

Ad Law in the Age of COVID and Regulatory Reactions

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and Regulatory Reactions

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Agenda

- COVID-19 FTC Enforcement & Education
- COVID-19 Grab-bag: State Attorneys General, NAD and Class Actions
- FDA Actions: Legal Landscape in the Age of COVID-19



COVID-19 FTC Enforcement & Education

Consumer Complaints

- As of July 21, 2020 we had 131,419 consumer complaints:
 - Stimulus check scams
 - Unsubstantiated health claims
 - Robocalls
 - Privacy and data concerns
 - Sham charities
 - Online Shopping Fraud
 - Phishing scams
 - Work at home scams
 - Fake mortgage and student loan relief scams
 - Credit scams



COVID-19 Summary

- To date, the FTC has sent more than 300 warning letters, with more than 80 being joint letters with the FDA.
- The compliance rate exceeds 95%.
- We have filed three federal court actions to stop fraudulent treatment or prevention claims.
- We have conducted an extensive consumer education campaign to protect consumers against COVID-19 related frauds. See <https://www.ftc.gov/coronavirus/scams-consumer-advice>

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 **FEDERAL TRADE COMMISSION**
PROTECTING AMERICA'S CONSUMERS

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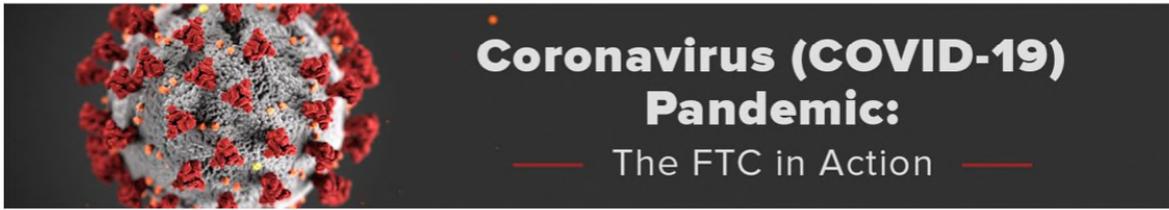
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Coronavirus (COVID-19) Pandemic:
The FTC in Action

CONSUMERS | BUSINESSES | ENFORCEMENT | RESOURCES | REPORT A SCAM

AVOID CORONAVIRUS SCAMS

- Learn how to **tell the difference between a real contact tracer and a scammer**. Legitimate tracers need health information, not money or personal financial information.
- **Don't respond to texts, emails or calls about checks from the government**. Here's [what you need to know](#).
- **Ignore offers for vaccinations and home test kits**. Scammers are selling products to treat or prevent COVID-19 without proof that they work.
- **Be wary of ads for test kits**. Most test kits being advertised have **not** been approved by the FDA, and



FINANCIAL IMPACT
of the Coronavirus



KEEP CALM and Avoid
Coronavirus Scams

https://www.ftc.gov/coronavirus

Who Received Warning Letters?

- Dietary supplement companies
- Medical clinics
- Wellness clinics/Aesthetic spas
- Doctors
- Chiropractors
- Naturopaths
- TCM practices
- Homeopaths
- Weird equipment companies
- Affiliate marketers

What Were They Selling?

- Herbal Teas
- Essential Oils
- Colloidal Silver
- Vitamins C&D
- Immunity Boost IVs
- Myer's Cocktail
- Viral Sonic Silicon Facial Brush
- Air purifiers
- Chiropractic Adjustments
- EMF Radiation Devices
- Homeopathic remedies
- Rife Generators
- Kratom
- Elderberry
- Stem Cells
- Ozone Therapy
- Traditional Chinese Medicine
- Pulsed Electromagnetic Field Therapy
- Vibroacoustics
- Zappers

Zapper



Provita Health Store

- “**Coronavirus** is a family of viruses that can cause respiratory diseases in humans. However, this family of viruses can circulate between animals including camels, cattle, cats and bats. The most recently discovered coronavirus is one that causes the disease globally known as **COVID-19**. . . . **VariZapper to remove viruses**. Dr. **Hulda Clark**, seeing the need to wipe out all kinds of pathogens, created **VariZapper**, an electronic device designed to eliminate all kinds of microorganisms including viruses. **VariZapper** works by sending frequencies that match the frequencies of pathogenic microorganisms and in the same way that a crystal can burst at a certain frequency, viruses die when attacked using their own frequency.”

