RE-TOOLING YOUR BUSINESS TO RESPOND TO THE CORONAVIRUS PANDEMIC? HERE'S WHAT YOU NEED TO KNOW

Hodgson Russ Business Litigation Alert
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Many companies have retooled their factories or workshops to manufacture products in response to the increased demand for health care products. Whiskey distillers are making hand sanitizer and design houses are sewing face masks. Everyone is receiving kudos for their great work, but what are the risks?

Fabric Face Masks Are Not Personal Protective Equipment

On April 3, the U.S. Centers for Disease Control and Prevention (CDC) issued updated guidance recommending that Americans wear "cloth face coverings in public settings where other social distancing measures are difficult to maintain," such as grocery stores or pharmacies, particularly in areas with significant community transmission.

As a result, many small apparel businesses, as well as large clothing manufacturers, are producing fabric face masks for sale to consumers. Companies producing fabric masks should be cautious when making claims about the protective properties of their products.

First, homemade masks are not the same as PPE or personal protective equipment used in health care settings. On March 17, 2020, the CDC said the following about the use of homemade masks by health-care personnel, or HCP:

"In settings where face masks are not available, HCP might use homemade masks [e. g., bandana, scarf] for care of patients with COVID-19 as a last resort. However, homemade masks are not considered PPE, since their capability to protect HCP is unknown. Caution should be exercised when considering this option. Homemade masks should ideally be used in combination with a face shield that covers the entire front [that extends to the chin or below] and sides of the face."

Therefore, small business should avoid marketing fabric masks as PPE or as suitable for use by health-care personnel or those caring for someone with COVID-19.

Second, businesses should exercise caution when using fabrics touted as containing "antimicrobial fibers." Such antimicrobial products must be registered with the EPA and are subject to strict guidelines regarding what claims can be made about the

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product. Some makers of antimicrobial fiber and textile technologies have already made unsupported claims globally about their products' effectiveness against COVID-19, which is both illegal in the U.S. and can be dangerous to people's health. If a business uses such fabric in finished goods, they, too, are not allowed to make any similar kinds of claims about the end products' ability to fight COVID-19.

Requirement to Add Bittering Agent to Alcohol Remains in Effect

On March 20, 2020, the FDA announced that it will not take action against companies not registered as drug manufacturers that begin producing hand sanitizer for consumers and health care workers. The FDA recently revised these guidelines to permit the use of food grade alcohol for use in hand sanitizers. However, companies must continue to comply with FDA guidelines that require the addition of a denaturant or bittering agent to the final product, to deter consumption—particularly by children.

Claims of "Preventing the Spread of Coronavirus" Could Result in Litigation

In January 2020, the FDA issued a letter to GOJO Industries, the maker of Purell-based hand sanitizers, warning the company to stop making unsubstantiated claims about its hand sanitizers to avoid giving consumers the impression that they are pharmaceutical products. The FDA advised that the company's labels claiming that Purell hand sanitizers are "effective in preventing disease or infection from pathogens such as Ebola, MRSA, VRE, norovirus, flu, and Candida auris, and in preventing the spread of infection, go beyond merely describing the general intended use of a topical antiseptic," and do not comply with relevant rules for such products. Moreover, the FDA warned that the company's website claims suggesting "that PURELL® Healthcare Advanced Hand Sanitizers are intended for reducing or preventing disease from the Ebola virus, norovirus, and influenza" are unsupported by any clinical trials and violate FDA regulations.

Following the FDA's warning letter, at least three class action lawsuits were filed against GOJO Industries in federal courts in New York and California echoing the FDA's complaints and alleging causes of action related to claims that Purell products could prevent the spread of everything from the flu to Ebola.

Companies that are producing hand sanitizer or alcohol for use in hand sanitizer and other health care products should be cautious in their labeling and advertising. Any claims that a product can prevent coronavirus infection or the spread of coronavirus will face scrutiny from both the FDA and plaintiffs' lawyers and should be avoided.

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Takeaway

In using their existing manufacturing facilities to produce products in high demand during the coronavirus pandemic, companies should consult relevant industry rules and regulations and take care not to overstate the effectiveness of products in advertising.

Do you have questions about the product your business is selling or need more information on potential liability? Contact Hodgson Russ attorneys Marissa Coheley (716.848.1687), Reena Dutta (716.848.1626), or Jane Bello Burke (518.433.2404).

Please check our Coronavirus Resource Center and our CARES Act page to access additional information related to these rapidly evolving topics.

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