes, R., Frazier, A., Rawlings, S. A., Smith, D. M., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A., & Sette, A., *Negligible impact of SARS-CoV-2 variants on CD4 + and CD8 + T cell reactivity in COVID-19 exposed donors and vaccinees*, BIORXIV, 2021.02.27.433180 (2021), https://doi.org/10.1101/2021.02.27.433180. 
<sup>33</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., *mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants*, BIORXIV: THE PREPRINT SERVER FOR BIOLOGY, 2021.01.25.427948 (2021), https://doi.org/10.1101/2021.01.25.427948.

<sup>&</sup>lt;sup>34</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., *CD8+ T cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants*, MEDRXIV: THE PREPRINT SERVER FOR HEALTH SCIENCES, 2021.02.11.21251585 (2021), https://doi.org/10.1101/2021.02.11.21251585.

Moran J., *Mutant variations and the danger of lockdowns*, THE CRITIC MAGAZINE (March 2, 2021), https://thecritic.co.uk/mutant-variations-and-the-danger-of-lockdowns/.

- 31. Third, the variants have been widely spreading in many countries these past months, even as cases have dropped. This is true, for instance, in Florida, where the U.K. variant B.1.1.7 was widespread this past winter<sup>36</sup>, but cases fell sharply over the same period that the variant has been spreading. That variants with an infectivity advantage but no more lethality make up a larger fraction of a smaller number of cases is an interesting scientific observation but not crucial for public health policy.
- 32. Fourth, the dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still perhaps be infected but rarely have severe symptoms in response to infection. Throughout last year, a rise in cases was inevitably accompanied by an increase in deaths with a two-to-three-week lag. However, during this most recent wave, there has been little rise in daily deaths to accompany the rise in cases because of the deployment of the vaccine in the vulnerable older population in the United States. The same is true in Sweden and the U.K., where vaccines have been provided to the entirety of the vulnerable elderly population and more.<sup>37</sup> Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are now effectively decoupled.

<sup>&</sup>lt;sup>36</sup> US Centers for Disease Control, *US COVID-19 Cases Caused by Variants* (2021), https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html.

<sup>&</sup>lt;sup>37</sup>Jay Bhattacharya, Martin Kulldorff, and Sunetra Gupta, *Sweden's Lessons for the UK's Third Wave*, THE SPECTATOR (July 12, 2021), https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting.

The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID patients ("Long COVID") Does Not Alter The Conclusion that Vaccine Mandates Are Unwarranted

33. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify vaccine mandates and lockdown measures. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.<sup>38</sup> One cross-sectional study found that about 30% of recovered COVID patients reported at least one symptom months after recovery, with fatigue and anosmia (loss of sense of smell) by far the most common.<sup>39</sup> A separate study with a more convincing longitudinal methodology, by contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.<sup>40</sup> Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.<sup>41</sup> A study of children who recovered from COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.<sup>42</sup> Some analysts have noted the similarity between "long COVID" symptoms and other functional somatic syndromes that sometimes occur after other viral infections and other triggers (and sometimes with no identifiable etiology).<sup>43</sup>

<sup>&</sup>lt;sup>38</sup> Nalbandian, A., Sehgal, K., Gupta, A. et al., *Post-acute COVID-19 syndrome*, NAT MED 27, 601–615 (2021), https://doi.org/10.1038/s41591-021-01283-z.

<sup>&</sup>lt;sup>39</sup> Logue JK, Franko NM, McCulloch DJ, et al., *Sequelae in Adults at 6 Months After COVID-19 Infection*, JAMA NETW OPEN (2021);4(2):e210830, doi:10.1001/jamanetworkopen.2021.0830.

<sup>&</sup>lt;sup>40</sup> Sudre, C.H., Murray, B., Varsavsky, T. et al., *Attributes and predictors of long COVID*, NAT MED 27, 626–631 (2021), https://doi.org/10.1038/s41591-021-01292-y.

<sup>&</sup>lt;sup>41</sup> Arnold DT, Hamilton FW, Milne A, et al., *Patient outcomes after hospitalisation with COVID-19 and implications for follow-up: results from a prospective UK cohort*, THORAX, 76:399-401 (2021).

<sup>&</sup>lt;sup>42</sup> Thomas Radtke, Agne Ulyte, Milo A Puhan, Susi Kriemler, *Long-term symptoms after SARS-CoV-2 infection in school children: population-based cohort with 6-months follow-up*, MEDRXIV (2021), https://doi.org/10.1101/2021.05.16.21257255.

<sup>&</sup>lt;sup>43</sup> Ballering A, Olde Hartman T, Rosmalen J Long COVID-19, *persistent somatic symptoms and social stigmatization*, J EPIDEMIOL COMMUNITY HEALTH (2021).

34. To summarize, as with other viruses, long COVID symptoms occur in a minority of patients who recover from COVID and pose a real burden on patients who suffer from it. However, this fact does not alter the logic of our argument. On the countrary. After suffering through COVID, with or without long COVID, such individuals should not be forces to also endure common but mild vaccine adverse reactions or risk rare but serious adverse reactions. Moreover, the successful vaccine rollout in the United States – where every teenager and adult has free access to the vaccines – addresses the problem of long COVID, just as it addresses COVID-associated mortality.

## CDC Recommendation for Vaccination of Recovered COVID Patients Applies With Equal Force to Previously Vaccinated

35. The CDC, in a frequently asked questions section of a website encouraging vaccination, provides the following advice to previously recovered patients:<sup>44</sup>

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.

36. The text of this advice by the CDC does not address any of scientific evidence we have provided in our declaration, herein, about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that we do not know how long lasting natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will

<sup>&</sup>lt;sup>44</sup> US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

last for years.<sup>45</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. We do not know 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.

- 37. 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. 46 On the same CDC FAQ webpage we cite above 47, the CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."
- 38. 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 CDC's statement in the FAQ is non-responsive, and ignores the scientific evidence.

<sup>&</sup>lt;sup>45</sup> Patel N (2021) Covid-19 Immunity Likely Lasts for Years. MIT Technology Review. January 6, 2021. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/

<sup>&</sup>lt;sup>46</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. May 28, 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm

<sup>&</sup>lt;sup>47</sup> US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

#### **Conclusion**

- 39. A fundamental ethical principle guiding the practice of medicine is that any medical intervention, whether surgical, pharmacological, or a vaccine, should be recommended and undertaken only if it is deemed medically necessary. Any medical procedure, including vaccination, involves risk. No medical procedure is 100% safe, especially those involving a new vaccine which by definition has not been studied for long-term adverse side effects. For this reason, it is a fundamental principle of medical ethics that the risks of the procedure be balanced against the potential benefits.
- 40. As we established earlier, based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable as that acquired through vaccination. In Professor Zywicki's case, there is no doubt that, based on recent measures of his antibody levels and his history of prior COVID infection, he is protected by natural immunity (Dr. Bhattacharya has examined the results from Prof. Zywicki's laboratory tests). 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. There is no good reason from the point of view of Professor Zywicki's personal health that he should be vaccinated. At the very least, the decision should be left to Professor Zywicki and his doctors without coercion applied by the University.
- 41. There is also no community health reason for the University to mandate vaccinations since the vaccine is available to all teens and adults who want it. Indeed, based on our analysis of the existing medical and scientific literature, any policy mandating vaccinations

that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.<sup>48</sup>

- 42. As we wrote in the *Wall Street Journal* this spring, "[t]he idea that everybody needs to be vaccinated is as scientifically baseless as the idea that nobody does. Covid vaccines are essential for older, high-risk people and their caretakers and advisable for many others. But those who've been infected are already immune . . . . If authorities mandate vaccination of those who don't need it, the public will start questioning vaccines in general . . . . Coercive vaccination policies would erode trust even further."
- 43. We criticized those pushing for and implementing vaccine mandates as "undermining public trust in vaccines. In this sense, they are more dangerous than the small group of so-called anti-vaxxers have ever been."
- 44. It is unethical to coerce low-risk Americans to take the vaccine, such as students and those with natual immunity, while older high-risk individuals in Asia, Africa and Latin America are dying from COVID19 because there are not enough vaccines available in those countries.
- 45. Now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is even weaker than it was in the spring when we wrote that *Wall Street Journal* piece. There is no good public health case for GMU to require proof of vaccination for employees and students to participate in University activities that do not involve care for high-risk patients. Since the successful vaccination campaign already protects the vulnerable population, the

<sup>&</sup>lt;sup>48</sup> Jay Bhattacharya, Sunetra Gupta, and Martin Kulldorff, *The Beauty of Vaccines and Natural Immunity*, SMERCONISH NEWSLETTER (June 4, 2021), https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity.