NaturalHealthSupply.com

- **“We don’t need a COVID-19 vaccine.** Welcome to the 2020 media circus that is called the COVID-19 global pandemic. . . . The latest from ‘authorities’ is that this is the new normal until a vaccine is released for the entire planet’s population. . . . I’m not buying into their paradigm. . . . 1. **Zap.** There are no studies performed on the novel coronavirus using the Hulda Clark Zapper [link to <http://clarkzapper.com/>] yet. Since hospitals stick to medical protocol, the only way we can learn if the Hulda Clark Zapper works is if people diagnosed with COVID-19 and are self-quarantined at home would use it and share their results. Hulda Clark stated, ‘Any positively offset *frequency kills all bacteria, viruses and parasites simultaneously* given sufficient voltage . . ., duration . . ., and frequency . . . In theory it should work. At the very least, the Hulda Clark Zapper can eliminate all other microorganisms so that our body’s immune system can focus on fighting the new virus in town.’”

Colloidal Silver

- “Coronavirus~Using Colloidal Silver to . . . Boost Your Immune system . . . Colloidal silver is the key to protecting yourself from the corona virus.”

Homeopathy

- “Best Homeopathy Preventive Medicine for Corona Virus Infection . . . Arsenicum album 30 could be taken as prophylactic medicine against Corona virus infections”

Essential Oils

- “Build and Manage Your Immunity: A Coronavirus Antidote? What if you had a magic key to help keep your immune system strong and less likely to succumb to illness? . . . “Essential oils are unique allies in times of airborne illness because of their volatile natures and their inherent . . . anti-viral qualities. . . . This quality makes them extremely effective for respiratory conditions by way of inhalation. It is this inherent, diffusive quality that allows essential oils to be used to strengthen the immune system.”

Rife Generators

- **“Corona Virus Immune System Boost Covid19. Advanced Rife Healing Frequencies To The Rescue. Rife Frequencies are named after Dr. Royal Raymond Rife who is referred to as ‘The Man Who Cured Cancer’ and found that certain frequencies destroyed cancer cells, viruses, parasites and bacteria. . . . **When a cell is resonated at its resonant frequency, the cell is destroyed.** Cancer, parasites, viruses, bacteria and other organisms all have their own resonant frequencies. . . . **We have produced a set of programs with frequencies that target Coronavirus/SARS viral infections”****

Vitamin C

- “...ASCORBATE IS A PROVEN, POWERFUL ANTIVIRAL...Vitamin C is already being used to prevent and treat COVID-19 in China and in Korea. And it is working... Vitamin C... is one of the few, if not the only, agent that has a chance to prevent us from getting, and can treat, COVID-19 infection.... ***even small amounts of Vitamin C dramatically decrease severity of symptoms, and increase survival rates, among severely ill viral patients.*** Large doses work better. Intravenous large doses work better still....”

FTC v. Marc Ching d/b/a Whole Leaf Organic

- Filed 04/26/2020
- TRO & administrative complaint
- Thrive (treat, prevent, reduce the risk of COVID-19)
- Vitamin C, Echinacea, ginger, pomegranate, turmeric extract, bilberry extract, citrus bioflavonoid complex, cranberry juice extract, organic carrot root
- CBD (cancer treatment claims)
- Stipulated cease and desist order



FTC v. Golden Sunrise Nutraceutical

- GSN sold a package of four supplements as part of a COVID treatment plan for \$23,000.
- Among other ingredients the products purportedly contained rosemary, olive leaf, yarrow, and cayenne extracts as well as bilberry, golden seal, and astragalus.
- According to the FTC's complaint, Golden Sunrise claimed that its treatment plan was "uniquely qualified to treat and modify the course of the Coronavirus epidemic" and that users could expect the "disappearance of viral symptoms within two to four days."
- April 2020 warning letter.
- Civil complaint for TRO and other injunctive relief filed on July 31, 2020.

