‘Immune’ claims and COVID-19

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Correction and Editor’s note The article, ‘Immune’ claims and COVID-19 (published 30 June 2021) incorrectly stated that Vi-Jon Inc. had received a warning letter from the FDA, when in fact it had not received such a letter. The article was corrected on 15 July 2021, but the correction was not appropriately noted on our website. The article was further updated on 27 August 2021 to remove an extraneous reference. REGULATORY FOCUS regrets these errors and apologizes.

Products such as elderberry, echinacea, and vitamin C have long been marketed for added support for the immune system. Although regulators have occasionally targeted claims for preventing or treating colds, flu, or other diseases, marketing products with “immune support” claims has generally proven to be a safe harbor for companies. As long as products include one or more ingredients with valid in vitro or other efficacy evidence, “immune support” claims have tended to be low risk for companies.

This article will examine whether, in an unprecedented global pandemic, such products can still be launched and marketed. The short answer is that they can be, but that context matters and careful execution is key. Regulators are scrutinizing the product category and taking action. Companies need to be

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aware of the enforcement and other challenges and avoid the same pitfalls. To that end, the authors review federal and state enforcement, self-regulatory actions, and class actions that are reshaping the landscape for foods and dietary supplements marketed for the immune system. They will also provide pointers for crafting low-risk claims in a post–COVID-19 market.

Federal and state regulatory action

Even before the pandemic-related shut-down began in the US, the Federal Trade Commission (FTC) and US Food and Drug Administration (FDA) began issuing warning letters targeting advertising and labeling claiming products could be used to treat or prevent COVID-19. This swift action around warning letters was in keeping with the agencies’ past responses and actions around outbreaks such as Zika and Ebola. The regulatory response to COVID-19 has been similar to those responses, only on a larger scale and at a more sustained level as the pandemic continued.

On 9 March 2020, the FTC and FDA announced their first round of warning letters, targeting seven companies that were marketing products, including teas, essential oils, and colloidal silver for treating or preventing COVID-19. The letters identified sweeping claims that expressly mentioned “COVID” or “coronavirus,” such as:

- “The most powerful antivirus essential oils to provide defence [sic] against coronavirus,”
- “Wellness!! Vital Silver!!! Simple!!! Go on the offense [sic] this year against viruses including the Coronavirus – it’s simple,” and
- “. . . with epidemics similar to CoronaVirus that are highly mutated and drug resistant, we need to use therapeutic benefits of essential oils to target the virus itself not just the specific gene type #coronavirus.”

Between April and November 2020, the FTC announced eight additional rounds of warning letters, issued either by both agencies or by the FTC alone, targeting hundreds of additional companies and individuals selling a variety of products. Even since the last official press announcement, in November 2020, both agencies have continued to issue warning letters. In general, the original theme has remained the same, with letters mostly targeting hard-hitting advertising or labeling that expressly mentions “COVID” or “coronavirus,” or fighting respiratory illness. For instance, a December 2020 FDA warning letter flagged claims such as “The time to start boosting [children’s] immune system is now . . . because of the coronavirus” and “Research demonstrates that probiotics are safe and effective for fighting the common cold and influenza-like respiratory infections.”

Some of the FTC and FDA warning letters have targeted softer advertising that used hedge language such as “may prevent COVID,” or other more subtle forms of advertising. For instance, one warning letter identified claims such as the following that appeared under a “Coronavirus” webpage tab: “products below are worth considering in supporting your immune system and helping your body fight off viruses.” As another example, a warning letter identified a social media post that included the following text: “A recent article by the New York
Post states New York’s largest hospital system is giving vitamin C to treat seriously sick COVID-19 patients” and “Our organic liposomal vitamin C boasts a 90% absorption rate while most are around 20%.” Although the article was seemingly authentic, the agencies objected to its use in promoting a vitamin C supplement given an alleged implied disease treatment message. In another letter, the agencies made clear that “traditional use” claims, normally allowed if truthful and for nondisease states, would not be tolerated in the context of COVID-19. The agencies specifically identified claims like the following as deceptive: “Colloidal silver is an ancient remedy commonly utilized for its . . . anti-viral activities.”

In addition to the many warning letters, in October 2020, the FTC entered into a settlement with a company and its owner over product, containing vitamin C and botanicals, that was being touted as “the perfect way to strengthen your immunity against pathogens like ‘Covid-19.’” The order does not impose monetary redress, but bars the respondents from disseminating any future claims for treating or preventing any disease unless the claims are supported by “randomized, double-blind, and placebo-controlled” human clinical testing. In July 2020, the FTC also filed a lawsuit against a company that allegedly marketed a $23,000 “Emergency-D Virus” plan as “FDA accepted” for treating COVID-19. That lawsuit followed a warning letter to the same company and, several days after the complaint was filed, the court granted a temporary restraining order barring the advertising as litigation continues.

