

NO.: 4D20-1765
L.T. CASE NO.: 502020CA006920XXXXMB

IN THE FLORIDA DISTRICT COURT OF APPEAL,
FOURTH DISTRICT

JOSIE MACHOVEC, et al.,
Appellants,

v.

PALM BEACH COUNTY,
Appellee.

From the Circuit Court for the Fifteenth Judicial Circuit
Palm Beach County, Florida

BRIEF OF ALACHUA COUNTY AS AMICUS CURIAE IN
SUPPORT OF DEFENDANT/APPELLEE, AND AFFIRMANCE

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Interest of Amicus Curiae

Alachua County is a charter county and political subdivision of the State of Florida. The population is approximately 289,000, and the three hospitals in Alachua County serve not only the population of Alachua County, but also the surrounding rural counties where the level of care available within Alachua County is not accessible. Alachua County issued its own emergency order, which is substantially similar in the requirements regarding facial coverings to the order at issue. Its order is intended to slow the spread of the virus, and to preserve the capacity of the hospitals to take in patients. Alachua County has been sued twice, and prevailed on the issue pending before this Court. One of those cases was appealed, and is pending before the 1st District Court of Appeal. Alachua County has an interest in supporting the ability of local government in the state to take appropriate action for their local communities in protecting the health and welfare of their citizens.

SUMMARY OF ARGUMENT

The sole basis of Appellants' case is that the requirement that a face mask worn in limited circumstances equates with medical treatment, whether the mask is worn for the wearer's benefit or to prevent the wearer from spreading the virus. The Appellants would have the mandated use of any item which is considered a medical device as having to meet the level of strict scrutiny, regardless of what context it is being used. While an individual may be free to decline invasive medical treatment, or free to determine whether they wish to pursue medical treatment, the question of whether something is medical treatment depends wholly on the context. For example, compression socks may be a prescribed medical treatment, or a podiatrist may prescribe special footwear, but simply because those socks or shoes may be considered medical devices does not mean that all socks and shoes meet that standard.

ARGUMENT

Appellant relies on the assumption that all face masks are medical devices, and therefore, requiring the use of a face mask is the same as requiring specific medical treatment. While some face masks may be designated as medical devices, since they serve the purpose of protecting or treating the individual wearing the face mask, other masks are primarily intended to curb the viral spread from its source, namely the wearer of the mask. As discussed in greater detail below, some face masks may serve a dual function, but the emergency order at issue is written in a way to give the wearer flexibility and discretion regarding what type of facial covering to use, many of which would not satisfy legal definitions of the terms “medical device” or “medical equipment.”

Additionally, in the absence of a statewide mandate, the requirement to wear face masks is a reasonable local approach to serve the compelling interest of curbing the spread of a deadly virus that has claimed thousands of lives in Florida alone. In Florida, local governments, particularly charter counties, have home rule authority to act without needing express legislative authorization. In this case, the County acted reasonably, and within its authority, to require measures intended to slow the spread of the virus and support the state and local economy by attempting to avoid a shutdown.

A. THE EMERGENCY ORDER DOES NOT REQUIRE MEDICAL TREATMENT

Appellants' core assumption is that the Palm Beach Order (App 3) requires Appellants and other members of the public to wear "medical devices" for the purposes of medical treatment, and this violates the Florida Constitutional protection of a right of privacy. The Court does not have to reach any Constitutional question, since the order in question does not require the use of anything that is considered a medical device, and the context in which it is being used is not medical treatment.

The emergency order does not prohibit the use of a surgical mask, which may be considered medical equipment in the right context. However, it expressly discourages use of an N95 mask. Otherwise, it allows homemade facial coverings, or the use of items which the CDC has endorsed as an alternative (App 11). The use of a clear facial shield is also allowed.

Appellants attempt to distract the Court with the Food and Drug Administration (FDA)'s regulations regarding which face masks can be certified as medical equipment. By citing to a broad statutory definition set forth in 21 U.S.C. 321(h), they attempt to bring in every sort of facial covering into the ambit of the FDA. Notably, the FDA's regulations only establish two types of face masks as being within their authority, face masks used in surgery – 21 CFR 878.4040 and filtering facepiece respirators for use by the public in public health medical

emergencies, which is found at 21 CFR 880.6260. As shown below, this particular section does not describe a cloth face covering or a non-surgical face mask.

(a) Identification. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

(b) Classification. Class II (special controls). The special controls are:

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: “Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies.” See § 880.1(e) for information on obtaining a copy of this guidance document. 21 CFR 880.6260.

It is evident that this specific type of PPE is regulated. If there is any additional question about the position of the FDA, its Letter of Authority, dated 4/24/2020 (App. 14) in footnotes 1 and 2, addresses the various types of items within the broad definition of face masks, and specifically notes that the FDA only regulates those intended for a medical purpose. Footnote 1 states in part:

“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, face masks fall within this definition when they are intended for a medical purpose. Face masks regulated under 21 CFR 878.4040 as Class I 501(k)-exempt devices (non-surgical masks).

The next footnote goes on to discuss “surgical masks” which are regulated by the FDA, and are not covered under the Emergency Use Authorization (EUA). The specific purpose of this EUA is set forth in the FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical) (App 21). The purpose from the beginning has been one of source control for the virus to prevent the wearer from spreading infection. They reference the CDC’s recommendation on the use of common materials to create facial coverings. While the FDA indicates that this is voluntary, this does not take away from local government’s actions since the FDA does not have the authority to mandate these non-medical items. Notably, the face masks that are addressed by the agency in the EUA are not considered Personal Protective Equipment that is intended to protect the wearer. Other devices exist for that. Instead, these are to protect the public from the wearer.

