ML STRATEGIES

Tackling False Claims Being Made for COVID-19 Treatments and Products

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Two weeks ago, on March 9, the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) sent **warning letters** to seven companies that allegedly made false or deceptive claims about their products' ability to treat Coronavirus Disease 2019 (COVID-19). The agencies warned the companies that their health claims lacked credible supporting evidence and emphasized the FDA does not recognize a vaccine, drug, or treatment for the disease. In addition to the warning letters, the **FTC**, **FDA**, **Department of Health and Human Services** (HHS), and **Department of Justice** (DOJ) have also issued guidelines to the public alerting consumers of potential scams that advertise and sell fraudulent products and treatment of COVID-19.

While the issuance of warning letters is laudable and serves as a precursor to further enforcement actions by these federal agencies, the letters may be limited in their efficacy because the FTC's enforcement authority in fraud cases is limited to proving violations on a case-by-case basis. With regard to the FDA, warning letters are among the first steps the agency takes to alert a company and the public of a fraudulent (i.e., misbranded or adulterated) product. Additional steps can include seeking an injunction to prevent the manufacture and distribution of violative products, seizing such products, and imposing fines. However, it typically takes a particularly egregious violation (e.g., one that could cause imminent harm to the public health) or an extended pattern of willful noncompliance for FDA to pursue these more serious penalties, and even then, it can take a long time for the government to build its case. And DOJ may seek enforcement actions for criminal violations of the Wire Act – as the Department has recently **done** against the operators of a fraudulent website that sought credit card numbers and charged fees for non-existing vaccine kits – which requires a higher burden of proof than civil actions.

As a result, Congress may act to specifically bolster the FTC's civil enforcement authority to more effectively thwart deceptive marketing claims on COVID-19 prevention and treatment. Specifically, Congress could enact legislation that enhances the Commission's existing statutory authority by explicitly defining certain conduct as unlawful and providing a bigger stick to deter such bad behavior.

The FTC Act's Limitations. Under current law, the FTC's authority stems from the broad prohibition against "unfair or deceptive acts or practices" found under Section 5 of the FTC Act. Although this venerable federal prohibition has been in effect since the Roosevelt Administration and serves as the bedrock of American consumer protection law, it has its limitations. First, in order to prove a Section 5 violation, the FTC must prove that a defendant engaged in unfair or deceptive acts or practices on a case-by-case basis. This means that the Commission does not have the luxury of citing a specific redline prohibition as the underlying cause of an enforcement action and, alternatively, must "prove" a violation (viz., a deceptive act) from scratch. Second, were the FTC to prevail in proving its case that the defendant violated Section 5 (i.e., committed an unfair or deceptive act or practice), the agency's available remedies are somewhat limited: it can seek an injunction from a federal district court and also ask the court to make the defendant disgorge ill-gotten gains. Notably, the Commission cannot seek civil penalties for violations of section 5 of the FTC Act.

For the most part, the FTC's Section 5 authority has proven to be an effective enforcement tool for consumer protection over the decades. Just this week, **the Commission settled** with a Nevada-based telemarketing company for targeting elderly consumers with health and wellness products that made unsubstantiated claims on their ability to cure a whole host of ailments. Pursuant to its authority outlined above, the settlement's proposed order prohibits the defendant from future unlawful conduct and imposes $8.62 million dollars in equitable monetary relief, contingent on a finding of consumer harm and/or the discovery of assets held by the defendant subject to disgorgement.

Nonetheless, in discrete circumstances, Congress has deemed Section 5's general prohibition against unfair or deceptive acts or practices to be insufficient in dealing with specific unlawful activities. Specifically, Congress has determined that under certain circumstances the FTC should have enhanced authority to enforce against specifically articulated unfair or deceptive activities and appropriately seek civil penalties (as opposed to equitable remedies) as a proper punishment for and deterrent to such unlawful conduct. Such was the case in 2018 with regard to fraudulent treatment claims on opioid addiction.

Lessons from Fraudulent Opioid Treatments. In 2018, the FTC and FDA sent out similar warning letters to companies, admonishing them for making unproven claims about the efficacy of their opioid cessation products. Congress deemed those letters to be insufficient in dis-incentivizing bad behavior or otherwise addressing the problem. In October 2018, when Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act **(PL 115-271)** – which was a comprehensive measure aimed at addressing the national opioid crisis – it included a subtitle that enhanced the FTC's authority to enforce against unfair or deceptive practices "with respect to any substance use disorder treatment service or substance use disorder treatment product." Furthermore, the law now subjects such violations to civil penalties. This provision was modeled after a **bill** introduced by Senators Capito Moore (R-WV) and Cortez Masto (D-NV), the Opioid Addiction Recovery Fraud Prevention Act. Although the original bill also allowed for state attorneys general to enforce the federal prohibition, the final version that made it into the SUPPORT Act did not.

Congress may deem a similar legislative response is warranted for false or misleading treatment claims for COVID-19. And this time, Congress may decide to empower state attorneys general to enforce any federal statute. Stimulus and emergency supplemental appropriations bills are viable legislative vehicles for such a specific statutory provision. Such a provision could even pass as a standalone bill. The issue's high profile could provide the necessary political support for lawmakers to act with urgency.

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