<sup>&</sup>lt;sup>49</sup> Martin Kulldorff and Jay Bhattacharya, *Vaccine Passports Prolong Lockdowns*, WALL STREET JOURNAL (Apr. 6, 2021), https://www.wsj.com/articles/vaccine-passports-prolong-lockdowns-11617726629.

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 and natural immunity, which provides benefits that are at least as strong.

- 46. With widespread vaccination of the vulnerable, asymptomatic people pose even less risk to the vulnerable than before the vaccine became available. At the same time, the requirement for a vaccine passport or other type of proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice that caution against warrantless discrimination against segments of the population (in this case, the unvaccinated).
- 47. We recently observed that "[u]niversities used to be bastions of enlightenment. Now many of them ignore basic benefit-risk analyses, a staple of the toolbox of scientists; they deny immunity from natural infection; they abandon the global international perspective for narrow nationalism; and they replace trust with coercion and authoritarianism. Mandating the COVID-19 vaccine thus threatens not only public health but also the future of science." <sup>50</sup>
- 48. Universities can be leaders in developing sensible policies grounded in sound scientific evidence and abide by the fundamental principles of medical ethics. Individuals who have recovered from COVID-19 should be exempt from any vaccine mandates and treated as in an identical position to those who have been vaccinated.

Respectfully submitted,

<sup>&</sup>lt;sup>50</sup> Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

Dr. Jay Bhattacharya, MD, Ph.D. Professor of Medicine Stanford University

Dr. Martin Kulldorff, Ph.D. Professor of Medicine Harvard University

### **ATTACHMENT B**

#### Exhibit A

#### Declaration of Dr. Hooman Noorchashm, MD, PhD

I, Dr. Hooman Noorchashm, MD, PhD, provide the following Declaration:

#### **Background**

- 1. I graduated from the Perelman School of Medicine at the University of Pennsylvania with a Doctorate degree in immunology and have taught and practiced clinical medicine for nearly two decades. In addition to an academic career in medicine, I am an advocate for patient safety and medical ethics.
- 2. I have served faculty appointments at the University of Pennsylvania School of Medicine, Harvard Medical School Brigham and Women's Hospital, Thomas Jefferson University Hospital, and Philadelphia VA Hospital. I have authored over 65 articles, abstracts, and reviews in peer-reviewed medical journals, including the New England Journal of Medicine, Journal of Immunology, Nature Medicine, American Journal of Transplantation, Critical Care Medicine, and Diabetes. I have testified on numerous occasions before the Food and Drug Administration (FDA) and state legislatures on issues related to medicine, patient safety, and patients' rights.
- 3. In 2013, my wife Dr. Amy Reed underwent an unnecessary hysterectomy operation, which we later learned caused stage 4 leiomyosarcoma, and she eventually died.
- 4. Before her death, my wife and I began spreading awareness of the procedure's danger and advocating for patient safety and patients' rights. In recognition of those efforts, I received a Health Policy Heroes Award from the National Center for Health Research in 2015.
- 5. To continue the work that Amy and I started, I founded the American Patient Defense Union, Inc. (APDU), an organization dedicated to advocating for patient rights and

autonomy, preserving the integrity and sacred relationship between doctors and their patients, and protecting doctor and patient decisions about medical treatments from third-party influence.<sup>1</sup>

#### **Professor Zywicki's Medical Condition**

- 6. On May 27, 2021, Professor Zywicki contacted me for advice on how to determine the status of his immunity to COVID-19 and the likelihood of having been infected. I agreed to review his case and provide my opinion.
- 7. During a phone call that same day, Professor Zywicki informed me of the following relevant facts:
  - a. In early March 2020 he fell ill with a set of symptoms (chills, night sweats, fatigue, mental fogginess) that have been identified as consistent with a COVID-19 infection.
  - b. At this early stage of the pandemic, COVID-19 tests were scarce and required a doctor's prescription, so Professor Zywicki tried but was unable to procure one.
  - c. Professor Zywicki subsequently tested positive several times for COVID-19 antibodies when donating blood at the American Red Cross.
  - d. He further informed me that he had recently recovered from a severe shingles infection that had caused paralysis in the left side of his face for nearly two weeks. Professor Zywicki was concerned by news reports that suggested a possible relationship between the COVID-19 vaccine and reemergence of shingles, which is a virus.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> See Hooman Noorchashm, Why Does Every American Need The American Patient Defense Union (APDU)?, MEDIUM.COM (Oct. 17, 2017), https://noorchashm.medium.com/why-every-american-needs-the-american-patient-defense-union-apdu-2912e1fee5d4.

<sup>&</sup>lt;sup>2</sup> See, e.g., American Academy of Allergy Asthma & Immunology, Shingles following Pfizer COVID-19 vaccine (Apr. 29, 2021), https://www.aaaai.org/allergist-resources/ask-the-expert/answers/2021/shingles-covid.

- e. After an extensive discussion about his medical condition, I issued a prescription for full COVID-19 serological screening, which was conducted on June 1, 2021, at LabCorp. I examined the results and, as expected, the test confirmed that Professor Zywicki had previously recovered from SARS-CoV-2 and had a positive IgG Spike Antibody assay and a positive SARS-CoV-2 Nucleocapsid result.
- f. Professor Zywicki's semiquantitative antibody reading measured 715.6 U/ml—approximately 900 times higher than the baseline level of <0.8. This level is comparable to that I have seen empirically in vaccinated persons who share his age and health profile, including myself. In my opinion, Professor Zywicki's spike antibody level is highly likely to be far above the minimum necessary to provide adequate protection against re-infection from the SARS-CoV-2 virus.

#### Principles of Medical Ethics and George Mason University's (GMU's) Vaccine Mandate

- 8. There are four basic principles governing medical ethics in the United States: (1) autonomy, (2) justice, (3) beneficence, and (4) non-maleficence.
- 9. A highly influential public health framework proposed by Childress, et al., lists five conditions that public health interventions must satisfy: (1) effectiveness, (2) proportionality, (3) necessity, (4) least infringement, and (5) public justification.<sup>3</sup>
- 10. The principle of necessity is reinforced by the principle of "least infringement," which requires that any intervention "seek to minimize the infringement of general moral considerations." In particular, "when a policy infringes autonomy, public health agents should seek

<sup>&</sup>lt;sup>3</sup> James F. Childress, et al., *Public Health Ethics: Mapping the Terrain*, 30(2) J. LAW & MED. ETHICS 170 (2002).

the least restrictive alternative; when it infringes privacy, they should seek the least intrusive alternative."

11. The principle of proportionality is also a defense against one-size-fits-all approaches that can cause harm in the context of medicine.

# <u>It is Medically Unnecessary for Professor Zywicki to Undergo Vaccination Against SARS-CoV-2, and Forcing Him to Do So Would Subject Him to an Elevated Risk of Adverse Side Effects</u>

- 12. It is my opinion that undergoing a full course vaccination (two doses of an mRNA vaccination or one dose of the Johnson and Johnson [J&J] vaccine) is medically unnecessary, creates a risk of harm, and provides no benefit either to Professor Zywicki or the GMU community.
- 13. Multiple positive antibody tests conducted over the past year have confirmed that Professor Zywicki contracted and recovered from the SARS-CoV-2 virus at some point in the past. His recent semi-quantitative antibodies screening test establish that his immune protection, as measured by his repeated antibody tests, remains quite high.
- 14. A series of epidemiological studies have demonstrated to a reasonable degree of medical certainty that natural immunity following infection and recovery from the SARS-CoV-2 virus provides robust and durable protection against reinfection, at levels equal to or better than the *most effective* vaccines currently available.<sup>5</sup>
- 15. For example, according to the Centers for Disease Control (CDC), in clinical trials the J&J vaccine provides an efficacy of only 66.3%—far below any measured efficacy of natural immunity to date.

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> Cites (Cleveland clinic, England, Israel, etc.); N. Kojima, et al., *Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees*, https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2 (July 8, 2021).

