

Mauricio Cardona, ISB #10748

Davillier Law Group
414 CHURCH ST Suite 308
Sandpoint, ID 83864-1347
208-920-6140
Email: mcardona@davillierlawgroup.com

Attorney for Plaintiff

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO**

HEALTH FREEDOM DEFENSE FUND,
INC., RYAN BLASER, on his own behalf and
as natural guardian for and on behalf of his
minor children, K.B.B. and K.S.B.,
MICHELLE SANDOZ, on her own behalf and
as natural guardian for and on behalf of her
minor children, R.S. and E.S., BARBARA
MERCER, an individual, EMILY
KNOWLES, on her own behalf and as natural
guardian for and on behalf of her minor
children, A.G.K. and A.T.K., and KENDALL
NELSON, an individual,

Plaintiffs,

vs.

CITY OF HAILEY, IDAHO, a municipal
corporation, and MARTHA BURKE, in her
official capacity as the Mayor of the City of
Hailey, as well as in her personal capacity for
purposes of Section 1983 claims asserted
herein.

Defendants.

Case No. _____

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

DEMAND FOR JURY TRIAL

I draw sweet air, Deeply and long, As pure as prayer, As sweet as song, Where lilies glow,
And roses wreath, Heart-joy I know, Is just to breathe.

Breath is Enough.

Plaintiffs, HEALTH FREEDOM DEFENSE FUND, INC. (“HFDF”), RYAN BLASER and his minor children, K.B.B. and K.S.B., MICHELLE SANDOZ and her minor children, R.S. and E.S., BARBARA MERCER, EMILY KNOWLES and her minor children, A.K. and A.K., and KENDALL NELSON, by and through their undersigned counsel, sue Defendants, the CITY OF HAILEY and MARTHA BURKE in her official capacity as the Mayor of the City of Hailey, as well as in her personal capacity for the Section 1983 claims asserted herein, and allege as follows:

PRELIMINARY STATEMENT

1. Plaintiffs challenge Public Health Emergency Order No. 2021-03 adopted by Defendant City of Hailey on May 11, 2021 (the “Mask Mandate”), a true and correct copy of which is attached hereto as Exhibit A. The Mask Mandate requires that every person in any indoor public place in the City of Hailey completely cover their nose and mouth with a face covering.¹ The wearing of “face coverings”² is purportedly required for a medical purpose, i.e., to “slow the community

¹ Public Health Emergency Orders were authorized pursuant to Hailey Ordinance No. 1277, enacted on February 8, 2020, which provides that such orders shall have a duration of no more than 90 days, which may be extended upon approval by the City Council. The Mask Mandate was originally instituted pursuant to City of Hailey Public Health Emergency Order No. 2020-05, which took effect on July 1, 2020. The Mask Mandate was subsequently renewed or amended via Emergency Order Nos. 2020-06, 2020-07, 2020-08, 2021-01, and 2021-02. The current iteration, Order No. 2021-03, withdraws the requirement of wearing masks in outdoor public spaces, but maintains the requirement for indoor public spaces.

² The FDA defines face masks as a device and includes face coverings as a subset. See Exhibit B, FDA April 24, 2020 letter to Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders. (“A face mask is a device, with or without a face shield, that covers the user’s nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth *face coverings as a subset*. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as “*face masks*” that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a “device” under section 201(h) of the Act. Generally,

Complaint for Declaratory and Injunctive Relief

spread and protect the health, safety, and welfare of individuals living, working and visiting the City of Hailey” from the virus known as SARS-CoV-2, which has been determined to cause the ailment known as COVID-19. The Mask Mandate also provides for an advertising and public awareness campaign to promote the use of masks to prevent the spread of COVID-19. The Mask Mandate must be struck down because:

- a. The Mask Mandate is preempted under the Supremacy Clause by the federal law under which the Food and Drug Administration (“FDA”) issued the Emergency Use Authorization (“EUA”) for mask use, which requires that use of masks must be optional to the user because the normal testing, evaluation, and approval process for use of such masks has been bypassed by the FDA due to an emergency;
- b. The Mask Mandate’s public awareness campaign is preempted under the Supremacy Clause because it violates the scope of the emergency use authorization for masks issued by the FDA, which provides that it is misleading to “state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction”;
- c. The Mask Mandate implements a mandatory human experiment under which residents of and visitors to Hailey are forced to use a medical device when the medical impact on adults and children (including physical and psychological short and long-term side-effects) of such use has not been tested, evaluated, and approved by the FDA under normal procedures and is therefore unknown (experimental), and thus violates international law, federal law, and Idaho law;
- d. The Mask Mandate violates Plaintiffs’ fundamental human rights deeply rooted in American history and traditions, including the right to breathe unencumbered,

face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks.)” emphasis added.

the right to breathe fresh air, the right to self-determination in medical care, and the parental right to determine a child's health care matters; it is not narrowly tailored to achieve a compelling state interest; and therefore violates the due process clause of the Fourteenth Amendment to the Constitution; and

- e. The Mask Mandate has been placed in force and enforced by the Defendants herein operating under color of law who have deprived Plaintiffs of rights, privileges and immunities secured by the Constitution and laws of the United States, as noted above.