FTC v. QYK Brands LLC, d/b/a Glowwy

- Filed 8/4/20
- Basic Immune IGC
- Serum derived bovine immunoglobulin concentration
- Allegations include that company made false or unsubstantiated claims that the product would prevent the transmission of COVID, and was clinically proven and FDA approved.

Partners

'Archbishop' of Florida church selling bleach 'miracle cure' arrested with son

Mark Grenon and his son, Joseph Grenon, arrested in Colombia and expected to be extradited to the US for selling solution Trump mentioned at briefing

Ed Pilkington *in New York*

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The Immune System Syllogism

1. The best defense against COVID-19 is a strong immune system.
 2. My product supports the immune system.
 3. Therefore, my product is effective in the treatment or prevention of COVID-19.
- Even if the initial statement is true, it does not necessarily follow that treatments that support the immune system will effectively treat or prevent COVID-19. Clinical studies using the novel coronavirus are required.
 - What part of the immune system are we talking about?
 - How much improvement is necessary to have a meaningful effect?
 - Does supplementation have the same effect as natural occurring immunity (e.g., HDL cholesterol example)
 - How effective is acute use?

Other Arguments

- Works in a Petri Dish
- Works for other coronaviruses

Substantiation

- COVID-19 treatment and prevention claims are not legal for dietary supplements.
- If you are trying to substantiate treatment or prevention claims, follow the FDA guidance.
 - *COVID-19: Developing Drugs & Biological Products for Treatment or Prevention, Guidance for Industry, May 2020*

Other FTC Enforcement Action

- Sent 12 warning letters to major MLM concerning earnings and health claims made by them or their representatives
- Filed a complaint against a firm that allegedly made false claims that it was an approved lender under the Paycheck Protection Program
- Pursued firms for failure to deliver, failure to meet delivery promises, and provide refunds
- Sent 15 warning letters (6 jointly with the FCC) to Internet Protocol (ViOP) service providers warning them that assisting and facilitating illegal telemarketing or robocalls is illegal



COVID-19 Grab Bag: State Attorneys General, NAD/Self-Regulatory Challenges and Class Actions

Overview

- State Attorneys General Activity
 - Deceptive advertising
 - Price gouging laws
- NAD and COVID
 - “Clean” claims
 - Health and safety claims related to dietary supplements
- Class Actions/private litigation
 - Online retailer/marketplace liability
- Recommendations

State Attorneys General Activity/Deceptive Advertising

- Michigan Attorney General Dana Nessel sent cease and desist letter to two related businesses, Frequency Apps Corp. and Biores Technologies Inc., for marketing a “Coronavirus Defender Patch” to consumers.
 - The companies falsely claimed patch will help protect people from contracting the COVID-19, claiming the patch would “help aid the immune system to defend itself against exposure to the virus,” and “can help lessen the effect of the virus if you already have” it.
- Arizona Attorney General Mark Brnovich partnered with Sen. Kyrsten Sinema, D-Ariz., to increase awareness among seniors of stimulus check scams.
- California AG Xavier Becerra issued consumer alerts warning consumers about (1) deceptive advertising and (2) fraudulent charitable appeals. “Do not be hustled by opportunistic tricksters claiming to have a miracle cure. There is not a cure for COVID-19.”
- Texas AG Ken Paxton sent a warning letter to a medical spa to cease claims its vitamin C intravenous infusions can prevent and cure COVID-19.