- 16. Natural immunity protection to SARS-CoV-2 has already proven long-lasting and experience with prior coronaviruses strongly indicates that T-cell immunity provided by natural immunity could last years or even decades.
- 17. I also believe that natural infection provides broad-based protection against current SARS-CoV-2 variants. Unlike vaccine-induced immunity, which is specialized to target the Spike-protein of the original Wuhan variant of the SARS-CoV-2 virus, natural immunity recognizes the full complement of SARS-CoV-2 proteins, enabling it to provide protection against a greater array of variants. Of course, my opinion will be subject to revision as variants arise in the future and clinical information becomes available.
- 18. Furthermore, based on my analysis of the clinical medical literature to date, undergoing a full course of vaccine treatment (two doses of mRNA or one dose of J&J vaccine) as required by GMU's vaccine mandate, in a setting of a prior infection and being immune, would expose Professor Zywicki to an elevated risk of adverse effects, including serious ones, when compared with individuals who have never contracted COVID-19.
- 19. In particular, Professor Zywicki's bout of Shingles concerns me because the causal virus, Herpes Zoster, resides in nerves and, in my opinion, can be reactivated by an unnecessary COVID-19 vaccination.
- 20. Any medical procedure carries the risk of adverse side effects. The SARS-CoV-2 vaccines are no exception. In many cases, the benefits of curing, mitigating, or preventing greater harm justifies undertaking a particular medical intervention notwithstanding any associated risk. But basic principles of medical ethics mandate that any potential benefits be weighed against the risks associated with the procedure.

- 21. Because Professor Zywicki has previously been infected with and recovered from SARS-CoV-2, in my opinion, a vaccination is unnecessary and could only subject the professor to the risk of harm.
- Additionally, it is becoming clear that undergoing vaccination in the setting of having had a prior infection subjects him to an elevated risk of adverse side effects compared to those who have not previously been infected. Existing clinical reports indicate that individuals with a prior infection and natural immunity actually face an *elevated* risk of adverse effects from receiving the vaccine compared to those who have never contracted COVID-19.
- 23. According to a study in the medical journal *Life* (March 2021), "our study links prior COVID-19 illness with an increased incidence of vaccination side effects and demonstrates that mRNA vaccines cause milder, less frequent systemic side effects but more local reactions." The elevated side effects identified in the article include events such as anaphylaxis, swelling, flulike illness, breathlessness, fatigue, and others, some requiring hospitalization.
- 24. A study published in *The Lancet Infectious Diseases* (July 1, 2021) examined reports from 627,383 individuals using the COVID Symptom Study app. The authors reported a higher incidence of both systemic and local side effects from receiving the first vaccine dose for those who had previously been infected with COVID-19 compared to those who had not previously been infected.<sup>7</sup>
- 25. A study conducted at Mount Sinai Icahn School of Medicine also found among those receiving their first vaccine dose, "vaccine reactogenicity" was "substantially more pronounced in individuals with pre-existing immunity" than those who had not previously been

<sup>&</sup>lt;sup>6</sup> Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).

<sup>&</sup>lt;sup>7</sup> Cristina Menni, Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021).

infected and those with pre-existing immunity experienced "systemic side effects with a significantly higher frequency" than those who had not previously been infected.

- 26. In addition, there are numerous nonsystematic reports of individuals who have had unusually severe adverse reactions to vaccination shortly after recovering from COVID-19 infections.<sup>8</sup>
- 27. Notably many of these studies focused on the adverse effects of receiving just the *first* dose of a vaccine. They do not examine the frequency or severity of receiving a second dose of a vaccine. This uncertainly is especially important in light of the widespread recognition that those with natural immunity gain no significant benefit from receipt of a second vaccine dose (as is required by GMU's mandatory vaccination policy).
- 28. It is a fundamental principle of immunology that "vaccinating a person who is recently or concurrently infected can reactivate, or exacerbate, a harmful inflammatory response to the virus. This is NOT a theoretical concern." This applies to SARS-CoV-2 just as it does to viruses such as shingles.
- 29. Notably, Professor Zywicki was specifically cautioned against receiving a shingles vaccine for several months after recovering from his shingles infection this spring. This is proper medical advice.
- 30. To date, none of the vaccines in current application have been systematically or adequately tested for safety or efficacy in individuals who have previously been infected and

<sup>&</sup>lt;sup>8</sup> See Multisystem Inflammatory Syndrome after SARS-CoV-2 Infection and COVID-19 Vaccination, 27 (Number 7) EMERGING INFECTIOUS DISEASE (July 2021) (Centers for Disease Control and Prevention Dispatch); see also Hooman Noorchashm, CDC Knows Vaccine Associated Critical Illness and Myocarditis are Linked to Prior COVID-19 Infections, MEDIUM.COM (Jun 2, 2021), https://noorchashm.medium.com/cdc-knows-vaccine-associated-critical-illness-and-myocarditis-are-linked-to-prior-covid-19-62942c39c5ca.

<sup>&</sup>lt;sup>9</sup> Homman Noorchashm, *The Recently Infected and Already Immune DO NOT Benefit from COVID-19 Vaccination*, MEDIUM.COM (Jun 1, 2021), https://noorchashm.medium.com/the-recently-infected-and-already-immune-do-not-benefit-from-covid-19-infection-7453886e8c89.

recovered from SARS-CoV-2. In fact, Covid survivors *have overall been largely excluded* from Phase III vaccine clinical trials.<sup>10</sup> Thus, any determination with respect to the safety profile of the vaccines in this population, of which Professor Zywicki is a member, can only be inferred from clinical studies in the time since the vaccines have been put into widespread application.

- 31. In contrast to the determination that Professor Zywicki and I have reached after consultation about the details of his personal situation and medical history, GMU is inappropriately, and in violation of the rules governing medical ethics, imposing a "one-size-fits-all" vaccine mandate on every member of the GMU community.
- 32. GMU does not know the details of Professor Zywicki's situation, including preexisting conditions he may have that could exacerbate the potential for adverse effects, the recentness of any COVID-19 infection, the presence of any other infections that might be relevant to his decision, and evidence of his existing immunity levels or potential for adverse effects, such as the results of any quantitative antibodies screening test.
- 33. GMU's vaccine mandate is forcing Professor Zywicki to choose between following his doctor's medical advice on one hand and being subject to GMU's punishment which includes being forced to socially distance, wear a mask, and undergo frequent COVID-19 testing on the other. No patient should be put in such a position.
- 34. As with all patients, Professor Zywicki and his doctors should determine his future course of medical treatment. Thus, I will continue to monitor Professor Zywicki's antibody levels as SARS-CoV-2 variants arise and/or immune protection starts to wane.

<sup>&</sup>lt;sup>10</sup> See Fabio Angeli, SARS-CoV-2 vaccines: Lights and shadows, 88 EUROPEAN J. OF INTERNAL MEDICINE 1-8 (2021).

# GMU's Goals in Promoting Community Safety Can Be Accomplished More Effectively and with Less Harm Through Alternative, Less-Restrictive Means

- 35. Protecting the GMU community from COVID-19 transmission can be achieved without exposing COVID survivors in the community to the risk of harm, in contrast to GMU's current vaccination plan.
- 36. The emerging consensus in the clinical literature on the protective benefits of natural immunity compared to the elevated risks of indiscriminately vaccinating these individuals has led me to start the #ScreenB4Vaccine movement.<sup>11</sup> #ScreenB4Vaccine contains two elements: (1) testing for the presence of natural immunity through widespread antibody testing, and (2) for those who lack natural immunity or sufficient immunity protection, to test for presence of an active infection, before vaccination.
- 37. In fact, growing recognition of the highly protective character of natural immunity in preventing reinfection, along with the elevated risk of vaccinating those who have natural immunity, has recently led the European Union to recognize "a record of previous infection" as a valid substitute for vaccination.<sup>12</sup>
- 38. In short, just because an individual is vaccinated does not guarantee he is immune and just because he is not vaccinated does not mean he is not immune.
- 39. Instead of focusing its policy on blanket vaccination, therefore, GMU's policy should instead focus on *immunity*, regardless of how it is obtained.

<sup>&</sup>lt;sup>11</sup> See Hooman Noorchashm, What is #ScreenB4Vaccine? And Why Is It Necessary for Keeping Every American Maximally Safe in the COVID-19 Pandemic? MEDIUM.COM (May 7, 2021), https://noorchashm.medium.com/what-is-screenb4vaccine-80b639c4984e.