INTRODUCTION

2. None of the currently available face coverings for COVID-19 has received final approval from the FDA. Rather, such face coverings are *unapproved products* that have been authorized for emergency use under an Emergency Use Authorization ("EUA"). A true and correct copy of the EUA authorizing the use of masks during the current emergency (the "Mask EUA") is attached hereto as Exhibit B.

3. The statute granting the FDA the power to authorize a medical product for emergency use requires, *inter alia*, that the person being administered the unapproved product be advised of his or her right to refuse administration of the product. *See* 21 U.S.C. §360bbb-3(e)(1)(A) ("Section 360bbb-3").

4. The FDA has taken the position that the terms and conditions of the Mask EUA preempts state and local laws that would impose obligations that are inconsistent with those terms and conditions. *See* Exhibit C, Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders at 39-40.³

³ "FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564... To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular

5. The Mask EUA specifies that “emergency use of face masks must be consistent with, and may not exceed, the terms of this letter...”. See Exhibit B. Further, the Mask EUA states that the product must not be:

“labeled in such a manner that would misrepresent the product’s intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction”.

6. Defendant City of Hailey’s promotional campaign therefore exceeds the terms of the EUA and misleads the public because it promotes the use of masks as preventing or reducing infection from SARS-CoV-2. It therefore not only misleads the public, but conflicts with the EUA and is preempted under the Supremacy Clause.

7. It is by now well-settled that medical experiments, better known in modern parlance as clinical research, may not be performed on human subjects without the express consent of the individual. This human right against human experimentation has its roots in the Nuremberg Code of 1947, has been ratified by the 1964 Declaration of Helsinki, the United States Code of Federal Regulations, the law of Idaho, and indeed is so universally recognized across the globe that it constitutes a *jus cogens* norm under international law. In short, forced human experiments are universally recognized as against the law. Such globally recognized international standards are binding upon the United States and, when violated, create a cause of action enforceable by citizens of the United States damaged thereby.

8. Masks are traditionally worn by healthcare workers, who are trained in their use, and only for short periods of time.

medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and “conflicts with the exercise of Federal authority under [§ 564].”

9. The short and long-term medical impact and psychological side-effects to children and adults from being forced to consistently wear masks, especially for hours on end while at school or work, have not been studied. Indeed, the evidence is that wearing masks for extended periods of time is harmful, and that this harm is in no way counterbalanced by any benefit.

10. The Mask Mandate thus constitutes a grand medical experiment and forcing every person in a public place in Hailey to wear a face covering constitutes a violation of international law, federal law, and Idaho law, all of which prohibit human experiments absent informed consent.

11. Even if the Mask Mandate does not constitute a mandatory human experiment, the Mask Mandate (a) violates Plaintiffs' fundamental human rights deeply rooted in American history and traditions (such as the right to breath fresh air, the right of self-determination in health care, and the right of parents to determine the health care of their children), (b) is not narrowly tailored to achieve a compelling state interest, and (c) therefore violates the due process clause of the Fourteenth Amendment to the Constitution. Indeed, the Mask Mandate serves no state interest at all (let alone a compelling one) in that it cannot, even according to the FDA, be said to reduce or prevent the spread of COVID-19.

12. There is no "pandemic exception" to the Constitution or any of the law relied upon by Plaintiffs. Plaintiffs therefore ask that the Court intervene to protect their rights.

PARTIES

13. Plaintiff HFDF (hereinafter, "Plaintiff HFDF"), is a not-for-profit public benefit Wyoming corporation with its headquarters in Sandpoint, Idaho. HFDF is a member organization that seeks to advocate and educate the public on the topics of medical choice, bodily autonomy, and self-determination, and that opposes laws and regulations that force individuals to submit to the administration of medical products, procedures, and devices against their will.

14. Several of Plaintiff HFDF's members reside in Blaine County, Idaho, and are

directly affected by the Mask Mandate, as more fully set out in Declarations 1 through 3 attached hereto and made a part hereof as Composite Exhibit D. Plaintiff HFDF's members therefore would have standing in their own right to bring the causes of action asserted by Plaintiff HFDF. As well, the interests at stake in this case are germane to Plaintiff HFDF's purpose, and neither the claims asserted nor the relief requested by Plaintiff HFDF require the individual participation of Plaintiff HFDF's members. Plaintiff HFDF therefore has standing to bring this case, which presents a justiciable issue for the Court.

15. Plaintiff Ryan Blaser is a resident of the age of majority of the State of Idaho domiciled in the City of Hailey. Mr. Blaser is of sound mind and has the capacity to bring this lawsuit. Mr. Blaser is the father and natural guardian of three minor children, including K.B.B. and K.S.B. Mr. Blaser is subject to the Mask Mandate, and, although Mr. Blaser objects to the Mask Mandate, he routinely wears a mask as required by the Mask Mandate, but does so against his will, and explicitly does not consent to the wearing of a face covering as required by the Mask Mandate. Moreover, Mr. Blaser disagrees with any requirement that K.B.B. and K.S.B. be required to wear a face covering as required by the Mask Mandate, does not consent to same on behalf of K.B.B. and K.S.B., and asserts his parental rights to determine whether or not K.B.B. and K.S.B. should wear a face covering. Mr. Blaser therefore has standing to bring this case, on his own behalf and on behalf of K.B.B. and K.S.B., which presents a justiciable issue for the Court.