New York Attorney General/Deceptive Advertising

- New York Attorney General Letitia James sent letters to GoDaddy and five other website domain name registrars requesting that they halt new registrations of – and de-list current – domain names associated with coronavirus and COVID-19, alleging many of these sites perpetuate scams.
- The registration and creation of these fraudulent websites could be a violation of multiple laws, including, but not limited to, General Business Law § 349, Executive Law § 63(12), and the Computer Fraud and Abuse Act, 18 U.S.C. § 1030, as well as the internet registrars’ terms of service for domain registration.
- Attorney General James had already sent multiple cease and desist letters to individuals and companies selling and marketing certain products as treatments or cures for the coronavirus, including Alex Jones, The Silver Edge company, Dr. Sherrill Sellman, televangelist Jim Bakker, and others.
 - *E.g.*, in March, 2020, AG ordered Jones to immediately cease and desist selling and marketing products through his website www.InfoWarsStores.com.
 - Jones had been marketing and selling toothpaste, supplements, creams, and other products as treatments to prevent and cure the coronavirus, fraudulently claiming the products are a “stopgate” against the virus and claiming the US government said his *Superblue Toothpaste* “kills the whole SARS-corona family at point-blank range,” when there is currently no FDA-approved vaccine to prevent the disease or treatment to cure it.
 - Silver Edge and Sellman marketed colloidal silver as a treatment/cure for the virus.

Price Gouging Laws

- Most states' price gouging laws are triggered upon a state of emergency declaration.
- Prohibitions, inconsistent standards for what constitutes an unconscionable price, exemptions/defenses, and application to specific actors vary across different states.
 - **Examples:**
 - California: Price is unconscionable if it exceeds by 10% the price charged immediately preceding the declaration.
 - New York: “no party within the chain of distribution” should offer or sell goods or services for an “unconscionably excessive price” – a question of law for the court.
 - Florida: employs several tests, including if the amount charged “grossly exceeds” the average price at which the same or similar commodity was readily obtainable in the trade area during the 30 days immediately prior to an emergency declaration.



Enforcement Activity: Price Gouging

- State Attorneys General have taken the lead in price gouging enforcement efforts against businesses and individuals, including:
 - Issuing cease and desist letters and subpoenas
 - Investigations
 - Issuing warning letters
 - Fines/penalties
 - Civil fines: includes injunctive relief, restitution, and fines ranging from \$1,000 to \$40,000 per violation, with additional fines if the affected consumers are elderly
 - Criminal penalties: includes a misdemeanor and imprisonment
 - Lawsuits
 - Requesting that online marketplace platforms like Amazon, Facebook, Ebay, Walmart and Craigslist more rigorously monitor violations by online sellers
 - Asking consumers to report violations



Price Gouging: State-Level Enforcement

State law/Attorney General enforcement examples:

- **Sales of PPE, health products online:** Egregious actors, including online retailers selling/reselling necessary products for unconscionably high prices.
 - On 3/25/2020, Pennsylvania AG and AGs from Connecticut, New Mexico and Vermont co-led a letter requesting that Amazon Facebook, eBay, Walmart, and Craigslist more vigorously act against price gouging practices by online sellers using their platforms. In total, the letter was supported by 33 State AGs.
 - On 4/1/2020, Alaska AG filed a complaint for price gouging against a man accused of purchasing N95 masks from Alaska stores and reselling them on eBay and Amazon for unconscionably high prices.
 - On 4/21/2020, Connecticut AG announced that he issued civil investigative demands to five online retailers following an internal review by Amazon that flagged large price increases in high-demand items including masks, sanitizer and antibacterial wipes.
 - Two Tennessee brothers stockpiled 17,700 bottles of hand sanitizer and sold 300 bottles on Amazon for \$8 to \$70 each; As part of settlement terms with the state AG, they agreed to donate all the supplies to their church for distribution to local emergency responders.
- **Other items:** Essential items like food and health products.
 - Minnesota AG settled price-gouging conduct by egg-producer that raised egg prices 150%. Under the settlement, the farm agreed to limit egg prices to 20% above pre-emergency prices.

People v. Quality King Distributors, Inc.

NY Attorney General sued in May 2020, alleged Quality King Distributors illegally increased wholesale prices of Lysol products to grocery and discount store customers in violation of NY GBL §396-r, seeking disgorgement plus \$25K civil penalty.