<sup>&</sup>lt;sup>12</sup> See Julia Buckley, EU Digital Covid Certificate: Everything you need to know, CNN.COM (June 9, 2021), https://www.cnn.com/travel/article/eu-covid-certificate-travel-explainer/index.html.

#### **Conclusion**

40. I call on GMU to act responsibly and, based on the principles of sound medical ethics and immunology, to recognize the importance of natural immunity in providing equal or better protection than existing vaccines. Such a policy would also acknowledge, and therefore avoid, the elevated risk of side effects from vaccination among those who have already survived a SARS-CoV-2 infection.

Respectfully submitted,

/s/ Hooman Noorchasm\_\_\_\_\_

Hooman Noorchashm MD, PhD.

# **ATTACHMENT C**

Message to university community on campus reopening and vaccination requirements

All currently enrolled students (including Mason Korea), faculty, staff, and con <GMU-USA-MK-L@LISTSERV.GMU.EDU>

on behalf of

Office of the President <gmupres@GMU.EDU>

Mon 6/28/2021 4:30 PM

To: GMU-USA-MK-L@LISTSERV.GMU.EDU <GMU-USA-MK-L@LISTSERV.GMU.EDU>

**Fellow Patriots:** 

We are just six weeks away from the kickoff of the fall 2021 semester, and I am thrilled to confirm that the campuses of George Mason University will be fully open to welcome a record number of students. It has been a long road back from March 2020 when we had to shut operations down to stay ahead of the pandemic, but we find ourselves on the verge of fully reopening.

We are about to return to a Mason that has changed due to the pandemic, and even though we are able to return, we do so as the COVID-19 virus and its variants continue to circulate through our communities.

I am writing to share how we will open in order to balance a return to full capacity while continuing to assure safe conditions of operation.

## Reopening

In keeping with our university value of putting students first, we will reopen campus fully starting Monday, August 2. At that time, we will pilot a hybrid work environment that allows for telework/remote work for one or two days per week – with the necessary assessment to ensure the responsibilities of the position are able to be achieved. The goals are to:

- Retain the efficiencies we gained in remote working.
- Capitalize on the contributions that result from the synergies and collaborations that occur when we are on campus.
- Serve the thousands of students who will come to campus every day and who call Mason home.
- Reinvigorate the campus environment that has come to define a significant part of the full Mason experience.

Recognizing that class will not be in session yet on Monday, August 2, either at Mason or at regional public schools and that some people have to manage transitional needs (childcare, transportation, etc.) we will use the first two weeks of August to transition

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back into this new framework. Thus it is expected that everyone will be fully integrated in their pilot working environment by **Sunday, August 15**. Note, this is a pilot program and we will evaluate its effectiveness quarterly.

The Office of Human Resources and Payroll will issue more detailed back-to-work guidelines shortly.

#### Vaccination and proof of status

Because we will come together as COVID-19 continues to circulate, we have an obligation to maintain a safe environment in which to study, work, and live. While those of us who are vaccinated are now able to enjoy a return to campus without masks or physical distancing, measures are still required as long as pandemic conditions persist among those who are unable or unwilling to receive the vaccine. Therefore, as previously announced:

#### **Students**

All students will be required to be fully vaccinated, and share proof of vaccination, via this link by **Sunday**, **August 1**. Appropriate medical and religious exemptions will be observed, and those who are not vaccinated will be required to wear masks while on campus and undergo frequent COVID-19 testing. Those who do not share proof of vaccination or an approved exemption will have their registrations held until they do so.

The Office of University Life will issue more detailed back-to-school guidelines shortly.

## **Faculty and staff**

All employees will be strongly encouraged to get vaccinated, and **required** to share their vaccination status <u>via this link</u> by **Sunday, August 1**. To see incentives that encourage faculty, staff, and students to share their vaccination documentation and for instructions on how to do so, <u>follow this link</u>. Disclosure of vaccination status – whether vaccinated or not – will be a prerequisite for eligibility for any future merit pay increases. Those who are vaccinated but do not disclose vaccination status and upload proof through <u>Mason COVID Health Check</u> by August 1, will be considered unvaccinated. Those who cannot or choose not to get vaccinated will be required to wear masks while on campus, physically distance, and undergo frequent COVID-19 testing.

All students, faculty, and staff should follow this link to upload their vaccination status.

## Focus on well-being

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It is important for us all to recognize that our return to an open campus is accompanied by a mix of excitement and uneasiness. We are excited to resume life that feels normal again – to be together on our campuses, and to see each others' full and healthy smiles. But it is also natural to feel reluctance to venture back onto campus, given the experience we have all been living through. Our plan gets Mason back on campus as it should be without endangering public health or compromising our ability to deliver excellence to our students and the community. We will all feel anxiety from time to time, and I encourage us to be good to ourselves and each other, and take these steps together, as one Mason Nation.

Onward!

Sincerely,

Gregory Washington President

# **ATTACHMENT D**

#### Mason announces new vaccination requirements for fall semester

All currently enrolled students (including Mason Korea), faculty, staff, and con <GMU-USA-MK-L@LISTSERV.GMU.EDU>

on behalf of

Office of the President <gmupres@GMU.EDU>

Thu 7/22/2021 2:10 PM

To: GMU-USA-MK-L@LISTSERV.GMU.EDU <GMU-USA-MK-L@LISTSERV.GMU.EDU>

Fellow Patriots:

As we make final preparations for fully reopening George Mason University, I am writing to share that we have new and urgent work at hand to ensure a safe return next month. Our community has done an admirable job at keeping one step ahead of COVID-19, preventing even a single known case of classroom transmission and keeping overall COVID cases to a minimum.

But COVID-19 is on the march with the spread of the far more contagious Delta variant, which the World Health Organization calls the "fastest and fittest" version of COVID yet. Children and adults under 50 are 2.5 times more likely to contract the Delta variant, according to <u>Yale Medicine</u>.

As CDC Director Rochelle Walensky has said, "This is becoming a pandemic of the unvaccinated." In just one week, new cases increased 70 percent in the United States. Hospitalizations rose 36 percent, and deaths rose 26 percent – with 97 percent of all new hospitalizations occurring among the unvaccinated.

For the sake of all who are unable to receive vaccination, the single most effective way to avoid the virus and stop its spread is for the rest of us to get <u>vaccinated</u> as soon as possible.

Therefore, Mason is joining the growing community of universities that require all students, faculty, and staff to get vaccinated, and to share verification of their vaccination status, in order to work, study, and live on campus. We will, of course, approve appropriate exemptions for medical and religious reasons. Following university policies and procedures, disciplinary action will be pursued against those faculty and staff who fail to receive an exemption and do not disclose their status and receive the vaccine. This action could include unpaid leave or possible loss of employment.

Mason students, faculty, and staff are required to share vaccination status through <u>Mason COVID Health Check</u> and, if vaccinated, your documentation through the <u>Health Service portal</u> by August 1. Faculty and staff that are not yet fully vaccinated by August 1, must receive their first shot by August 15.

Students seeking a <u>medical</u> or <u>religious</u> exemption must do so by August 1. Employees seeking a medical or religious exemption must do so by August 15. For more information on how to satisfy Mason's vaccine and documentation requirements students should visit <u>here</u> and employees should visit <u>here</u>.

Vaccines are available on the first floor of the Johnson Center on the Fairfax Campus. They are also widely available through community clinics and healthcare providers. Visit <u>vaccines.gov</u> to locate vaccination providers nationwide.

This requirement is consistent with Mason's longstanding history of protecting our community through requiring students to be immunized against diphtheria, tetanus, poliomyelitis, measles (rubeola),

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German measles (rubella), mumps, Hepatitis B, and meningitis. It is extended to faculty and staff for COVID-19 because the extraordinary nature of the pandemic demands it.

I recognize that a mandate is an extraordinary step to take, and one not taken without serious consideration of the public health situation and the safety of our community. This week I received the unanimous support of my Executive Council to move forward with the universal vaccine requirement, and I have taken this step for the sake of the health and safety of every Mason Patriot.

Thank you in advance for your continued commitment to maintaining your own health and that of your fellow Mason Patriots. We will see you on campus very shortly.