16. Plaintiff Michelle Sandoz is a resident of the age of majority of the State of Idaho who is domiciled in and owns a business in Hailey. Ms. Sandoz is of sound mind and has the capacity to bring this lawsuit. Ms. Sandoz is the mother and natural guardian of two minor children, R.S. and E.S., both of whom live and go to school in Hailey. Ms. Sandoz, R.S., and E.S. are subject to the Mask Mandate. Although Ms. Sandoz objects to the Mask Mandate, she

routinely wears a mask as required by the Mask Mandate, but does so against her will, and explicitly does not consent to the wearing of a face covering as required by the Mask Mandate. Moreover, Ms. Sandoz disagrees with any requirement that her children be required to wear a face covering as required by the Mask Mandate, does not consent to same on behalf of R.S. and E.S., and asserts her parental rights to determine whether or not her children should wear a face covering. Ms. Sandoz therefore has standing to bring this case, on her own behalf and on behalf of R.S. and E.S., which presents a justiciable issue for the Court.

17. Plaintiff Barbara Mercer is a resident of the age of majority of the State of Idaho who is domiciled in Blaine County, Idaho and owns a business in the City of Hailey. Ms. Mercer is of sound mind and has the capacity to bring this lawsuit. Ms. Mercer is subject to the Mask Mandate, and, although Ms. Mercer objects to the Mask Mandate, she routinely wears a mask as required by the Mask Mandate, but does so against her will, and explicitly does not consent to the wearing of a face covering as required by the Mask Mandate. Ms. Mercer therefore has standing to bring this case, which presents a justiciable issue for the Court.

18. Plaintiff Emily Knowles is a resident of the age of majority of the State of Idaho who is domiciled in the City of Hailey, Idaho. Ms. Knowles is the mother and natural guardian of two minor children, A.G.K. and A.T.K. Ms. Knowles, A.G.K., and A.T.K. are subject to the Mask Mandate, and, although Ms. Knowles objects to the Mask Mandate, she routinely wears a mask as required by the Mask Mandate, but does so against her will, and explicitly does not consent to the wearing of a face covering as required by the Mask Mandate. Moreover, Ms. Knowles disagrees with any requirement that A.G.K. and A.T.K. be required to wear a face covering as required by the Mask Mandate, does not consent to same on behalf of her children, and asserts her parental rights to determine whether or not her children should wear a face covering. Ms. Knowles therefore has standing to bring this case, on her own behalf and on behalf

of A.G.K. and A.T.K., which presents a justiciable issue for the Court.

19. Plaintiff Kendall Nelson is a resident of the age of majority of the State of Idaho who is domiciled in Ketchum, Idaho, and frequently shops and visits public places and businesses in the City of Hailey. Ms. Nelson is subject to the Mask Mandate, and, although Ms. Nelson objects to the Mask Mandate, she routinely wears a mask as required by the Mask Mandate, but does so against her will, and explicitly does not consent to the wearing of a face covering as required by the Mask Mandate. Ms. Nelson therefore has standing to bring this case, which presents a justiciable issue for the Court.

20. Plaintiffs Blaser and K.B.B. and K.S.B., Sandoz and R.S. and E.S., Mercer, Knowles and A.G.K. and A.T.K., and Nelson are referred to herein as the “Individual Plaintiffs”.

21. Allegations regarding “Plaintiffs” hereinbelow shall be deemed to include the Individual Plaintiffs and Plaintiff HFDF.

22. Defendant, City of Hailey, is a municipal corporation that has enacted laws that deprive and infringe, or threaten to deprive and infringe, Plaintiffs of certain rights, privileges, and immunities under the laws and Constitution of the United States, under the laws and Constitution of the State of Idaho, and under international law so widely adopted and accepted as to establish *jus cogens*. The City of Hailey is therefore a person under 42 U.S.C. § 1983. *See Monell v. Dep’t of Soc. Servs.*, 436 U.S. 658 (1978).

23. Defendant, Martha Burke, is the Mayor of the City of Hailey and ultimately charged with enforcing all City of Hailey ordinances, including those complained of herein, and personally signed the Mask Mandate into law. Ms. Burke is being sued in her official capacity as the Mayor of the City of Hailey well as in her personal capacity.

JURISDICTION AND VENUE

24. This Court has jurisdiction to hear all federal claims asserted in this case under 28

U.S.C. § 1331, which confers original jurisdiction on federal district courts to hear suits arising under the laws and Constitution of the United States; the Supremacy Clause of the Constitution of the United States, which allows federal district courts to hear suits alleging preemption of state and local laws by the Constitution and federal laws made in pursuance thereof; and 42 U.S.C. § 1983 and 28 U.S.C. § 1343 in relation to Defendants' deprivation and infringement under color of law of the Individual Plaintiffs' rights, privileges, and immunities secured by the United States Constitution and laws, as detailed further herein.

25. This Court has jurisdiction over the claims asserting violations of the laws and Constitution of the State of Idaho through its supplemental jurisdiction under 28 U.S.C. § 1367(a), as those claims are so closely related to the Plaintiffs' federal question and Section 1983 claims that they form part of the same case or controversy under Article III of the United States Constitution.