- Prices went from \$4.25 → \$9.15 per can between January and April; customers then charged as much as \$16.99 per can, when they had previously sold product at \$5-8.
- NY price gouging law prohibits unconscionable price increases, but allows seller to preserve margin and/or rebut prima facie case with evidence of price increase.
- Same day that case was filed, NY passed a bill that expanded the scope of its price gouging law to also target entities upstream in the supply chain.
- 9/23/20: NY Superior Court dismissed case in its entirety, holding no evidence defendant “unconscionably” raised prices, that QK’s costs increased, and that their prices were indeed competitive.

Private Litigation

- N95 mask manufacturer promised not to raise prices for its masks from the start, but multiple downstream sellers began offering at high prices—often without product in-hand. Seller sued multiple vendors misusing reputation and trademark to price gouge.
 - Law suits included trademark infringement, unfair competition, false association, false endorsement, false designation of origin, dilution, false advertising, deceptive acts and business practices and other state law claims.
- One vendor attempted to sell 10 million N95 masks to the Florida Division of Emergency Management at nearly 460% over list prices.
- U.S. Attorney for S.D.N.Y. filed first criminal action against a used car dealer in Brooklyn who tried to bilk NYC out of \$45M.



NAD and COVID – “Clean” Claims

Challenges to air purification and “clean” claims.

- NanoTouch Material, LLC (NanoSeptic Surfaces), Report #6390, *NAD Case Reports* (July 2020).
 - “Clean based on technology, not toxins. NanoSeptic skins and mats turn dirty, high traffic public touchpoints into continuously self-cleaning surfaces.”
 - Implied claim that individuals and items that come into contact with NanoSeptic surfaces do not need to worry about bacteria or viruses associated with public surfaces.
 - NAD reminds advertisers of the obligation to inform consumers that a “continuously self-cleaning” surface is supplemental to other cleaning controls and that they should still take normal precautions especially during a pandemic.
- IONaer International, LLC d/b/a CleanAir EXP (CleanAir EXP Air Purification System), Report #6402, *NAD Case Reports* (August 2020).
 - NAD questioned testimonial claiming CleanAir Exp “kills 99.9% of COVID-19 within 10 minutes.”
 - “CleanAir EXP just completed rigorous 3rd party testing...and is extremely pleased to announce that the results demonstrated a 99.9% elimination of airborne coronavirus test surrogates...” NAD recommended discontinuance and the advertiser modified the claim to make clear that the product has not yet been demonstrated to be effective on COVID-19.

NAD and COVID – Health/Safety Claims

Challenges to misleading health claims that certain dietary supplements can treat or cure COVID-19.

- Provezza Health, LLC (Provezza Elderberry Syrup), Report #6380, *NAD Case Reports* (June 2020).
 - NAD questioned whether an Instagram post of Elderberry Syrup with claims “Potent Immune Support During A Severe Season” and “Provezza is highly concentrated to deliver antioxidant action for immune defense” implied that taking the product protects users against COVID-19.
 - The company discontinued the post. NAD stated that “NAD shares the FTC and FDA’s concerns and is using its monitoring resources to find claims for dietary supplements and other products touting misleading health-conferring benefits related to coronavirus or COVID-19 as part of its public interest mission to protect consumers particularly during this unprecedented time.”
- Infinity Superfoods (Infinity-C Dietary Supplements), Report #6398, *NAD Case Reports* (August 2020).
 - NAD requested substantiation for implied health and safety claims – “The Link Between Vitamin C and the Coronavirus” and “Twenty-three hospitals, alone in New York are now treating patients who test positive for COVID-19 with large doses of vitamin C....”
 - NAD stated “Dietary supplement advertisers are touting immunity-boosting capabilities of their products...NAD appreciates the advertiser’s discontinuance....”



