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US Food and Drug Administration closely monitoring COVID-19-related fraud

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The COVID-19 pandemic has given rise to rampant fraud in the health sector, as unscrupulous companies try to cash in on fear and a lack of certainty regarding the treatment of the virus. At the same time, many companies are pivoting to manufacture products that are in high demand during the pandemic, which carries significant compliance concerns[1] as companies enter industries with which they have little experience.

Companies often underestimate the regulatory requirements or assume the products they are selling do not come under intense scrutiny. Chinese auto manufacturer BYD Auto Co., Ltd., for example, spent months trying to receive approval for its N95 masks[2] and risked losing a lucrative contract with California in the process, not to mention the reputational hit had it failed to gain approval in the end. Face masks intended for medical purposes are treated as medical devices by the U.S. Food and Drug Administration (FDA),[3] and as such must undergo a rigorous series of tests and review.

Another matter altogether are the many fraudulent products on the market claiming to cure or help cure COVID-19. The FDA has sent dozens of warning letters[4] since the start of the pandemic, and the agency has made it very clear that it is "exercising its authority to protect consumers from firms selling unapproved products and making false or misleading claims, including, by pursuing warning letters, seizures, injunctions or criminal prosecutions against products and firms or individuals that violate the law."