Sincerely,

Gregory Washington President

# **ATTACHMENT E**

#### Mason announces new vaccination requirements for fall semester

All currently enrolled students (including Mason Korea), faculty, staff, and con <GMU-USA-MK-L@LISTSERV.GMU.EDU>

on behalf of

Office of the President <gmupres@GMU.EDU>

Thu 7/22/2021 2:10 PM

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#### Case 1:21-cv-00894-TSE-MSN Document 1-6 Filed 08/03/21 Page 3 of 3 PageID# 87

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Thank you in advance for your continued commitment to maintaining your own health and that of your fellow Mason Patriots. We will see you on campus very shortly.

Sincerely,

Gregory Washington President

# **ATTACHMENT F**

## New Civil Liberties Alliance

July 21, 2021

Dr. Gregory Washington President of George Mason University president@gmu.edu

Mr. Thomas Moncure University Counsel and Senior Assistant Attorney General tmoncure@gmu.edu

Mr. David Farris Executive Director, Safety and Emergency Management dfarris@gmu.edu

Ms. Julie Zobel Assistant Vice President of Safety, Emergency, and Enterprise Risk Management jzobel@gmu.edu

#### VIA EMAIL

Re: GMU's Reopening Policy for Fall 2021
On Behalf of NCLA Client, Professor Todd Zywicki

Dear Dr. Washington, Mr. Moncure, Mr. Farris, and Ms. Zobel:

It has come to our attention that George Mason University (GMU) has announced a reopening policy (the Policy) related to COVID-19 for the Fall 2021 semester. The Policy requires all unvaccinated faculty and staff members, including those who can demonstrate natural immunity through a prior COVID-19 infection, to wear masks on campus, physically distance, and undergo frequent COVID-19 testing. The Policy also seeks to strip employees who choose not to share their vaccination status (the statement delineating the Policy does not specify with whom), of their eligibility for future merit pay increases.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> The student policy is even more stringent, as it threatens students with suspension if they make the personal decision

The New Civil Liberties Alliance (NCLA) represents Professor Todd Zywicki of the Antonin Scalia Law School's faculty in this matter. Professor Zywicki contracted and has fully recovered from COVID-19. As a result, he acquired robust natural immunity as confirmed in multiple positive SARS-CoV-2 antibody tests conducted over the past year. Professor Zywicki's immunologist, Dr. Hooman Noorchashm, has advised him that, based on his personal medical and immunity status, it is not only *medically unnecessary* to undergo a vaccination procedure at the current time, but that doing so would create an affirmative risk of harm to him (*see* Declaration of Dr. Hooman Noorchashm, attached as Exhibit A). Yet, if he follows his doctor's advice and chooses not to receive a COVID-19 vaccine, relying on the robust natural immunity that he earned the hard way, he will be forced to abide by the rules governing unvaccinated employees. Since those rules—including wearing a mask and physically distancing on campus—diminish Professor Zywicki's efficacy in performing his professional responsibilities, the Policy coerces him into receiving the vaccine.

Given his robust immunity, the Commonwealth of Virginia has no compelling state interest in overriding Professor Zywicki's personal autonomy by effectively forcing him to be vaccinated (or suffer adverse professional consequences if he refuses). As a result, GMU's Policy infringes upon Professor Zywicki's rights under the Ninth and Fourteenth Amendments to the United States Constitution, and he should be exempted from it immediately. NCLA also urges GMU to reconsider its unconstitutional vaccination policy as a general matter, especially for students, faculty, and staff who can show naturally acquired immunity from an antibody test.

#### I. THE NEW CIVIL LIBERTIES ALLIANCE'S INTEREST IN THIS MATTER

NCLA is a nonpartisan, nonprofit civil-rights organization and public-interest law firm devoted to protecting constitutional freedoms and restoring civil liberties. The "civil liberties" of the organization's name include rights at least as old as the Virginia and U.S. Constitutions themselves, such as trial by jury, due process of law, the right to be tried in front of an impartial and independent judge, the right to free expression without fear of censorship or reprisal, and the right to privacy and personal autonomy. Yet these selfsame rights are also very contemporary—and in dire need of renewed vindication—precisely because Congress, state legislatures, and federal, state, and local administrative agencies, including state university administrations, have trampled them for so long.

Even where NCLA has not yet brought a lawsuit to challenge an unconstitutional exercise of state power or infringement of fundamental rights, it encourages governmental entities to cease

to forgo COVID-19 vaccination.

encroaching upon civil liberties of their own volition. We believe that these governmental entities should continuously strive to establish meaningful limitations on administrative policymaking, rulemaking, adjudication, and enforcement, thereby avoiding unconstitutional overreach. For these reasons, NCLA advises GMU to reexamine and revamp its Policy.

#### II. PROFESSOR ZYWICKI AND GMU'S VACCINATION POLICY

Todd J. Zywicki is a GMU Foundation Professor of Law at the Antonin Scalia School of Law. He has been employed at GMU since August 1998, except for occasional service as a visiting professor at other law schools (including Georgetown University Law Center, Vanderbilt University Law School, and Boston College Law School) as well as high-level service in the United States government. He is one of the Law School's most frequently cited and influential scholars and has been an exemplary leader in service to GMU and the community.

On or around March 2, 2020, Professor Zywicki manifested symptoms of COVID-19 for several days, including chills and recurrent night sweats.<sup>2</sup> Fortunately, Professor Zywicki made a full recovery. In April of 2021, Professor Zywicki became ill with the Shingles virus, which caused facial paralysis that lasted for two weeks (*see* Ex. A at ¶ 7(d)).

Since his recovery from COVID-19, Professor Zywicki has undergone repeated SARS-CoV-2 antibody testing, confirming both that he previously contracted COVID-19 and that he has robust antibodies that prevent reinfection. Through American Red Cross (ARC) blood donation testing, Professor Zywicki received an unbroken string of positive COVID-19 antibody tests on July 25, 2020, September 29, 2020, December 16, 2020, and February 9, 2021. Professor Zywicki requested these tests because he had volunteered to teach in-person beginning in the Fall 2020 semester and wanted to reassure students of his immunity status.

Following consultation with Dr. Noorchashm on June 1, 2021, Professor Zywicki obtained a full antibody screening test from LabCorp, which confirmed in greater detail and specificity the ARC test results. According to Dr. Noorchashm, Professor Zywicki's current levels of antibodies and immune protection are "comparable to those" of individuals in his age range and in similar health who have received COVID-19 vaccinations, and these levels provide sufficient and durable protection against reinfection and transmission (*see* Ex. A at ¶ 7(f)).

Based on his analysis of Professor Zywicki's antibodies screening test and overall medical

<sup>&</sup>lt;sup>2</sup> Owing to the scarcity of COVID-19 tests at the time, and the requirement that such tests only be provided by a doctor's order, Professor Zywicki was unable to obtain a PCR test.

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history, Dr. Noorchashm concluded that it is not medically necessary for Professor Zywicki to undergo a full-course vaccination procedure in order to protect himself or the community from infection. In addition, he determined that such treatment would expose Professor Zywicki to a heightened risk of adverse side-effects that would exceed any speculative benefit the vaccine could confer on someone already protected with antibodies (see Ex. A at ¶¶ 12-34). For this reason, Dr. Noorchashm's expert medical opinion is that prescribing a full vaccine course would violate medical ethics rules which stipulate that any treatment be "medically necessary" (see Ex. A at ¶¶ 9-12) (emphasis added).

On June 28, 2021, via email, GMU announced its "campus reopening and vaccine requirements" for the upcoming Fall term. According to the email, "[a]ll employees will be *strongly encouraged* to get vaccinated, and required to share their vaccination status[.]" (emphasis added). Furthermore, disclosure of vaccination status "will be a prerequisite for eligibility for any merit pay increases." The Policy requires unvaccinated employees to "wear masks while on campus, physically distance, and undergo frequent COVID-19 testing" and contains no mention of exemptions for faculty and staff with naturally acquired immunity to COVID-19 via recovery from prior infection.

