

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

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 [8 5641]”

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.