The no-money settlement and little additional enforcement beyond warnings at the time prompted criticism that the FTC was failing to do enough to combat fraud around COVID-19. Subsequently, one of the federal relief bills granted the agency temporary civil penalty authority with regard to marketing claims to treat or prevent COVID-19. The civil penalty authority will remain in place as long as the federally declared public health emergency remains in place. The current maximum civil penalty per violation of the Federal Trade Commission Act is $43,280, and FTC staff has signaled the agency will interpret each ad and each day an ad runs as separate violations – meaning monetary amounts could accumulate very quickly.

In April 2021, the FTC flexed its new authority, filing a lawsuit seeking an unspecified amount of civil penalties against a chiropractor in Missouri who allegedly touted vitamin and zinc supplements as something that should be used instead of vaccination. According to the FTC, it had issued a warning letter to the chiropractor about a year earlier but had not received an adequate response. FDA and FTC enforcement action is likely to continue along similar lines as long as the pandemic continues, with the FTC seeking civil penalties in its actions.

Apart from the FDA and FTC, the Department of Justice (DoJ) has been actively pursuing criminal charges against similar alleged fraud schemes around products promoted for treating or preventing COVID-19 infection. For instance, a Utah man was indicted, and is currently being criminally prosecuted,
Based on allegations that he posed as a doctor to sell ingestible silver products as a COVID-19 cure.25

Similar to federal regulators, states have been active in policing largely clearly violative COVID-19 marketing for foods, supplements, and many other types of products. For instance, in June 2020, the Oregon attorney general announced settlements with 6 companies and medical practitioners advertising products or services as a “so-called Covid-19 ‘cure[s]’” or able “to boost immunity and keep people healthy from the disease.”26 As another example, the New York attorney general issued numerous cease-and-desist letters to businesses making claims around COVID-19.27 One letter targeted a beverage product, Sacramental Cleansing Water, which the company promoted as having “the 20-20-20 essentials that can kill the coronavirus.”28 The state’s attorney general also targeted Craigslist, ordering it to remove posts “attempt[ing] to sell fake items that purportedly claim to provide ‘immunity’ to the coronavirus or allow individuals to test for the disease.”29

Regulators in states, including Arkansas and California, have also launched high-profile investigations into COVID-related marketing for Silver Solutions, a purported dietary supplement, sold by televangelist Jim Bakker, a church and for-profit company.30,31 A court in Missouri refused to grant an injunction sought by Bakker and the groups to prohibit two of the investigations, and all investigations (normally conducted in a nonpublic manner) are presumably ongoing.32 As with the federal enforcement, such DoJ and state actions will likely continue as the pandemic continues.

NAD cases
The National Advertising Division (NAD) is a self-regulatory body offering an alternative forum where private actors or the NAD itself may challenge advertising and labeling claims.33 The NAD is not able to order monetary relief, but it regularly issues decisions upholding advertising claims or recommending modifications or discontinuation. If an advertiser refuses to participate or abide by a decision, the NAD will forward its case file to the appropriate federal regulator, such as the FTC or FDA.34 The FTC prioritizes cases referred by the NAD and routinely encourages companies choosing not to participate in NAD proceedings to reconsider.

Throughout the pandemic, the NAD has focused primarily on implied claims, flagging advertising that may not mention “COVID-19” but that the NAD nevertheless believes conveys messages about treating or preventing the disease. In each case, the advertiser has agreed to discontinue the identified advertising, which has been mostly advertising on social media. Below are representative examples of social media posts that the NAD has challenged:

- An image of a woman wearing a mask, accompanied by the claims “Strong IMMUNITY needs glutathione” and “Building your immunity during these times is more important than ever;”
• An image of an elderberry syrup, accompanied by the claims “Potent Immune Support During a Severe Season” and “[Product] is highly concentrated to deliver antioxidant action for immune defense;”

• An image of a company’s dietary supplement, accompanied by the claims, “As restrictions are gradually lifting, it’s more important than ever to keep your immune system strong. Our [product] keeps you protected with vitamin C, zinc, elderberries, garlic, echinacea; a powerful immune-boosting combo”; and

• Claims such as “Twenty-three hospitals alone in New York are now treating patients who test positive for COVID-19 with large doses of vitamin C. While this is an extraordinary breakthrough in the medical world, high Vitamin C foods have proven for millennia to do far more for our health than just fighting off the winter bug. Infinity-C works by delivering 1000mg of real Vitamin C per serving purely from plant foods for a 100% absorption rate, making it a superior upgrade from the all-too-common ascorbic acid.”

Class actions
Although few class actions have targeted COVID-19 advertising or labeling claims, immune claims, generally, have been a perennial class action target. The following are examples of cases in the last 13 years:

• A class action filed in January 2021 in which plaintiffs allege the following claims for a line of elderberry supplements lack adequate substantiation: “Stress can wreak havoc on our immune system. This leaves us open to the possibility of more frequently catching a virus or other illness. Sambucol Black Elderberry helps to support a healthy immune system so even on my most hectic days, I am giving my body the immune support it needs.”