26. This Court has the authority to award the requested declaratory relief under 28 U.S.C. § 2201; the requested injunctive relief under 28 U.S.C. § 1343(a); and attorneys' fees and costs under 42 U.S.C. § 1988.

27. The United States District Court for The District of Idaho is the appropriate venue for this action pursuant to 28 U.S.C. § 1391(b)(1) and (2) because it is the District in which Defendants reside, and/or have deprived the Individual Plaintiffs of the rights and liberties under the laws and Constitution of the United States, and have violated the laws and Constitution of the State of Idaho, all as is further alleged herein. It is also the District in which a substantial part of the events giving rise to Plaintiffs' claims have occurred and continue to occur.

FACTUAL BACKGROUND

The Universal Prohibition on Human Experimentation Without Consent.

28. Among the horrors that emerged from the rubble of World War II were stories of

barbaric medical experiments performed on unwilling victims of Nazi Germany's concentration camps.

29. On August 8, 1945, the prevailing Allies established an International Military Tribunal (the "IMT"). Under the aegis of the IMT, the law authorized the creation of U.S. military tribunals for the trial of "lower-level" war criminals, such as doctors accused of conducting medical experiments without the subjects' consent.⁴

30. A U.S. military tribunal subsequently found 15 doctors guilty of conducting nonconsensual experiments, which included the testing of drugs for immunization against malaria, epidemic jaundice, smallpox, and cholera. "In every single instance appearing in the record," the tribunal concluded, "subjects were used who did not consent to the experiments. . . ." The tribunal sentenced seven of the doctors to death, and the remaining eight to life in prison.

31. As part of its final judgment, the tribunal promulgated the Nuremberg Code on Permissible Medical Experiments. Point One of the Nuremberg Code states: "**The voluntary consent of the human subject is absolutely essential.**"

32. This standard has since been repeatedly ratified and adopted around the globe, in laws, treaties, regulations, and ethical guidelines for medical research. For example, in 1964, the World Medical Association adopted the Declaration of Helsinki, which provides that human subjects "must be volunteers and informed participants in the research project." Declaration of Helsinki at Art. 20.

33. Although themselves non-binding, the principles underlying the Declaration of Helsinki and the Nuremberg Code have been incorporated into international conventions, as well as the laws and regulations of countries around the world, including the United States of America.

⁴ Sources for the historical facts set forth herein can be found in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009), which explains in detail the history and reasons why the prohibition against nonconsensual human experimentation should be regarded as a *jus cogens* norm.

34. The International Covenant on Civil and Political Rights of the United Nations, which went into effect in 1976, provides in Article I that “[a]ll peoples have the right of self determination” and in Article 7 that “no one shall be subjected without his free consent to medical or scientific experimentation.”

35. The informed consent principles of the Declaration of Helsinki were also incorporated by a 2001 Directive passed by the European Parliament and the Council of the European Union.

36. In addition, 35 members of the Council of Europe have signed the Convention on Human Rights and Biomedicine, which provides that informed consent is required for a subject’s involvement in medical research.

37. In 2005, the General Conference of UNESCO adopted the Universal Declaration on Bioethics and Human Rights, requiring free and informed consent for participation in medical research-oriented treatments.

38. On December 1, 2020, the High Court of Justice, Queen’s Bench Division, Administrative Court in the United Kingdom concluded that minors lack the ability to give informed consent to the administration of puberty blockers to treat gender dysphoria because the procedure remains experimental.⁵

39. These principles have been adopted by statutes and regulations in the United States.

40. In 1979, the Department of Health, Education and Welfare issued the Belmont Report, which addressed the issue of informed consent in the human experimentation setting. The Report identified respect for self-determination by “autonomous persons” as the first of three “basic ethical principles” which “demands that subjects enter into the research voluntarily and

⁵ See *Bell v. The Tavistock and Portman NHS Foundation Trust*, Case No. CO/60/2020, [2020] EWHC 3274 (Admin) (Engl. & Wales) <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>. (Last viewed on 5/14/21)

with adequate information.”

41. Ultimately, the principles of the Belmont Report, which itself was guided by the Nuremberg Code and the Declaration of Helsinki, were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. *See* 21 C.F.R. § 50.20.⁶

42. The Department of Health and Human Services has similarly adopted this standard in its regulations governing grants for medical research. *See* 45 C.F.R. § 46.116. The United States clearly regards itself as bound by the provisions of the Nuremberg Code and the Declaration of Helsinki.

43. The State of Idaho has adopted the principle of informed consent for all medical treatment. *See* I.C. § 39-4501 (requiring informed consent for medical treatment).

44. For these and other reasons, the prohibition against nonconsensual human experimentation must be regarded not only as established by U.S. law and regulations, but also as so broadly recognized by all nations as to constitute a *jus cogens* norm under international law.

The Use of Face Coverings by the General Population is Experimental, and the Mask Mandate is a Forced Human Experiment.

45. Prior to the COVID-19 pandemic, the only time masks were prescribed for use in public spaces in the United States was during the 1918 flu pandemic. Even then, they were only mandated in certain cities for a matter of a few weeks – certainly not for months on end. Studies of mask use in 1918 have concluded either that they were useless against the flu or that their efficacy was, at best, inconclusive.

