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PRODUCT SAFETY RISKS ARE A CIRCULAR CHALLENGE FOR PHARMACEUTICAL COMPANIES

The COVID-19 pandemic continues to dominate the national consciousness, and we expect FDA to continue to marshal its resources in support of the response. While this focus includes the emergency review of promising therapies, it also includes a focus on bogus treatments and misleading COVID-19 claims.

Securing the drug supply against fraudulent products during these anxious times is a top priority for the agency, as evidenced by "Operation Quack Hack" – a joint FDA-FTC program designed to address products sold online that fraudulently claim to diagnose, treat, cure or prevent COVID-19.

By May 7, 2020, FDA had issued a total of 42 warning letters to companies making bogus COVID-19 claims. By June, the number had climbed to 90. The FDA also worked with federal prosecutors in USA v. Grenon et al to enjoin four individuals and a "nonreligious church" entity from illegally distributing a "Miracle Mineral Solution" advertised as a cure to COVID-19 - *see USA v. Grenon et al., No. 1:20-mj-03050-AOR (S.D. Fla. June 30, 2020).*

FDA estimates there are more than 700 fraudulent and unproven COVID-related medical products offered to American consumers, and the agency will almost certainly continue to direct its enforcement resources against them. These products, which include Chinese herbal medications, music therapy, homeopathic treatments and "shields claimed to boost the immune system by protecting the wearer from electromagnetic fields," were added to the array of treatments the FDA and FTC found promoted false COVID-19 claims.

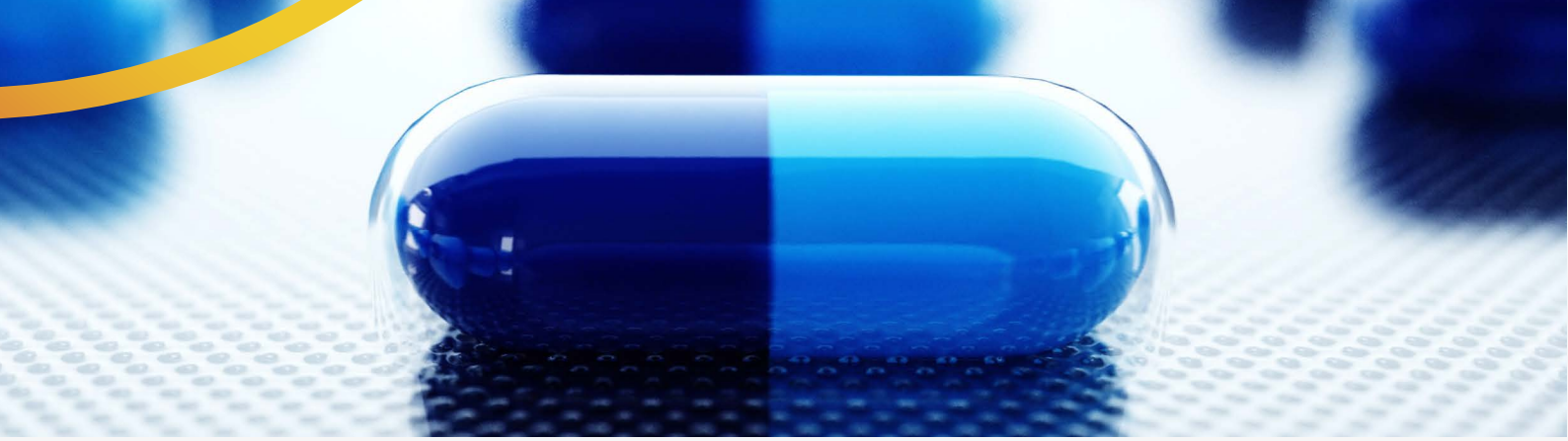
The FDA has also sent hundreds of abuse complaints to domain name registrars and internet marketplaces that sell such products. The current reality is that any firm distributing products associated with COVID-19 should expect the highest levels of scrutiny.

Claims-based regulatory actions from the FDA aren't the only risks companies face when trying to support or capitalize on the COVID-19 response. The presence of physically adulterated products in the marketplace has also been a priority for FDA over the past several months. The myriad enforcement activities focused on hand sanitizers are perhaps the best known – and most pervasive – example. The list of implicated companies and products grows every day. The first phase of enforcement started with sub-potent products that contained "concerningly low levels" of active ingredients such as ethyl alcohol or isopropyl alcohol.

Shortly thereafter, the detection of methanol in hand sanitizers manufactured in Mexico and imported into the United States prompted numerous import alerts and massive nationwide recalls. FDA promulgated consumer alerts on these products in June 2020 and soon established a dedicated page on its website to coordinate information on the dozens of recalls initiated as the number of Mexican manufacturers implicated increased.

Now, most recently, the FDA expanded its hand sanitizer warnings to include 1-propanol contamination. But the growing list of contaminants is not the only threat to the product category.

But the growing list of contaminants is not the only threat to the product category. The issues surrounding the adulterated products follow on the heels of an FDA warning and class action lawsuit against GOJO Industries, manufacturer of Purell hand sanitizer, over disease prevention claims.



FDA's concerns with these products warrant close attention, as its administrative options have grown during the pandemic. Among other things, the Coronavirus Aid, Relief, and Economic Security (CARES) Act enacted in March 2020 quietly modified the OTC drug monograph process FDA, and FDA now has the latitude to update or modify OTC monographs outside the traditional rulemaking process.

One lesson from many of the FDA actions in 2020 is that the threat of adulteration or fraud is not unique to a single product category or manufacturer. The number of facilities implicated in the hand sanitizer contamination – combined with the number of facilities producing defective devices (including personal protective equipment) – punctuate the fact that increased consumer demand strains supply chains and quality is often sacrificed in a rush to meet needs. Traditional tools like robust Quality Agreements, thorough product testing, and strict supply agreements take on outsized importance in light of these recent events.

Meanwhile, on July 10, 2020, FDA announced plans to resume domestic facility inspections following the suspension of most foreign and domestic facility inspections in March 2020. FDA has said that these oversight activities will be preannounced, except for secret shopper programs in retail tobacco facilities.

To help inform its decision-making process, FDA developed an Advisory Rating system to determine where and when it is safest to conduct inspections during the pandemic. A region's Advisory Level is dependent on the outcome of three metrics: (1) the "phase of the state," as defined by White House guidelines; (2) county-level statistics evaluating the current trend of infection; and (3) county-level statistics evaluating the intensity of infection. Based on this Advisory Rating, FDA will implement one of three regulatory approaches in the region: (1) resumption of mission critical inspections only, (2) resumption of all inspections, with caveats to help protect staff who have self-identified as being in a vulnerable population, and (3) resumption of all regulatory activities.

Even with this framework in place, however, companies were left to wonder who would receive a call and when, especially given the ebb and flow of COVID-19 infection statistics across the country.

On August 19, 2020, the FDA attempted to answer some of these questions through new guidance. The agency clarified, for instance, that it would determine if inspections were "mission-critical" by looking to several factors, such as whether the products at issue received breakthrough therapy designation or regenerative medicine advanced therapy designation, or if they were products used to diagnose, treat, or prevent a serious disease or medical condition for which there was no other appropriate substitute.

It's clear the FDA is eager to resume its traditional oversight activities, and every company under its jurisdiction should be ready for the call at any moment. FDA is rightfully focused on mission-critical products, but the spate of regulatory activity directed at misbranded and adulterated drug products indicate the agency will direct its resources against fraudulent and dangerous products of any stripe. Regulated companies should expect more of the same as long as the pandemic persists.

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