Class Actions

- **Hand sanitizer claims class actions**, e.g., *Gonzalez v. Gojo Indus.*; *David v. Vi-Jon*; *Taslakian v. Target*: Allegations advertising/labeling for hand sanitizers is misleading because it claims it can eliminate 99.99% of viruses.
- **Event and Festival cancellation class actions.** Online event ticket exchange and resale platforms such as StubHub, Vivid Seats, have been challenged in Wisconsin for failing to refund tickets for postponed events due to the COVID-19 pandemic. Plaintiffs are asking the court to prohibit StubHub from issuing coupons instead of offering full refunds. *McMillan, Matthew v. Stubhub Inc.*
 - Festival organizers have also been sued for refusing to issue refunds of festival tickets, after government orders prohibiting public gatherings resulted in event cancellations. *Jimenez v. Do Lab, Inc.* Similar suits have been filed for other festival cancellations with no refund policies, such as the 2020 South by Southwest, Austin, Texas festival, and Lightning In a Bottle festivals.
 - Sport leagues also face similar challenges while fans claim full refunds for cancelled games. Major League Baseball claim that it merely postponed the games and has refused to refund ticket holders.
- **Memberships and subscriptions.** Numerous gyms and other membership organizations have been sued (and/or investigated by state AGs) for continuing to charge members even when the gym was shut down.
- **Airline ticket refunds.** Airlines issuing refund coupons that expire.
- **Price gouging class actions, e.g., *Armas v. Amazon.com, Inc.***: Florida plaintiff allegedly paid \$99 for 36-pack of toilet paper and \$199 for two-pack of hand sanitizer. *See also*, Egg class actions.

Public/Private Litigation

- N95 cases: Leading manufacturer of N95 masks promised not to raise prices for its masks from the start, but multiple downstream sellers began offering at high prices—often without product in-hand.
 - Seller sued multiple vendors misusing reputation and trademark to price gouge.
 - Claims included trademark infringement, unfair competition, false association, false endorsement, false designation of origin, dilution, false advertising, deceptive acts and business practices and other state law causes of action.
 - One vendor attempted to sell 10 million N95 masks to the Florida Division of Emergency Management at nearly 460% over list prices.
 - U.S. Attorney for S.D.N.Y. filed first criminal action against a used car dealer in Brooklyn who tried to bilk NYC out of \$45M.
- Egg litigation: In April, Texas AG accused country’s largest egg producer of unlawfully increasing its prices; NY and West Virginia AGs also brought price gouging cases
 - The NY lawsuit accuses egg producers of colluding with a market research firm to inflate the price of eggs beyond mere cost increases, alleging that they engaged in a “feedback loop system where the suppliers provided the market research firm with information about its egg prices that was then used to create pricing indices that justified higher prices by other egg suppliers.”
 - Private plaintiffs in CA and TX brought suits alleging price gouging of eggs, targeting not only egg producers but also several grocery stores.

Online Retailer/Marketplace Liability

- Watch for new trend of holding e-commerce platforms liable for claims made by marketplace sellers.
 - NY: Quality King/extension of price-gouging law to clearly cover distributors
 - Pursuit of Amazon and other platforms for price gouging, etc.--multiple courts have found Amazon liable for defective product defects sold by third party merchants on its marketplace.
- *Bolger v. Amazon.com*: California Appellate Court ruled that Amazon is strictly liable for defective products sold on its Marketplace in case where consumer was injured by a laptop battery purchased on Amazon.
 - Court ruled that Amazon took possession of the battery, accepted order, billed it and shipped the battery in its packaging. “Amazon’s own acts, and its control over the product in question, form the basis for its liability.”
 - More cases in Third Circuit, Texas, Tennessee
- *McQueen v. Amazon.com Inc.* (price gouging): Two consumers accused Amazon.com of unlawfully increasing prices for high-demand items amid the pandemic. Alleged “Amazon is the functional seller of [third-party] products and is responsible when price-gouged sales violate the law.”