46. Accordingly, the scientific literature regarding the short-term and long-term

⁶ The exceptions to this standard are extremely narrow, and require certification by a researcher and an independent physician that, for example, “[t]he human subject is confronted with a life-threatening situation necessitating the use of the test article”; informed consent cannot be obtained from the subject; time does not permit obtaining informed consent from the subject’s legal representative; and “there is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.” 21 C.F.R. § 50.23. *See also* 21 C.F.R. § 50.24 (providing a similarly narrow exception to informed consent requirements for emergency research).

medical and psychological impact of wearing face masks as a general practice throughout the day by children and adults is sparse. General scientific consensus on the short-term and long-term medical and psychological impact on children and adults of wearing face masks as a general practice throughout the day simply does not exist.

47. According to the National Institute of Health, “clinical research is medical research involving people.” “**Clinical trials** are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective in people.”⁷ According to Merriam Webster, an experiment is to “try out a new procedure, idea, or activity.”⁸

48. Plaintiffs allege, and will show at the trial of this matter, that the Mask Mandate is in fact a medical experiment being forced on unwilling participants. The Mask Mandate meets the definition of an experiment in that it is a new procedure, idea or activity. It also meets the definition of a clinical trial in that the result of the Mask Mandate will be to determine whether a medical device, the face covering, is safe for people for extended use, because at this time that issue is unknown.

49. As a factual matter, the Mask Mandate is a human experiment forced on the citizens and visitors to the City of Hailey, including Plaintiffs.

Masks Have No Benefit in Reducing or Preventing Infection From SARS-CoV-2.

The FDA and Scholarly Studies Establish Masks Have No Benefit.

50. The FDA has determined that the efficacy of face coverings for reducing or preventing infection from SARS-CoV-2 has not been established, and that it would be

⁷ U.S. Department of Human Services, National Institute on Aging, What Are Clinical Trials and Studies?, <https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies> Last viewed on May 14, 2021

⁸ *Experiment*, Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/experiment>. Last viewed on May 14, 2021

misleading to state that they are effective in preventing or reducing such infection.

51. In the EUA authorizing general emergency use of face masks, Exhibit B hereto, the FDA stated that it would “would misrepresent the product’s intended use” to state that it “is for use such as infection prevention or reduction”.

52. Similarly, in its Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised),⁹ the FDA stated in three instances that face masks are not intended to reduce or prevent infection:

The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses ***or uses for infection prevention or reduction or related uses*** and does not include particulate filtration claims. *Id.* at 7, repeated twice on page 8.

53. The first and only randomized controlled trial evaluating the impact of mask-wearing on the spread of SARS-CoV-2 in six thousand individuals concluded that masks were ineffective in reducing or preventing infection from SARS-CoV-2.¹⁰

54. A study published in the Emerging Infectious Disease Journal in May, 2020 found that ten randomized control trial studies of the use of face masks to control the influenza virus, a virus essentially the same size as the SARS-CoV-2 virus, showed no significant reduction in influenza transmission with the use of face masks.¹¹

55. Similarly, as study of nearly two thousand United States Marine Corp recruits published in the New England Journal of Medicine in November 11, 2020, indicated that masks

⁹ Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised May 2020), <https://www.fda.gov/media/136449/download> Last viewed on May 14, 2021

¹⁰ Henning Bundgaard et, al, Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial: *Annals of Internal Medicine*: Vol 174, No 3, <https://www.acpjournals.org/doi/pdf/10.7326/M20-6817> Last viewed on May 14, 2021

¹¹ Xiao J, Shiu E, Gao H, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. *Emerging Infectious Diseases*. 2020;26(5):967-975. doi:10.3201/eid2605.190994,

https://wwwnc.cdc.gov/eid/article/26/5/190994_article?fbclid=IwAR1wgGi1n82n8eGLEFTIbzV3atyHqop9DqK-rhx7itJ0SY3eZm5erwTZw6g, Last viewed on May 14, 2021

did not reduce or prevent the spread of SARS-CoV-2.¹²

56. The WHO announced in 2020 that “at present, there is no direct evidence (from studies on COVID-19) on the effectiveness face masking of healthy people in the community to prevent infection of respiratory viruses, including COVID-19.”¹³

57. Cloth masks, such as those generally used by the public, are particularly problematic according to a randomized control trial conducted on cloth masks with regard to the influenza virus in 2015. The study concluded that due to moisture retention, reuse of cloth masks and poor filtration, cloth masks may result in increased risk of infection.¹⁴

58. Accordingly, science does not support the proposition that the Mask Mandate can or will reduce or prevent the spread of SARS-CoV-2, and may indeed cause increased risk of infection.

The Physical Properties of Masks Establish That They Cannot Prevent Virus Spread.