Based on personal information and correspondence, Professor Zywicki has been informed that the GMU "campus reopening and vaccine requirements" policy is led by two individuals: David Farris, Executive Director of Safety and Emergency Management<sup>3</sup>; and Julie Zobel, Assistant Vice President, Safety, Emergency and Enterprise Risk Management.<sup>4</sup> Mr. Farris has an undergraduate degree in Biology, a master's degree in Business Administration, and a Ph.D. in Education. He began employment at GMU as "Chemical Hygiene Officer" and subsequently was also tasked with fire safety management responsibilities. Ms. Zobel holds a bachelor's degree in Hazardous Materials/Environmental Management and Civil Engineering, a master's degree in Civil Engineering, and a Ph.D. in Biodefense. Based on their publicly available biographies, neither Mr. Farris nor Ms. Zobel has any medical credentials.

#### III. GMU'S POLICY WOULD NOT WITHSTAND A LEGAL CHALLENGE, IN ALL LIKELIHOOD

As an administrative unit of the Commonwealth of Virginia, and in contrast to private employers, those who make policy at public universities such as GMU are legally obligated to ensure that those policies do not violate the United States Constitution.<sup>5</sup> GMU's policy amounts to a vaccine

<sup>&</sup>lt;sup>3</sup> See https://ehs.gmu.edu/faculty\_staff/david-farris/.

<sup>&</sup>lt;sup>4</sup> See https://ehs.gmu.edu/faculty\_staff/julie-zobel/.

<sup>&</sup>lt;sup>5</sup> See, e.g., Tinker v. Des Moines Indep. Community Sch. Dist., 393 U.S. 503, 506 (1969) (explaining that "[i]t can hardly be argued that either students or teachers shed their constitutional rights to freedom of speech or expression at the schoolhouse gate. This has been the unmistakable holding of this Court for almost 50 years.").

mandate. As courts have recognized, "the line between 'incentive' and 'coercion' is thin." Coercion "by definition, is designed to induce a person to do that which the person offering the incentive wishes done."

Forcing faculty who are not vaccinated to wear masks and socially distance impairs their ability to perform their professional duties. Face coverings impede a professor's ability to effectively communicate with students in a lecture environment. A conspicuous face covering also stigmatizes the wearer, and may create irrational fear, anxiety, and animus from students and other faculty.

Social distancing requirements similarly inhibit a professor's ability to hold office hours or have lunches with students, participate in faculty workshops and meetings, and attend certain academic events. Such impediments mean that unvaccinated professors cannot carry out their responsibilities as effectively as their vaccinated counterparts, jeopardizing teaching evaluations, future student enrollment, opportunities for academic collaboration, reputational standing, pay raises and other professional opportunities. Thus, while the Policy purports not to require vaccination, it places such an enormous amount of pressure upon employees to receive the vaccine (to avoid being professionally handicapped) that it amounts to an ineluctable mandate.<sup>8</sup>

The Supreme Court has recognized that various parts of the Bill of Rights, including the Ninth Amendment, as well as the Fourteenth Amendment, grant privacy rights to individuals. On this basis, it has held that a "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" Subsequent Supreme Court decisions have made explicit that the right to "refus[e] unwanted medical care" is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." Because the Policy infringes upon a fundamental, constitutional right not to receive a vaccine against one's will, should GMU face a lawsuit on that basis, the school will be required to demonstrate that its Policy furthers a compelling state interest and is narrowly tailored to effectuate that interest.<sup>12</sup>

<sup>&</sup>lt;sup>6</sup> Enterprises v. Volvo Cars of N.A., LLC, 2:14-CV-360, 2016 WL 4480343, at \*10 (S.D. Ohio Aug. 25, 2016). See also Kansas v. U.S., 214 F.3d 1196, 1202 (10th Cir. 2000) (explaining, in reference to Congress's spending powers, "[t]he boundary between incentive and coercion has never been made clear[.]").

<sup>&</sup>lt;sup>7</sup> Enterprises, 2016 WL 4480343 at \*10.

<sup>&</sup>lt;sup>8</sup> See Needleman v. Bohlen, 457 F. Supp. 942, 945-46 (D. Mass. 1978) (recognizing that public employees, including tenured faculty, have a legitimate expectation that future pay-raises or promotions will not be withheld).

<sup>&</sup>lt;sup>9</sup> Washington v. Harper, 494 U.S. 210, 229 (1990).

<sup>&</sup>lt;sup>10</sup> Cruzan v. Director, Missouri Department of Public Health, 497 U.S. 261, 278 (1990).

<sup>&</sup>lt;sup>11</sup> Washington v. Glucksberg, 521 U.S. 702, 722 n.17 (1997).

<sup>&</sup>lt;sup>12</sup> See, e.g., Mohamed v. Holder, 266 F. Supp. 3d 868, 877 (E.D. Va. 2017) ("If a fundamental right is implicated and strict scrutiny therefore applies, a law will not be upheld unless the government demonstrates that the law is necessary to further a compelling governmental interest and has been narrowly tailored to achieve that interest.").

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Similarly—and also under the Fourteenth Amendment—government policies that are premised upon treating groups of people differently must be "rationally related to a legitimate state interest." Thus, to prevail in a legal challenge to its Policy, GMU would have to demonstrate that it has a compelling state interest in treating employees with natural immunity differently from those who have been vaccinated, and that this Policy is the least restrictive means of achieving that end.<sup>14</sup>

GMU cannot show that it has a compelling interest in coercing Professor Zywicki into receiving a COVID-19 vaccine. Nor can GMU show a compelling interest in treating him differently from employees who have received the vaccine. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust and long lasting as that achieved through vaccination (*see* Ex. A at ¶¶ 16-17; Affidavit of Drs. Bhattacharya and Kulldorff, attached as Exhibit B at ¶¶ 15-23). For example, a recent study conducted by researchers at Cleveland Clinic of 1,359 unvaccinated individuals previously infected with COVID-19 found *zero* reinfections. The researchers' conclusion that "individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination[,]" echoes other studies determining that natural immunity is no less effective in combatting COVID-19 infection – whether from the original virus or any of the mutant variants – than immunity conferred through any of the three vaccines approved for use in the United States (*see* Ex. A at ¶¶ 12-34; Ex. B at ¶¶ 15-23, 28-32).

Nor is there any evidence or reason to believe that natural immunity provides less durable immunity than vaccination. <sup>16</sup> This is especially so in light of Professor Zywicki's recent antibodies screening test, which shows that he has ongoing and robust immune protection. In fact, growing recognition of the highly protective character of natural immunity has recently led the European Union to recognize "a record of previous infection" as a valid substitute for natural immunity (*see* Ex. A at ¶ 27). Likewise, the Commonwealth of Virginia's rule governing vaccination of school children for measles, mumps, rubella, and varicella (chickenpox) explicitly exempts from the requirements those who can demonstrate existing immunity through serological testing that measures protective

<sup>&</sup>lt;sup>13</sup> See, e.g., City of Cleburne, Tex. v. Cleburne Living Ctr., 473 U.S. 432, 432 (1985).

<sup>&</sup>lt;sup>14</sup> See id.

<sup>&</sup>lt;sup>15</sup> Nabin K. Shrestha, et al., Necessity of COVID-19 Vaccination In Previously Infected Individuals, MEDRXIV (June 5th, 2021), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2.

<sup>&</sup>lt;sup>16</sup> Id. See also Yair Goldberg, et al., Protection of Previous SARS-Cov-2 Infection is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience From Israel, MEDRXIV (April 20, 2021), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full.pdf; Smerconish, Should Covid Survivors and the Vaccinated be Treated the Same?: Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (CNN June 12, 2021), https://www.cnn.com/videos/tv/2021/06/12/should-covid-survivors-and-the-vaccinated-be-treated-the-same.cnn; Marty Makary, The Power of Natural Immunity, WALL STREET JOURNAL (June 8, 2021, 12:55 PM), https://www.wsj.com/articles/the-power-of-natural-immunity-11623171303 (last visited June 29, 2021).

antibodies.<sup>17</sup> To put it bluntly, natural immunity has long been recognized by the medical community and in public policy as a reason not to receive a vaccine, and certainly not to mandate one. Nothing is achieved in the way of promoting his own or the community's safety by requiring Professor Zywicki to undergo a COVID-19 vaccine procedure against his will.

To the contrary, Professor Zywicki's physician has advised him that, given his natural immunity, a COVID-19 vaccination is medically unnecessary. Thus, forcing him to receive the vaccine is itself a violation of the rules governing medical ethics because *any* medical procedure, including any vaccination, runs *some* risk of adverse effects (*see* Ex. A at ¶¶ 12-34; Ex. B at ¶¶ 25-27). The currently approved COVID-19 vaccines are no exception.