• In 2018, a class action targeted claims, such as the following, for Barlean’s Greens Supplement Powders: “Promote a healthy immune system,” “Aid the body’s natural detoxification,” and “Help improve digestion.” In July 2021, the case was voluntarily dismissed, suggesting that the parties may have reached an individual settlement.

• In 2014, the makers of Emergen-C agreed to a $6.45-million settlement over allegations that claims such as the following were deceptive: “The powerful blend of vitamins, antioxidants, and minerals boost your immunity, increase your metabolic function and ignite your energy level without caffeine.”

• In 2013, Kellogg’s entered a $5-million settlement over allegations that it misled consumers with claims such as “Kellogg’s Cocoa Krispies has been improved to include antioxidants and nutrients that your family needs to help them stay healthy;” and “Enjoy this wholesome breakfast and help keep your family healthy.” This case followed a settlement with the FTC over the same claims.

• In 2008, the makers of Airborne entered a $30-million joint FTC and class action settlement over allegations that the product was promoted with deceptive claims for preventing colds and reducing the severity or duration of colds.
Such cases will likely continue to be filed throughout and following the pandemic, as they have been for years.

**COVID-related class actions**
COVID-19 has spurred a wave of class action lawsuits in many other areas. There were class actions relating to confidentiality issues on the Zoom platform and plaintiffs suing China for causing the coronavirus. There were also refund cases for everything from tuition to vacations to concerts to monthly gym memberships; insurance coverage cases from all types of businesses; employment based claims for alleged unsafe working environments resulting from potential virus exposure; claims against financial institutions for the way they distributed pandemic relief loans; the inevitable stock drop cases; and some virus exposure or risk of exposure cases for having large gatherings in confined spaces. Grocery stores and other entities in the food chain were hit with price gouging cases on products, including protective masks, toilet paper, sanitizers, and even flour and eggs.

The most notable advertising or labeling cases involved cleaning and disinfectant products and the products’ effectiveness against viruses. At the core of these cases was whether the product satisfied what was stated on the label. Hand sanitizer cases were likely the most publicized of such cases. The Center for Disease Control and Prevention advised that alcohol-based hand sanitizers inactivate viruses related to the coronavirus and recommended their use. The FDA, however, sent a warning letter to manufacturer Gojo, noting that label claims about effectiveness were insufficiently supported and had many flaws. Class action lawsuits ensued.43

As already noted, other than the cases on cleaning and disinfectant products, we have not seen advertising or labelling cases relating to food or dietary supplements and COVID-19. If they were to arise, the defenses would be those prevalent in many advertising and labeling cases, beginning with “truth” – the claims are not false, and certainly not to all or the majority of the purported class. Individualized issues may also be prevalent in certain labelling cases, giving rise under some state laws to arguments to defeat class certification. Primary jurisdiction and preemption defenses are also often available.

**Take-aways and tips for crafting low-risk claims**
Against the above regulatory background, the following are tips to craft low-risk claims:

- **Avoid claims, imagery, or other elements that reference any disease including cold, flu, or COVID-19.** As the federal and state enforcement, in particular, demonstrates any express mention of COVID-19 – or any other disease – in the context of promoting a dietary supplement or food without question increases the chances of enforcement. As the NAD cases demonstrate, imagery like people wearing masks or language alluding to pandemic “restrictions” can be equally risky even if no disease is expressly mentioned.
• **Avoid claims for “boosting,” “building,” or “protecting” the immune system, as opposed to “supporting” or “maintaining” the immune system.** Under FDA rules, claims to “support” or help “maintain” the immune system are considered acceptable structure/function claims. On the other hand, claims to “boost,” “build,” or “protect” the immune system are normally considered unauthorized disease claims. As discussed above, such claims have drawn not only governmental enforcement but also class actions like the case involving Emergen-C.

• **Confirm claims are substantiated.** Even if a claim uses FDA-allowed language, it will still normally present risk if not adequately substantiated. Regulators have not generally required human clinical data for claims to “support” or “maintain” the immune system versus claims to boost immunity or prevent or treat colds or other disease. Nevertheless, an immune “support” or “maintain” claim requires reliable in vitro or other evidence demonstrating a positive effect on immune function.

• **Bear in mind that just because a statement is truthful, that does not mean it is allowable.** As reflected in both the governmental enforcement and NAD cases discussed above, just because a statement is truthful, that does not necessarily mean it is allowable or low risk. Both an FDA warning letter and the NAD challenged social media posts that shared truthful information about hospitals in New York treating COVID-19 patients with vitamin C. Although such discussion outside of the context of advertising or labeling is normally First Amendment protected, it becomes fair game for regulation when integrated into product promotion. Similarly, it may very well be true that “Colloidal silver is an ancient remedy commonly utilized for its . . . anti-viral activities,” but as reflected in the FTC and FDA warning letters, such traditional use claims entail risk given the discussion of disease.

Conclusion
COVID-19 has raised the risk profile in the immune support category. However, with careful execution and an eye to ongoing regulatory developments, companies can continue to provide consumers the immune support products they desire more than ever, while avoiding legal pitfalls.

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