59. From a physical standpoint, the properties of masks versus the SARS-CoV-2 virus prove that masks simply cannot prevent the virus from exiting the nose and mouth of infected individuals into the air around them to be breathed in by others. According to the current knowledge, the SARS-CoV-2 virus has a diameter of 60 nm to 140 nm [nanometers (a billionth of a meter)]. Medical and non-medical facemasks’ thread diameter, on the other hand, ranges from 55 µm to 440 µm [micrometers (one millionth of a meter)], which is more than 1000 times larger than the diameter of the virus. Due to the difference in sizes between SARS-

¹² Andrew G. Letizia, M.D et al, **SARS-CoV-2 Transmission among Marine Recruits during Quarantine**, <https://www.nejm.org/doi/full/10.1056/NEJMoa2029717>, last viewed on May 14, 2021

¹³ World Health Organization. (2020). Advice on the use of masks in the context of COVID-19: interim guidance, 5 June 2020. World Health Organization. <https://apps.who.int/iris/handle/10665/332293>. License: CC BY-NC-SA 3.0 IGO. Last viewed on May 14, 2021

¹⁴ C Raina MacIntyre et al, A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, <https://pubmed.ncbi.nlm.nih.gov/25903751/>, Last viewed on May 14, 2021

CoV-2 diameter and facemasks thread diameter (the virus is 1000 times smaller), SARS-CoV-2 can easily pass through any facemask like a mosquito can pass through a chain link fence.

60. The physical impossibility of filtering the SARS-CoV-2 virus with masks is exacerbated by the lack of any seal between the wearer's face and the mask, which allows breath to exist wholesale sans any filtering whatsoever into the air around the wearer to be breathed in by others.

61. The Occupational Safety and Health Agency has set standards for the use of masks to prevent infection by viruses. These masks seal effectively around the nose and mouth, and prevent the inhalation or exhalation of viruses into the air by those wearing them but can only be used with an external source of oxygen being pumped into the mask, much like a diver wearing an oxygen tank. The face coverings being used by the public at large are not such masks, and are therefore not designed to, nor do they, prevent or reduce infection by the SARS-CoV-2 virus.

62. The Mask Mandate therefore serves no compelling state interest.

63. The Mask Mandate promotional program undertaken by the Defendants is also contrary to federal law, factually incorrect, misleads the public, and serves no compelling state interest.

Prolonged Use of Masks is Harmful to Children and Adults.

64. Not only does the Mask Mandate not reduce or prevent the spread of SARS-CoV-2, the prolonged use of masks by children and adults is detrimental in the following specifics which will be shown by Plaintiffs in the trial of this matter:

- a. Breathing is one of the most important and necessary physiological functions to sustain life and health. Humans are welcomed into the world with their first breath, and ushered from it with their last. The human body requires a

continuous and adequate oxygen supply to all organs and cells for normal function and survival. Breathing is also an essential process for removing metabolic byproducts, like carbon dioxide, occurring during cell respiration. Masks are significantly detrimental to human breathing function because they force users to rebreathe their own expelled air over extended periods of times increasing levels of carbon dioxide and other detrimental elements in the body;

b. Wearing a mask mechanically restricts breathing by increasing the resistance of air movement during both the inhalation and exhalation process. Masks therefore deprive users of oxygen and raise carbon dioxide levels in the body, which causes the following non-exhaustive list physical symptoms and damage:

- i. Fatigue;
- ii. Loss of concentration;
- iii. Headaches;
- iv. Loss of Reaction Time;
- v. Loss of Brain Cells and Brain Function;
- vi. Long-term Neurodegenerative Diseases;
- vii. Lack of Normal Cognitive Development in Children;
- viii. Increased Disposition for Viral and Infection Illnesses;
- ix. Hypertension;
- x. Cardiovascular Disease;
- xi. Exacerbation of Existing Chronic Conditions;
- xii. Premature Aging; and, without limitation,
- xiii. Premature Death.

c. Masks cause the following non-exhaustive list of detrimental physiological effects:

- i. Hypoxia;
- ii. Hypercapnia;
- iii. Shortness of Breath;
- iv. Increased Lactate Concentration;
- v. Acidosis;
- vi. Toxicity;
- vii. Chronic Inflammation;
- viii. Self-Contamination;
- ix. Increase in Stress Hormone Levels;
- x. Increased Muscle Tension; and, without limitation,
- xi. Immunosuppression.

d. Masks cause the following non-exhaustive list of psychological effects:

- i. Fear;
- ii. Claustrophobia;
- iii. Mood Disturbances;
- iv. Compromised Cognitive Performance;
- v. Peer Pressure.

65. Masks have been used as a form of torture in prisons, to isolate prisoners from one another and dehumanize them.

66. Masks dehumanize society, by separating members of society from one another. The face is the avatar of the person; the essential tool for inter-human recognition and interaction. Hiding the face isolates people from one another, atomizing the members of society, and breaking

down the social structure naturally social humans require.

Masks Disrupt Normal Child Development.

67. Requiring children to wear masks, especially for extended periods of time, disrupts their development, for reasons that include but are not limited to the following:

- a. Nonverbal communication is one of the most important channels for the social development of younger children. Furthermore, facial expression is one of the central signals through which we communicate our own emotional state and infer the emotional state of others, which makes this one of the fundamental building blocks for the development of high emotional and social competence. Children in particular have yet to learn how to reliably interpret these signals in the faces of others, which is critical to the development of empathy. The wearing of masks inhibits the development of this important ability.
- b. Mask-wearing can also cause children to experience a negative distortion of emotional experience. Fear and sadness are more likely to be read from the eyes and joy from the mouth region. The wearing of masks could therefore lead to the perception of less positive and more negative emotions in the faces of others.
- c. The inability to see faces also interferes with a child's early education. One of the goals of daycare and preschools is to teach children cooperation and communication skills, but this pedagogical work is jeopardized when the child cannot see the teacher or caregiver's face. As well, a masked face impairs the development of attachment and relationships, which are essential for the education and upbringing of children. It is precisely the personal and familiar contact with between child and staff that is enormously important for early

childhood education. That is why it is important that employees in daycare and pre-k facilities do not cover their faces during normal activities.