It is also critically important to understand that none of the currently approved vaccines has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Indeed, survivors of previous COVID-19 infections have specifically been excluded from the trials conducted so far. Current evidence indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19 (see Ex. A at ¶¶ 22-26; Ex. B at ¶ 27). Confirming the opinion of Dr. Noorchashm, a recent research paper concluded that "we cannot exclude the possibility that the vaccination of a growing number of [individuals] with preexisting immunity to SARS-Cov-2 may trigger unexpectedly intense, albeit very rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Dr. Noorchashm is particularly concerned due to Professor Zywicki's recent bout of shingles. As the doctor explains, "the causal virus, Herpes Zoster, resides in nerves and, in my opinion, can be reactivated by an unnecessary COVID-19 vaccination" (see Ex. A at ¶ 19).

GMU's Policy forces Professor Zywicki to choose between risking injury to his health on one hand and sustaining injury to his career on the other. By threatening adverse professional and personal consequences, GMU's Policy directly harms Professor Zywicki's autonomy and dignity. It also forces him to endure the stress and anxiety of choosing between his commitment to his health and to his teaching career. Given that his demonstrated natural immunity renders his vaccination status irrelevant with respect to his ability to safely teach students and perform his duties as a faculty colleague, GMU's irrational Policy constitutes no less a needless assault on Professor's Zywicki's privacy and dignity than requiring him to make daily disclosures of other private and potentially embarrassing medical conditions (see Ex. B at ¶¶ 35-44). For this reason, the Policy entails a clear and unequivocal violation

 $<sup>^{17}</sup>$ 12 Va. Admin. Code  $\S$  5-110-80 (2021).

<sup>&</sup>lt;sup>18</sup> Angeli et al., SARS-CoV-2 Vaccines: Lights and Shadows, 88 EUR. J. INTERNAL MED. 1, 8 (2021).

of Professor Zywicki's Ninth and Fourteenth Amendment Constitutional rights.

Masking and social distance requirements also unnecessarily restrict Professor Zywicki's First Amendment rights, specifically his freedom of expression, association and assembly.<sup>19</sup> Because, for the reasons discussed above, the classification between vaccinated faculty and those with natural immunity defies rationality, the University's discriminatory policy is unlawful. In fact, the irrationality of GMU's Policy is further exposed by its acceptance of the Johnson & Johnson/Janssen vaccine, which is shown to be only 66.3% effective in clinical trials<sup>20</sup>, a level of immunological protection substantially lower than that conferred by natural immunity.<sup>21</sup>

In addition to violating Professor Zywicki's constitutional rights, the Policy conflicts with federal law. None of the three vaccines approved for use in the United States has received full Food and Drug Administration (FDA) approval. Rather, they have only been granted Emergency Use Authorization (EUA) status. The governing federal statute mandates that those being administered a medical product approved for use under it be informed of the option to accept or refuse its administration, and of alternatives. <sup>22</sup> GMU's coercive Policy flies in the face of the intent and the spirit of the EUA statute. It thus violates the Supremacy Clause of the United States Constitution, which dictates that a state or local law is preempted when is creates "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." The federal policy to allow individuals to choose for themselves to refuse the COVID vaccines is for naught if GMU creates a contrary policy requiring such vaccines to be taken. In short, the federal and state policies cannot coexist.

Finally, tying the disclosure of medical records to merit-based pay raises—as GMU's Policy does—raises significant privacy concerns. The Virginia Department of Human Resource Management has advised state agencies that "asking for vaccination status is sensitive to many and can also lead to legal liabilities that agency leaders may not be prepared to address." Additionally, the recent proliferation of data breaches raises substantial security concerns about the ability of organizations,

<sup>&</sup>lt;sup>19</sup> See *Tinker*, 593 U.S. 503 (holding that a student's wearing of an armband was a type of symbolic act protected by the First Amendment's free speech clause).

<sup>&</sup>lt;sup>20</sup> Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety, CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), June 23, 2021, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html.

<sup>&</sup>lt;sup>21</sup> MEDRXIV, *supra* note 9.

<sup>&</sup>lt;sup>22</sup> See 21 U.S.C. § 360bbb-3(e)(1)(A).

<sup>&</sup>lt;sup>23</sup> Arizona v. United States, 567 U.S. 387, 399-400 (2012); see also U.S. Const. art. VI, cl. 2.

<sup>&</sup>lt;sup>24</sup> Guidance on Face Coverings and Vaccinations Resulting from CDC Update on May 13, 2021 and Executive Order 72, Virginia Department of Human Resource Management (May 15, 2021).

such as universities, to safely store sensitive medical records.<sup>25</sup> Virginia personal and medical data breach statutes, which impose significant penalties for statutory violations, may also raise liability issues with respect to the requirement that GMU faculty upload medical records to an online portal.<sup>26</sup>

It is true that forcing all employees (and students) to disclose confidential medical information into an online portal would ease the bureaucratic burden of surveilling the private health decisions of those who work and attend school at GMU. Indeed, the "online portal" could be used to monitor students, faculty, and staff to ensure that they are eating enough vegetables, exercising regularly, abstaining from alcohol, not staying up too late, and otherwise adopting health habits that will strengthen their immunity and thereby protect the GMU community from the risk of COVID-19 spread. But there is no "bureaucratic convenience" exception to the Constitution. Before a state actor can impose on or restrict an individual's privacy and autonomy, the state must demonstrate that its end is justified by a legitimate state interest and that the means it has chosen are the least-intrusive available to accomplish that end.

#### IV. GMU RISKS LEGAL ACTION IF IT DOES NOT CHANGE ITS POLICY IMMEDIATELY

As noted by Drs. Bhattacharya and Kulldorff in their Declaration, universities hold a unique position of public trust in building respect for sound principles of science and ethics (*see* Ex. B at ¶¶ 35-44). Bhattacharya and Kulldorff also observe that "[i]t is unethical to coerce low-risk Americans to take the vaccine, such as students and those with natural immunity, while older high-risk individuals in Asia, Africa and Latin America are dying from COVID19 because there are not enough vaccines available in those countries" (Ex. B at ¶ 40). GMU has an opportunity to be a leader in developing a rational, scientifically-based, and humane policy that honors the judgment of Professor Zywicki and others who have natural immunity to be free from invidious discrimination though they choose not to subject themselves to medically unnecessary vaccinations that could benefit people who need them (*see* Ex. B at ¶¶ 35-44).

The motto of GMU is "Freedom and Learning." This vision is backed by the "Mason idea," which is that "Mason at its core is innovative, diverse, entrepreneurial, and accessible." The motto of the law school, where Professor Zywicki has dedicated his professional career, is "Learn. Challenge. Lead." These values are exemplified by the life of George Mason himself, who refused to sign the

<sup>&</sup>lt;sup>25</sup> Lance Whitney, 2020 Sees Huge Increase in Records Exposed in Data Breaches, TECHREPUBLIC (Jan. 21, 2021, 10:50 AM), https://www.techrepublic.com/article/2020-sees-huge-increase-in-records-exposed-in-data-breaches/.

<sup>&</sup>lt;sup>26</sup> Va. Code Ann. § 18.2-186.6; § 32.1-127.1:05.

<sup>&</sup>lt;sup>27</sup> https://vision.gmu.edu/the-mason-vision/.

United States Constitution because it lacked a Bill of Rights to protect individual liberties, and of Justice Antonin Scalia, who through force of intellect, independent thinking, and commitment to the rule of law transformed American jurisprudence. GMU employees are told that the Mason idea "reminds us that we are committed to be a university *for* the world, drawn together to work across cultures, bring new perspectives and solutions to the world's most pressing problems and preparing our solutions to navigate in it."<sup>28</sup>

In sum, although the Policy may be well-intentioned, GMU has breached its constitutional and ethical obligations by interfering with health decisions that should reside with individuals and their medical providers. Given the lack of GMU's knowledge as to Professor Zywicki's specific health circumstances, the University is in no position to evaluate the risks and benefits associated with vaccinating the professor. As Professor Zywicki possesses natural immunity to the virus, GMU similarly lacks any interest—let alone a compelling one—in coercing him into receiving a COVID-19 vaccine or foisting burdens upon him that jeopardize his ability to perform his professional responsibilities. NCLA therefore urges GMU to re-examine its Policy, to deem natural immunity at least equivalent to that achieved through vaccination, and to confirm that Professor Zywicki will not lose eligibility for future pay raises (merit or otherwise) if he does not wish to share his vaccination status. Please inform the undersigned of any decision to change GMU's policy as soon as possible, but certainly before July 28. Professor Zywicki would have to receive the vaccine as the Policy currently stands by August 1. Rest assured that NCLA is always prepared to file appropriate legal action to protect the rights of our clients and all Americans.

