This serves as notice to all employers that any compulsory face mask requirement imposed upon an employee violates federal law. Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”) vests the Secretary of Health and Human Services with the permissive authority to grant Emergency Use Authorizations (“EUAs”). However, the statute requires that:

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

On April 24, 2020 the Food and Drug Administration (“FDA”) issued an EUA letter to all “Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders,” allowing manufacturers to produce cloth and non-surgical face masks to sell and distribute to the general public and health care practitioners, so long as, “[the] product is not 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[.]

Thus, by the FDA’s own admission, face masks such as those in common use by the public are not intended to protect the wearer or others from the COVID-19 virus, as they do not prevent or reduce infection.

Even if wearing a face mask were effective enough to protect the wearer and the general public from COVID-19, which they are not, the EUAs issued pursuant to FD&C Act’s authority are extremely limited in legal scope and effect. Specifically, as long as EUAs pertaining to face masks remain in force and effect, any mandate requiring employees to wear face masks would conflict with Section 360bbb-3(e)(1)(A)(ii)(I-III), which requires that the employee be informed of the option to refuse the wearing of such ‘device.’

We at the Health Freedom Defense Fund urge U.S. employers to comply with the FD&C Act, not misrepresent the use of a mask as being intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction, and advise all employees that they have the right to refuse to wear a mask as a measure to prevent or reduce infection from COVID-19. Any other course of action is contrary to federal law.