- d. The wearing of masks is also associated with the impairment of verbal skills development. A mask mutes the voice's higher frequencies, while visual signals from mouth and lip movement are completely obstructed. This has a particularly detrimental effect on a child's ability to learn language, which especially impacts children for whom English is a second language.

Plaintiffs' Injury and Standing to Seek Declaratory and Injunctive Relief

Plaintiff Blaser and His Minor Children Have Been Injured by the Mask Mandate, and Their Rights Have Been Violated.

68. Plaintiff Blaser is subject to the Mask Mandate, to which he objects. He is also the father of three children, including a seven-year-old daughter, K.S.B., and an eleven-year-old daughter, K.B.B. K.S.B. and K.B.B. are subject to the Mask Mandate, even though their father, Plaintiff Blaser, objects to having his daughters wear the masks. K.S.B. and K.B.B. have both been negatively impacted by the Mask Mandate in that they are being denied the normal social, psychological and developmental experience essential to normal development of children their age. They are under stress and being damaged by the Mask Mandate physically, emotionally, and psychologically. They are isolated, lonely, and depressed.

Plaintiff Sandoz and Her Minor Children Have Been Injured by the Mask Mandate, and Their Rights Have Been Violated.

69. Plaintiff Sandoz and her minor children, R.S. and E.S., have been adversely affected by the Mask Mandate. As a mother, Sandoz is worried about the emotional and physical impact of the masks on her children and herself. Sandoz finds it emotionally distressing to watch the impact of the mask mandate on her children. The mask mandate causes her emotional distress because she can't see other's faces and engage with them in a normal manner. E.S.'s face has broken out as a

result of prolonged mask-wearing. Both children are under stress and being damaged physically, emotionally, and psychologically. They are isolated, lonely, and depressed. The emotional and physical toll is undermining the community of Hailey and the Sandozes' connection to it.

Plaintiff Mercer Has Been Injured by the Mask Mandate, and Her Rights Have Been Violated.

70. Plaintiff Mercer has an office in downtown Hailey where she tutors children from second grade through high school. Ms. Mercer has allergies and breathing is already difficult for her without a mask; with a mask it becomes challenging. Ms. Mercer has been harassed and ostracized, and her business has suffered, due to the Mask Mandate.

Plaintiff Knowles and Her Minor Children Have Been Injured by the Mask Mandate, and Their Rights Have Been Violated.

71. Plaintiff Knowles' minor son, A.T.K., has suffered headaches and inability to concentrate as a result of wearing masks. Ms. Knowles' minor daughter, A.G.K., is unable to wear a mask without feeling claustrophobic and suffering from panic attacks.

72. A.G.K. was also forced to wear a mask in her dance classes, which was one of her primary extracurricular and social activities. Due to the Mask Mandate, and her inability to tolerate wearing the mask, she was forced to drop out of her dance class. As a result, A.G.K. does not get the normal social interaction essential to proper childhood development. She is no longer a member of any team. She cannot play sports. She is isolated, lonely, and depressed as a result of not having normal human interaction and connection as she grows from childhood into an adult. Ms. Knowles is very worried about the physical and psychological damage being done to both A.T.K. and A.G.K. as a result of the Mask Mandate.

73. Ms. Knowles herself is active in sports and regularly works out. Ms. Knowles also teaches Pilates classes part-time in Hailey, where her students are required to wear masks. However, the masks prevent normal interaction and communication with students as they create a

barrier between her and the students she teaches. Ms. Knowles, who is normally a cheerful person by nature, feels gloomy and depressed when forced to wear a mask, and feels like she is being suffocated it. As such, wearing a mask feels like torture.

Plaintiff Nelson Has Been Damaged by the Mask Mandate and Her Rights Have Been Violated.

74. Plaintiff Kendall Nelson routinely shops and does business in Hailey and is therefore subject to the Mask Mandate. Shopping in Hailey is a practical necessity for residents of Ketchum, where options are limited and more costly. Ms. Nelson objects to the Mask Mandate, and only complies with it where absolutely necessary. She feels that she cannot breathe when wearing a mask, which causes her to feel a sense of panic, like she is being suffocated. She feels like she is going to pass out, gets headaches and feels hot and dizzy when forced to wear a mask. These issues have forced her to curtail her activities in Hailey due to the Mask Mandate. For example, she used to enjoy attending a yoga class in Hailey but has not returned because she cannot wear a mask while exercising. Ms. Nelson also believes, based on factual, scientific data, that extended mask-wearing can cause infections such as bacterial pneumonia.

The Right to Breathe Fresh Air is a Fundamental Human Right Deeply Rooted in American History and Traditions.

