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A Guide To Evaluating And Advertising COVID-19 Products

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The nation's economy is slowly reopening. As businesses consider how to reopen safely, they may be evaluating products, such as disinfectants, sanitizers, ultraviolet sterilizing devices, antimicrobial coatings and air filtration devices, that could help mitigate the transmission and spread of COVID-19 in the workplace or retail establishment.

Some businesses see tremendous new opportunities in manufacturing and marketing these products. However, care must be taken in doing so because while the virus may be novel, the standards for evaluating advertising claims for products claimed to prevent its spread are not. Indeed, the plaintiffs bar and competitors are constantly watching for overstated claims, resulting in self-policing.

There is a wealth of published enforcement and guidance covering each of the product categories and claims. It's imperative that companies venturing into this market understand these guideposts.

This article sets forth some of the key considerations and rules of the road for the advertising and marketing of such products.

How are these products regulated?

A number of federal and state agencies oversee labeling and advertising claims for products that claim to reduce the spread of disease.

U.S. Food and Drug Administration

The U.S. Food and Drug Administration oversees regulation of "medical devices," which are any physical instrument, apparatus or machine intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. This definition sweeps in everything from tongue compressors to complex and higher-risk devices such as ventilators, and even certain software applications. A medical device may generally not be sold unless it has gone through a premarket application or

premarket notification (510(k)) to demonstrate that it is safe and effective.


Chalana Damron

As a business either purchasing or attempting to manufacture a product for COVID-19 prevention, you should be asking yourself: (1) does the device maker claim that the device diagnoses or prevents the spread of COVID-19, and (2) if so, has the device been approved by the FDA? If it hasn't, the device maker may be subject to enforcement and the devices could be seized by the agency. And, of course, the devices may not work as claimed.

U.S. Environmental Protection Agency


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Under federal law, bacteria, viruses and other microbes in the environment are considered "pests," and products intended to kill, destroy or otherwise mitigate pests are regulated by the Environmental Protection Agency as "pesticides" or "pest control devices." In general, the EPA's jurisdiction only extends to products that are intended to kill or mitigate microbes in the environment (e.g., on hard surfaces like counters or door handles, in the ambient air, and in water). The EPA does not exercise jurisdiction over products intended to kill microbes that are present in or on living people, for example.

Chemical products (such as disinfectant sprays or wipes) must be approved by the EPA (i.e. registered) before they can be sold or offered for sale; devices (such as air filters) do not require preapproval by the EPA, but they must comply with other regulatory requirements (for example, they must be manufactured in an EPA-registered facility).

Moreover, the EPA strictly regulates the types of claims that can be made for both categories. If your business intends to manufacture or sell a chemical product or a device that claims to kill, destroy or otherwise mitigate viruses or other microbes in the environment, this should be a red flag alerting you to the need to assess whether that product is subject to regulation by the EPA.

Federal Trade Commission

The FTC has long overseen advertisements making health claims, which include claims regarding the prevention of the spread of disease. Claims that a product is useful for slowing or preventing the transmission of disease will receive the FTC's highest level of scrutiny, requiring "competent and reliable evidence" that the product has been shown to perform as claimed. The agency is typically unwilling to accept data relating to some other analogous product or ingredient as proof that the advertised product achieves the same or similar results.

The FTC has stepped up consumer protection efforts in response to the coronavirus pandemic, having sent dozens of warning letters regarding false and unsubstantiated claims related to coronavirus.[1] Many of the letters have focused on unsubstantiated health claims that state or imply that a product can cure, treat or prevent coronavirus, reminding advertisers that "[t]here currently are no vaccines, pills, potions, lotions, lozenges or other prescription or over-the-counter products available to treat or cure Coronavirus disease 2019 (COVID-19)."

The FTC has also actively disseminated consumer education to inform consumers about common false advertising claims and fraudulent practices in the marketplace related to the coronavirus pandemic.

State Attorneys General

State attorneys general can institute enforcement proceedings under state unfair and deceptive acts and practices acts, or UDAP acts, which operate like little FTC acts. Generally speaking, these laws give AGs broad discretion over consumer protection, empowering them to investigate and undertake enforcement actions for conduct that is misleading, deceptive, fraudulent or unconscionable, including false advertising.

During the coronavirus pandemic, the states have substantially ramped up enforcement, focusing on a variety of consumer protection issues, including false health claims. We also expect that we may see multistate activity against practices and claims related to coronavirus that have had a widespread negative impact on consumers.

Private Enforcement

A wave of private class actions is building, focused on allegations that various products marketed as useful for the prevention of COVID-19 are not effective for such uses. False advertising litigation can also be brought by competitors under the federal Lanham Act. And, the National Advertising Division of BBB National Programs frequently reviews challenges to substantiation for devices' claims to prevent disease.

Specific Standards for Claims

A variety of product categories are being marketed for their potential usefulness in preventing the spread of COVID-19. These range from hard-surface cleaners and disinfectants, to novel devices like ultraviolet C lights and air filters.

Each category brings with it unique substantiation concerns, which we summarize below. The level of substantiation and regulatory treatment will be driven to a significant degree by what the advertiser wishes to claim about the product. The more direct the claim regarding prevention of disease, the higher the level of support that will be required (or even FDA or EPA preapproval).