Recommendations

- Advertising:
 - Companies should provide adequate substantiation for its advertising claims.
 - It is important that companies avoid conveying potentially deceptive messages to customers regarding the true effectiveness of a product, especially during a pandemic.
 - Be conscious of implied as well as express claims.
- Price gouging:
 - Companies should seek legal counsel to understand the applicable state laws/exceptions that impact their business.
 - Keep careful records of all costs charged for the 30 day period prior to an emergency declaration especially costs attributed to other actors in the supply chain and distribution channel.
- Supply chain: Monitor supply chain, as may be liable for claims/pricing downstream.
 - What kind of contractual protections can you obtain?
 - What are the limits of those protections?



FDA: Legal Landscape in the Age of COVID-19

Agenda

- FDA vs. FTC authority (*i.e.* labeling vs. advertising)
- FDA Policies in Response to COVID
- FDA Regulated Products vs. Consumer Product
 - Face Masks
 - Temperature Scanners
 - Hand Sanitizer
- FDA Enforcement: Unapproved drug claims
 - Impermissible dietary supplement claims
 - Warning Letters re: COVID disease claims
 - FDA Logo, “FDA Approved” or “FDA cleared” claims
- Platform monitoring/compliance
- Recommendations
- Resources

FDA vs. FTC Jurisdiction

- The FTC regulates product **advertising**. The FTC Act prohibits “unfair or deceptive acts or practices.” This includes any “material representation, omission or practice that is likely to mislead a consumer acting reasonably in the circumstances,” including health claims lacking proper substantiation.
- FDA’s authority focuses on product **labeling**. Jurisdiction over foods (including pet/animal foods), drugs, cosmetics, supplements, and medical devices.
 - Whether a product is FDA regulated depends on its ‘intended use’ which is largely established through labeling and other promotional marketing
- Due to concurrent and overlapping authority in some instances, both the FDA and FTC have issued joint warning letters to companies making unsubstantiated claims about products claiming to treat or prevent COVID-19.

FDA Policies in Response to COVID: EUAs and Enforcement Policies over PPE & Related Products

- Issuance of various Emergency Use Authorizations (EUA) and Temporary Enforcement Policy Guidance to increase access to PPE, diagnostic tests, and related products.
- Intended to help expand the availability of diagnostic tests, face masks/respirators, thermometers, hand sanitizer, and respirators the period of the COVID public health crisis.
- No specific timeframe for FDA to pull the EUAs/guidance, yet FDA is constantly updating its policies.
- ***Product claims are the key driver in whether and to what extent a product is subject to FDA regulation***

General Consumer Product vs FDA-Regulated

- **Face Masks:**

- FDA-regulated medical device when intended for a ‘*medical purpose*’, including claims for
 - use by HCPs or in a healthcare setting
 - use in preventing spread of COVID transmission or other disease transmission
 - use of “antimicrobial” / “antiviral” agents or properties in the mask
- Non-FDA regulated when a face mask/shield is marketed for general, non-medical purposes (i.e., use in construction and other industrial applications)

- **FDA Temporary Enforcement Policy:**

- Permits marketing of FDA-regulated face masks to public, absent full FDA regulatory compliance, but limited claims:
 - Makes clear it is not a surgical mask or respirator
 - Does not include uses for antimicrobial or antiviral protection or related uses for infection prevention or reduction (**no promises to prevent COVID!**)
- FDA has a similar policy governing surgical masks absent FDA compliance

General Consumer Product vs FDA-Regulated

▪ Thermal Temperature Scanners:

- FDA regulated medical device when advertised/labeled for health-related use, including:
 - use by HCP, health-care facility, or
 - use in taking body temperature measurement for diagnostic purposes— including when used in airports, schools, work environments, etc.
- FDA has a temporary enforcement policy guidance to ease regulatory requirements so long as certain requirements are met, including:
 - Making clear that the measurement should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, and
 - Explaining that the reading should be confirmed by secondary thermometer
- FDA has a related enforcement policy for clinical electronic thermometers

General Consumer Product vs FDA-Regulated

▪ Hand Sanitizers:

- Products claiming to serve as a hand sanitizer vs. general moisturizing / cleansing cosmetic product are subject to FDA regulation as a drug.
 - Drug = “**antibacterial**” “**hand sanitizer**” “*alcohol*” content related claims, “**kills germs**”, labeled with **Drug Facts** panel
 - Cosmetic = moisturizes, cleanses, largely avoids claims related to specific ethanol content or other implied claims to act like a sanitizer
- Hand sanitizers must comply with very specific OTC drug monograph requirements for ingredients and labeling.
- FDA issued a temporary policy in place to ease requirements for preparation of certain alcohol-based hand sanitizers. Policy guidance sets forth very specific requirements for claims and labeling of product.