75. Breathing in a free and unobstructed manner sufficient to oxygenate blood and expel various waste products of cell activity has been a time-honored tradition of each and every citizen of this Nation since well prior to its founding. This essential tradition is thus deeply rooted in our history. Indeed, ancient texts refer to the “breath of life.” Poets have written odes to breath itself. The reason water boarding is considered torture is because it makes its victim feel unable to breathe, creating the terrorizing feeling that death is imminent. Research has not revealed any human who did not constantly breathe from the time he or she was born, until the time he or she died. It is a universally accepted practice undertaken by citizens of the United States as well as by

citizens of each and every nation across the globe.

76. The current situation in the United States is the first time in our history when members of the public in general have been required to wear face masks that obstruct their right to breathe freely in a manner sufficient to oxygenate their blood and expel various waste products of cell activity. It is massively invasive of a fundamental human right deeply rooted in our Nation's history and tradition, an invasion which serves no purpose at all, as the science shows and as Plaintiffs will prove at trial.

77. All conditions precedent to bringing this lawsuit have been performed, excused, or waived.

COUNT I

(All Plaintiffs vs. The City of Hailey)

DECLARATORY JUDGMENT ACTION BASED UPON FEDERAL PREEMPTION / VIOLATION OF THE SUPREMACY CLAUSE

78. Plaintiffs reallege and incorporate by reference their allegations in Paragraphs 1 – 77, as if fully alleged herein, and further allege:

79. Federal laws and regulations governing the approval and administration of medical products such as masks completely preempt any and all contrary or inconsistent laws of the States and/or local governments.

80. The masks remain an investigational product in accordance with the FDA's Emergency Use Authorization of the masks.

81. Title 21 United States Code, Section 360bbb-3(e)(1)(A)(ii), and regulations and internal protocols of the United States Food and Drug Administration promulgated thereunder, provide in relevant part that all individuals to whom an investigational product is to be administered under an Emergency Use Authorization be informed **“of the option to accept or refuse administration of the product. . . .”**

82. Because the masks are an investigational product, approved for use under an Emergency Use Authorization, the laws and regulations of the United States prohibit its administration to any person who does not consent to its administration.

83. Plaintiffs do not consent to being required to wear masks.

84. The Mask Mandate is therefore patently contrary to United States law, and thus preempted and invalid.

85. As well, Title 21, Part 50 of the Code of Federal Regulations governs the protection of human subjects in the conduct of all clinical investigations regulated by the U.S. Food and Drug Administration.

86. 21 C.F.R. § 50.20 provides that, “[e]xcept as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.”

87. Under the EUA, the masks remain in the clinical investigation stage.

88. None of the exemptions provided in sections 50.23 and 50.24 would apply to Plaintiffs.

89. Accordingly, the Mask Mandate patently violates federal law and regulations governing the administration of experimental medicine, and is thus preempted.

90. Plaintiffs have no adequate remedy at law available against Defendants for the injuries and the irreparable harm they will imminently suffer as a direct result of the Mandate.

WHEREFORE, Plaintiffs respectfully request that the Court enter a declaratory judgment that Defendants' Mask Mandate violates and is preempted by the laws and regulations of the United States governing the administration of investigational medical products, for an injunction prohibiting

enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

COUNT II

(All Plaintiffs vs. All Defendants)

VIOLATION OF SUBSTANTIVE DUE PROCESS

42 U.S.C. § 1983

91. Plaintiffs reallege and incorporate by reference their allegations in Paragraphs 1 – 77, as if fully alleged herein, and further allege:

92. Plaintiffs have a protected liberty interest, secured by the Due Process Clause of the United States Constitution, international protocols and treaties adopted by and entered into by the United States, and by the laws and regulations of the United States, to be free from forced medical experimentation.

93. This right is further recognized as a *jus cogens* norm under the laws of nations.

94. As set forth more fully above, the forced administration of masks is, under the circumstances, experimental medicine.

95. As well, or in the alternative, Plaintiffs have a protected liberty interest, secured by the Due Process Clause of the United States Constitution, to be free from non-consensual administration of medical procedures and devices, and/or to be free from the forced administration of medical procedures and devices that Plaintiffs reasonably believe may cause them harm.

96. As well, or in the alternative, Plaintiffs have a fundamental right, secured by the Due Process Clause of the Fourteenth Amendment of the United States Constitution:

a. to breathe fresh air;

b. to control and/or consent to the administration of medical products and medical care to their minor children; and, without limitation,

c. to self-determination in matters of medical care and the administration of medical products and devices.

97. Defendants' Mandate is not sufficiently narrowly tailored, or lacks a rational basis, as the FDA itself has stated that Defendants may not represent masks as being effective against viral spread, numerous studies have confirmed that masks are not effective against viral spread, and Plaintiffs will show at trial that masks are damaging in a variety of way to those who are forced to wear them consistent with the requirements of the Mask Mandate.

98. Plaintiffs have no adequate remedy at law available against Defendants for the injuries and the irreparable harm they will imminently suffer as a direct result of the Mandate.

WHEREFORE, Plaintiffs respectfully request that the Court enter a declaratory judgment that Defendants' Mask Mandate violates Plaintiffs' substantive Due Process rights, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury for all matters so triable.

DATED this 14th day of May, 2021.

The Davillier Law Group

/s/ Mauricio Cardona

Mauricio Cardona, ISB# 10748 - Of the Firm

Counsel for Plaintiff