IMPORTANT FACE COVERING PURCHASER ADVISORY

CDC *Scientific Brief* Expands Utility of Face Coverings

New National and International Standards Pertaining to General - Purpose Barrier Face Coverings are Imminent

International standards intended to regulate general-purpose face coverings do not address the use of antimicrobial or antiviral materials, finishes, or mechanisms, many of which are subject to oversight by the U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) and may warrant additional testing and regulatory oversight as to their efficacy and safety. Further, there are several aspects that relate to the material composition and design of face coverings that are not addressed by many standards but warrant attention relative to the safety, health, and environmental impact of face coverings including, but not limited to potentially toxic finishes, inhalable substances from materials, and bioburden inhibitors. Understanding this, the **Research Consortium** believes it is important that end users familiarize themselves with the specific special claims being made for products and ask for information to verify such claims.

The ***Stay Safer Reusable Protective Face Covering*** neither a CDC/NIOSH certified respirator nor an FDA-approved surgical mask. It is technically a "medical device" per the FDA which classifies ALL face coverings that are intended to curb community spread as a medical device. Like other general purpose face coverings, it is authorized for use by the FDA under an Emergency Use Authorization (EUA) by the general public to help slow community spread during the COVID-19 pandemic. Without specific EPA or FDA approval, claims cannot be made about any antimicrobial agent's protection or prevention against specific organisms infectious to humans or that of any fabric treated with the agent. As such, while this face covering does not cause damage nor bring additional risk to wearers when used as intended, it cannot be stated that it can prevent or protect the wearer from any form of risk to a person's health or safety, illness or disease. Accordingly, the research, studies and data provided in support of the science and technology behind our face covering — while truthful, accurate and complete — is presented for informational and educational purposes only. For more on this topic, see below.

Summary

- In November 2020, the CDC acknowledged for the first time that in addition to source control general-purpose face coverings can also serve to reduce the number of infected particles a wearer might inhale.
- New standards will soon be released in Europe and the US that will impose design, leakage, filtration efficiency, breathability, safety and consumer labeling requirements on general-purpose face coverings.* **Research Consortium*'s Richard Nicholas is on the ASTM workgroup developing the US standard.***
- Traditional particle filtration efficiency (PFE) and bacterial filtration efficiency (BFE) testing will be obsolete. Manufacturers will need to meet new testing standards that are far most broad, stringent and challenging.
- Laboratory testing requirements are more specific to eliminate the great variations allowed by other standards (e.g., particle filtration tests have specific face velocity, particle polarity and size range/mix requirements, etc.)
- Ordinary face coverings will not likely meet the new standards. Many manufacturers will have to abandon or curtail their product claims and acknowledge the use of unsafe, unhealthy and non-ecofriendly characteristic

Import of CDC Scientific Brief

The CDC, in a monumental move, recently issued a ***Scientific Brief*** in that for the first time stated that wearing a face covering can help to reduce the wearers' exposure by filtering infectious droplets. ***Community Use of Cloth Masks to Control the Spread of SARS-CoV-2*** (found here) states that while it is well known that cloth masks block most large droplets effectively, they also block aerosols and can be excellent source control for exhaled viral particles (noting that some multi-layer masks can perform "on par with surgical masks as barriers for source control".

This acknowledgement of the expanded utility of face coverings to include wearer protection, is consistent with initiatives, *and worldwide*, to develop a community face covering standard that addresses both in- and outbound filtration as a means by which to spurn the creation of better face coverings and to provide users with the confidence they need to feel safe about wearing in public.

Current Regulatory Compliance Requirements

Presently, although no formal national standard exists for general-purpose, community use barrier face coverings in general, various government agencies are responsible for regulating certain aspects of such coverings. By example, both the EPA and FDA are charged with regulating antimicrobial agents based on their intended application. * In general, antimicrobial agents used on inanimate objects are regulated by the EPA as antimicrobial pesticides under FIFRA; and antimicrobials used in or on living animals or humans are regulated by the FDA under FFDCA.

The EPA has established strict rules regarding marketing claims made about the capabilities of anti-microbials. Among them are prohibitions against making claims beyond that of the "treated article" itself. Without specific EPA approval, claims cannot be made about an antimicrobial's protection against or prevention from specific organisms infectious to humans or that of the treated fabric. Any claim must be limited to the face covering itself; be specific and not unqualified; refrain from referencing health-related microbes and from denoting personal (e.g., "for skin, wound, or respiratory") protection. These prohibitions cover product packaging, advertising and communications. Graphic representations of the covering's antimicrobial protections cannot include or imply protection of public health significance or take prominence above other normal product claims.

New Community Face Covering Standards

New standards are being developed that will transform voluntary specifications into requirements for community face coverings throughout the Europe and the US. An *American Society for Testing and Materials (ASTM) International* workgroup, overseen by the CDC/NIOSH, has been hard at work developing a "standard" for barrier face coverings to be published in early 2021. This standard will require meeting minimum performance levels on tests similar to those used to evaluate respirator devices and measure leakage, particle filtration and breathability. Community mask specifications are in the process of being converted into a standard by the European Committee for Standardization (CEN) as well. Ordinary (lower quality) fabric face coverings will not likely meet these requirements. It is also likely that certain manufacturer performance and safety claims will to be limited or prohibited. *

The Foundation of Our Authority

The **Research Consortium** took an early interest in face coverings at the outset of the pandemic as it was in keeping with our work: to evaluate new medical technologies/health innovations for health plan sponsors. Our study, **COVID-19, ITS TRANSMISSION AND FACE MASK EFFICACY**. has been downloaded thousands of times.

The *Research Consortium*'s Richard Nicholas has done extensive research on face mask guide-lines. He is a member of the *American Association of Textile Chemists & Colorists* committee that created M14-2020 Guidance and Considerations for General Purpose Textile Face Coverings and the *American Society for Testing and Materials International* workgroup that is developing (with the CDC/NIOSH) a soon-to-be-released national "standard" for barrier face coverings.

Mr. Nicholas has studied most all of the community face covering specifications issued by the leading international standards entities, as well as those of dozens of other countries that have modified them or developed their own specifications. All totaled, the specifications below have been adopted by more than 120 countries.

- CWA17553 Community Face Coverings: Guide to Minimum Requirements, Methods of Testing and Use
- AFNOR Specification S76-001: Masques Barrières
- NM ST 21.5.200/2020 Réglementation Relative aux Masques de Protection (Islamic Countries)
- TU 13.92.29-005-00302178-2020: Hygienic Face Masks (Russian Federation)
- Health Commission Policy Update: Community Use of Face Masks (African Union)

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* The FDA regulates all face coverings used for source control as medical devices if they employ an antimicrobial. As such, the ***Stay Safer Reusable Protective Face Covering*** is presently undergoing a spectrum of bespoke lab testing to support its claims. Our face covering is also undergoing leakage, filtration and air flow testing designed to satisfy the requirements of the AATCC M14-2020 Guidance and Considerations for General Purpose Textile Face Coverings specification as well as the new face covering standards that are expected to be released in early 2021 by both the *ASTM International* and the *European Committee for Standardization* (CEN).

Although claims are made by manufacturers about an antimicrobial's perceived ability to kill the COVID-19 virus, no entity can justly make such a claim as, to date, there has been no approval, or any form of government-sanctioned testing performed to prove the effectiveness of any antimicrobial agent against COVID-19. Despite this, many face covering manufacturers disregard these prohibitions or maintain that the intended purpose of their antimicrobial is for odor control, a default position.