Air Filters

We have seen numerous examples of air filtration devices being claimed to remove or destroy airborne viruses. Such claims are considered by the FTC to be presumptively material — in other words, likely to affect a consumer's choice or use of a product or service. The FTC made this clear in a recent closing letter to a manufacturer of high-efficiency particulate air, or HEPA, filters that purportedly "can filter out the COVID-19 virus" and "can greatly reduce the spread AND capture the Covid virus in your home and workplace."[2]

Thus, we have advised generally that filtration makers may make claims regarding the pore size of filters and also that HEPA filters can capture particles as small as certain viruses and bacteria. However, the maker must be careful to avoid linking such claims to prevention of disease. Claims regarding efficacy at filtering out bacteria and viruses will likely cause a filter to be subject to regulation by the EPA, or even the FDA, even in the absence of implied (or express) health claims.[3]

UV Lights and Wands

The use of ultraviolet light to sterilize surfaces is well-established in the hospital setting, and some devices have been approved by the FDA as medical devices for this purpose. UV lights may also be regulated by the EPA as pest-control devices.

Not all ultraviolet lights are the same. It is generally understood that light in the UV-C spectrum is most effective for virus destruction, but in order to achieve a sufficient level of pathogen kill, the pathogen must be exposed to the light at a sufficient power and for a sufficient duration. Moreover, as with the other products in this list, any advertiser must be careful not to promise that the device will "prevent" COVID-19.

Similarly, even if health claims like "prevent COVID-19" are avoided, if claims are made for efficacy at killing microbes, the product will be regulated by the EPA. UV lights can also be dangerous to the eyes, and require careful warnings.

Antimicrobials

Chemical products such as sprays or wipes that are intended to kill microbes are subject to stringent regulation by the EPA. In order to obtain the required approval from the EPA to sell such a product, the manufacturer must supply the agency with extensive safety and efficacy data.

The EPA also tightly controls the types of claims that can be made for such products. Words such as "sanitizer" and "disinfectant" have very specific meanings under the EPA's regulations and can only be used with EPA approval. In addition, the EPA must specifically approve claims for effectiveness against SARS-CoV-2, the virus that causes COVID-19, and the agency has created a dedicated webpage to assist business and others in identifying antimicrobial products approved for this use.[4]

Antimicrobial additives have also been a popular feature of plastic products. These are sometimes marketed as inhibiting the growth of pathogenic bacteria on surfaces. Even if the EPA has approved the additive for such a purpose, the advertiser must exercise caution in marketing the benefit. The additive can be claimed to protect the surface from microbial growth, but it generally cannot be marketed to reduce the risk of disease spread to humans.

Hard-Surface Cleaners

Because there is evidence that viruses can spread when people touch contaminated surfaces and then rub their faces, cleaning surfaces has been widely acknowledged as an essential feature of disease prevention. However, not all hard surface cleaners are the same.

To make a so-called "germ-killing" or "virus-killing" claim, or virtually any antimicrobial claim, the product must be registered with the EPA, as discussed above. Companies should also be mindful of claims suggesting that the product is intended to be used in a health care setting, which may cause it to be subject to FDA regulations.

Masks and PPE

Many local governments are now requiring that people wear masks when going outside, traveling, shopping or working in communal spaces. There are a variety of masks, some of which are marketed

(and approved) to serve a medical purpose. All of these are regulated by the FDA and generally must be approved by the FDA prior to distribution.

However, the FDA has loosened its regulations to meet an increase in consumer demand in light of the pandemic to allow unapproved masks to be distributed subject to its enforcement discretion or under an emergency use authorization following an emergency declaration. A trade-off is that such masks and personal protective equipment should not be labeled in a manner that would state or imply that the products are intended for antimicrobial or antiviral protection, infection prevention or reduction, or particulate filtration.

Therefore, masks intended for social distancing use need not comply with strict filtration standards that are needed for medical-grade masks. Thus, there has been an explosion of nonmedical-grade and even fashion-forward masks being sold online. Any such masks may not be marketed as a device that prevents the wearer from contracting disease. Indeed, we recommend the makers include disclaimers to the effect that such devices are not intended to prevent the wearer from contracting the virus.

Conclusion

Reopening is complicated for many reasons. As businesses evaluate products that are claimed to make workplaces safer, or they wish to market such products themselves, they should be aware of the highly regulated world of disease prevention claims if they wish to avoid enforcement litigation to their list of concerns.

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[1] FTC Coronavirus Warning Letters to Companies, available at https://www.ftc.gov/coronavirus/enforcement/warning-letters.

[2] FTC Letter to Vaniman Manufacturing Co., available at https://www.ftc.gov/system/files/warning-letters/covid-19-letter_to_vaniman_manufacturing_co.pdf?utm_source=govdelivery.

[3] See, e.g., In re EMD Millipore Corp., Consent Agreement and Final Order (July 30, 2013), https://www.epa.gov/sites/production/files/2014-07/documents/emdmillipore-cafo.pdf, in which a manufacturer of water filters making antimicrobial claims paid a penalty of $2.6 million for failing to comply with EPA regulations.

[4] https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.