Sincerely,

Jenin Younes
Litigation Counsel
Harriet Hageman
Senior Litigation Counsel
Mark Chenoweth
General Counsel
New Civil Liberties Alliance

cc: Mr. Ken Randall Dean of Antonin Scalia Law School George Mason University krandall@gmu.edu

# **ATTACHMENT G**



# Certificate of Medical Exemption for COVID-19 Immunization Requirement

Todd	Zywicki		/1966	G#00007223
Legal First Name	Legal Last Name		Date of Birth	G# (if applicable)
The above named individ of the immunizing agents				administration
Medical Diagnosis: Acq	wired Pre-existing In	nmunisty to SAR	S-6V-2	
Pregnancy EDC (if applic	able):			
Additional Information:				
Professor Zywichi he Covso-19 Vaccine lack of medical ne on unnecessary	exception is medic exception is medic ecessity and the helihood of a New b	ally warrant. possistiff	to COVID.  I on the ,  I have in  In his ann	19. This besis of the absence unity from
Medical Provider Printed Name  N PJ			er Phone Number	
Medical Provider Signature	7	7/23 <sub>)</sub> Date	04	
(270)				

# **ATTACHMENT H**



#### Office of University Counsel

4400 University Drive, MS 2A3, Merten Hall Suite 5400, Fairfax, VA 22030 Phone: 703-993-2619; Fax: 703-993-2340

July 30, 2021

Jenin Younes New Civil Liberties Alliance <u>jenin.younes@ncla.legal</u>

#### BY ELECTRONIC MAIL

Dear Ms. Younes:

I write in response to your July 21, 2021 letter regarding Professor Todd Zywicki and George Mason University's ("Mason") COVID-19 prevention policies for the Fall 2021 semester. Your letter asks us to update you on any changes to our policies since your letter. As I believe you are aware, since your letter Mason has announced that all employees are required to have received at least one dose of a COVID-19 vaccine by August 15, 2021 (and provide proof of vaccination) or receive an approved exemption. Mason's COVID-19 immunization policy can be found here: <a href="https://universitypolicy.gmu.edu/policies/covid-19-public-health-and-safety-precautions-immunization/">https://universitypolicy.gmu.edu/policies/covid-19-public-health-and-safety-precautions-immunization/</a>. Information about how employees can apply for an exemption can be found here: <a href="https://seerm.gmu.edu/gmu-covid-19-vaccine-clinics/vaccine-requirement/">https://seerm.gmu.edu/gmu-covid-19-vaccine-clinics/vaccine-requirement/</a>.

As an employee of Mason, Professor Zywicki is required to comply with the vaccination policy as a condition of employment and, if he receives an exemption from the requirement to be vaccinated, to comply with Mason's requirements for unvaccinated employees and students (e.g, masking, physical distancing, and testing).<sup>1</sup>

"significantly greater leeway" then when the government acts as a sovereign as was the case in the above

cited cases. See Enquist v. Or. Dep't of Agric., 553 U.S. 591, 598 (2008).

<sup>&</sup>lt;sup>1</sup> We note that courts have consistently upheld the ability of the government to require vaccines dating back to 1905 in *Jacobson v. Commonwealth of Mass.* and as recently as this month in *Klassen v. Trustees of Indiana Univ.* Courts have also repeatedly rejected cases challenging face covering requirements and other COVID-19 prevention measures based on *Jacobson. See, e.g., Tigges v. Northam,* 473 F. Supp. 3d 559 (E.D. Va. 2020); *Whitfield v. Cuyahoga Cty. Pub. Libr. Found.*, No. 1:21 CV 0031, 2021 WL 1964360 (N.D. Ohio May 17, 2021); *Stewart v. Justice*, No. 3:20-0611, 2021 WL 472937 (S.D. W. Va. Feb. 9. 2021); *Forbes v. Cty. of San Diego*, No. 20-cv-00998-BAS-JLB, 2021 WL 843175 (S.D. Cal. Mar. 4, 2021); *Oakes v. Collier Cty.*, No.: 2:20-cv-568-FtM-38NPM, 2021 WL 268387 (M.D. Fla. Jan. 27, 2021). In addition, Mason acts as a government employer and thus has "far broader powers" and

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Mason is not currently exempting individuals who previously had COVID-19 from the vaccination requirement as such an exemption is not consistent with the guidance issued by the CDC. See <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html</a> ("[Y]ou 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... Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19"), and <a href="https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html">https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html</a> (unvaccinated individuals should wear masks when in indoor public places). As with all of its COVID-19 requirements and policies, Mason is continuously reviewing the medical science and the guidance from federal and state public health agencies and updating its requirements and policies as necessary.

While Professor Zywicki would not automatically be exempt from these requirements because of his previous COVID-19 infection, he may be eligible for other exemptions. If Professor Zywicki and his physician(s) believe that administration of the immunizing agents in the COVID-19 vaccine may be detrimental to his health, he should follow the instructions on the above-referenced Mason website to submit a request for a medical exemption. Requests for medical exemptions are reviewed by University medical professionals, and such requests may be granted if supported by appropriate documentation and current medical science.

Please be aware that other exemptions are available to employees. If an employee has a religious objection to the vaccine, the employee can apply for a religious exemption using the process provided on the above Mason website. An employee could also seek approval for a fully remote telework agreement and agree not to come to campus, which if approved would also exempt the employee from the vaccine requirement. Finally, if an employee requires an accommodation from the face covering requirement due to a disability, the employee can seek an accommodation from Mason's ADA Coordinator.

It would be premature for Professor Zywicki to file legal action before he has sought any applicable exemption and/or accommodation through these processes.

Please feel free to contact me directly at <u>bwalther@gmu.edu</u> should you wish to discuss this matter further.

Sincerely,

Brian Walther

University Counsel

George Mason University

D. G. Wal

# **ATTACHMENT I**

#### **COVID Documentation Upload Reminder**

George Mason HR <vaccine@gmu.edu>

Mon 8/2/2021 3:00 PM

To: Todd J Zywicki <tzywick2@gmu.edu>



## #PatriotsThisIsOurShot

Dear Todd,

The university's requirement regarding COVID vaccinations, an important and necessary part of our Safe Return to Campus Plan, will help to assure the health of all members of the Mason community.

Our records indicate that you have not yet posted your proof of Covid-19 vaccination, nor is there an approved exemption, on the university's <u>Medicat portal site</u>.

In order for you to comply, you must immediately <u>post your proof of vaccination</u> or have an approved exception in Medicat. You can find <u>step-by-step instructions for upload</u> (<u>PDF)</u> and <u>information on pathways to compliance</u> on the Safety, Emergency, and Enterprise Risk Management website.

Should you not provide this documentation by August 16, 2021, you will be out of compliance with this requirement and subject to disciplinary action, which can lead to being placed on unpaid administrative leave or eventual termination of employment.

If you believe you are compliant with this requirement and have received this note in error, review the **pathways to compliance website** or email <u>vaccine@gmu.edu</u>.

Please refer to the university's **Safe Return To Campus website** for additional information on our approach to and management of COVID-19.

Please remember that everyone must do their part to ensure that we maintain a healthy and safe working and learning environment.

We appreciate your compliance with this requirement to help keep our campus safe.

Best regards,

George Mason Human Resources

**Vaccine Documentation Upload** 

## STOP THE SPREAD OF COVID-19







Stay home and get tested if you feel sick



Wear a face covering



Practice physical distancing



Wash your hands

For information about Mason's public health and safety plans visit Mason's Safe Return to Campus website and please remember, if your plans change and you will come to campus, visit <u>HealthCheck.gmu.edu</u> to complete the Mason COVID Health Check ™ before visiting campus.

Mason COVID Health Check

Safe Return to Campus Website

Safe Return to Campus FAQs Basic Health and Safety Protocols

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