The Center for Disease Control (CDC)’s recommendations are specifically referenced (App 11) in EO-12. These recommendations specifically discourage the use of masks intended for health care workers, specify the construction of masks, and include the use of gaiters, which have not been suggested by Appellants to be

regulated by the FDA.¹ The CDC also provides instructions on how to make your own masks, which are certainly not regulated by the FDA, as they do not move in interstate commerce (App 23).²

The CDC has continued to investigate the effectiveness of masks in observational and epidemiological studies. They continue to support the use of multi-layer cloth masks, noting that they are effective anywhere from 50-80% in blocking fine particles, which relates to the fit and selection of fabric³ (App 26).

The use of face coverings finds support from not only the FDA and CDC, but also the American College of Occupational and Environmental Medicine (App 31). While their recommendation is specific to workplaces, like the CDC, their recommendation is that surgical masks or N95 respirators not be used. They note that the face covering is not intended to be used as respiratory protection for the wearer.

The use of facial coverings for purposes of source control in the current circumstances is much different from the use of PPE in work environments as protection for employees from work hazards. An Occupational Safety and Health

¹ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html> Last accessed 11/17/20

² <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-make-cloth-face-covering.html> Last accessed 11/17/20

³ <https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html> Last accessed 11/17/20

Administration Publication 3951 gives a brief overview of this (App 35). A detailed listing of the various areas where specific types of masks must meet certain standards are found in the OSHA rules at 29 CFR 1910.134. (App 39). A brief scan of these various areas and types of PPE make clear that even though they are designed to protect the individual, they are not the sort of items that are regulated by the FDA as medical devices. An exception might be the N95 respirator, which is common in a number of industries for particulate protection. The agency that sets the standards for these devices is the National Institute for Occupational Safety and Health (NIOSH), established by the Occupational Health and Safety Act of 1970. Their focus is in part on the use of FDA certified material in healthcare and related fields and the use of other PPE in non-healthcare fields. They are a branch of the CDC. OSHA publication 3079 (App 58) discusses the use of respirators (N95 is a respirator), or other types of loose or tight fitting devices used in specific situations to protect the individual. This is not considered to be medical treatment by OSHA, but as prevention of an occupational hazard, although it is focused on occupational health.

While some face masks may fall under the classification of a “medical device” or “medical equipment,” it is clear that not all face masks would. If an individual chooses to wear a mask that may be classified as a medical device, that is a choice. However, the County’s emergency order does not mandate that such a mask be worn,

and it even discourages the use of those types of face masks that are intended to protect the wearer and may be classified as “medical equipment.” There is no question that the types of facial coverings being mandated do not meet the definition of medical devices under the Food and Drug Act. As a result, Appellants fail to establish that the behavior mandated by the emergency order, the wearing of masks, constitutes any sort of medical treatment that may be anticipated and protected by the Constitutional right to privacy. Based upon the totality of information available, it is clear that this is not medical treatment, and so no analysis under the right of privacy arising under the Florida Constitution is required.

B. THE COUNTY ACTED REASONABLY IN ADOPTING THE EMERGENCY ORDER TO ADDRESS THE COMPELLING INTEREST OF CURBING THE SPREAD OF THE VIRUS

Unlike OSHA or the FDA, which each have specific, limited grants of authority under Federal law, local governments, especially charter counties, have broad authority to enact legislation or, as appropriate, emergency orders under Section 252.38, Florida Statutes in an appropriate situation. We are in a global pandemic, and the incidence of the virus in Florida continues to rise. Nationally, nearly a quarter of a million individuals have died in the United States alone due to the virus. Local governments have a compelling interest in minimizing the disruption to the health care system that individuals who need inpatient care for COVID-19 can

cause, as well as limiting the spread of the virus to allow the economy to stay up and running. Similarly, under the general police power, local governments may take action for the public health and welfare. Not only is COVID-19 a risk to the public at large, but also there is increasing evidence that even in healthy individuals there can be health issues that persist after recovery.⁴ (App 73) In the population of those with comorbidities, the risks are even greater⁵ (App 76). The CDC, Florida Surgeon General (App 85) and the World Health Organization⁶ now recommend the use of face masks along with social distancing, avoiding crowded spaces, cleaning hands, and other steps individuals can take to prevent the spread of the virus. There is no question that there is a nexus between the use of the mask to provide source control and the virus. Appellants fail to establish how the County's response to the pandemic, particularly the requirement to wear face masks, is an unreasonable approach to addressing such a catastrophic event.

Additionally, Appellants fail to make their case that EO 12 is not narrowly tailored to meet the goal of slowing the spread of the virus. The County acted reasonably in developing the Emergency Order to provide individuals with the flexibility of choosing a face mask in order to curb the spread of the Coronavirus,

⁴ <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351> Last Accessed 11/17/20

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html> Last Accessed 11/17/20

⁶ <https://www.who.int/news-room/q-a-detail/coronavirus-disease-covid-19-masks> Last Accessed 11/17/20

and to prevent a shutdown of local businesses. In requiring the use of face masks only in certain situations, the County acted reasonably and consistently with the recommendations of the CDC and the Surgeon General.

CONCLUSION

Appellant cannot show that any sort of medical treatment is being compelled by the use of facial coverings as the items being recommended by the CDC and covered by the Emergency Order do not fall within the type of facial coverings regulated by the FDA and, so far as any constitutional analysis is required, under the present circumstances the Emergency Order met the rational basis standard and the lower tribunal's order should be affirmed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been electronically filed with the 4th District Court of Appeal by using the Florida Courts E-Filing Portal, and that a copy has been sent via e-mail to the attached Service List this 19th day of November, 2020.

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this brief complies with the font requirements of Florida Rule of Appellate Procedure 9.210(a)(2).

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