Claims: Drug vs. Dietary Supplement

- Drugs: intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- Dietary Supplement: contains a dietary ingredient generally intended to supplement the diet.
- Dietary supplement vs. Drug (disease) Claims
 - Dietary supplements are permitted to make “structure/function claims” to describe the effect a dietary supplement may have on the structure or function of the body (e.g. supports the immune system)
 - Dietary supplements cannot make claims to treat, cure or prevent a disease.
 - Disease claims require prior approval by FDA and claim to diagnosis, cure, mitigate, treat, or prevent a disease.
 - Disease claims for a product marketed as a supplement will render the product an unapproved drug in violation of the Federal Food, Drug, and Cosmetic Act.

Claims: Drug vs. Dietary Supplement

- **Dietary Supplements can claim to keep healthy people healthy, not make sick people well.**
 - *“Supports a healthy immune system”*
 - *“Promotes healthy bone development”*
 - *“Helps maintain joint health and flexibility”*
 - *“Helps maintain a healthy heart”*
 - *Helps maintain healthy blood sugar levels already within the normal range”*
 - *“Helps protect the body against infection”*
 - *“Supports your immune system to reduce or prevent the risk of COVID”*
 - *“Helps your body fight off viruses”*
 - *“Offers added protection to the heart and lungs to reduce the severity or onset of infection”*
 - *“Boost immunity” to reduce likelihood of infection*

FDA Enforcement: Unlawful Drug Claims

- FDA exercises its authority to protect consumers from companies selling unapproved products making false or misleading claims that their products can treat, prevent, mitigate, or cure COVID-19
- As of September 1, 2020, FDA has identified more than 1068 fraudulent and unproven medical products related to COVID-19
- Recent wave of FDA Warning Letters regarding the use of aggressive claims on products treating or preventing COVID-19
- In these letters, FDA has raised concerns about product safety and the ability of nefarious actors to exploit consumers during the pandemic by selling unproven medical products with fraudulent claims

Warning Letters

- Pharmacy Plus, Inc. dba Vital Care Compounder (Sept. 9, 2020)
 - Joint FDA/FTC warning letter involving claims for “COVID PACK” and “treatment and recovery from the Covid-19 virus” among others. Letter requests corrective action within 48 hours.
- 1 Party at a Time (Sept. 1, 2020)
 - “Organic antiviral against COVID-19”
- Living Senior, LLC (August 19, 2020)
 - “Dr. Bob Melamed discusses how NAC and CBD Fight Viral Infections like Coronavirus...”
- Center for Wellness and Integrative Medicine (June 30, 2020) - “COVID Supplement Protection Pack”
 - “During the COVID pandemic, we will be sourcing, stocking, and shipping for your home-use products personally vetted by Dr. Tom for their Immuno-Supportive effects.”
 - “Easiest way to prevent Coronavirus exposure from developing into severe COVID infection: Vitamin C.”
- Apollo Holding LLC (May 21, 2020) - “NoronaPak”, including CBD and other supplement products
 - “Selenium is not only important in boosting the immunity...but also to slow the development of more virulent strains of some viral pathogens...CBD may suppress the productions of cytokines in the setting of infection.”
- Corona-cure.com (March 26, 2020)
 - “Corona-Cure Antiseptic Nasal Defense kills viruses of the *Coronaviridae* family including the 2019 Novel Coronavirus and SARS at their point of entry into your body.”
 - FDA issued a warning letter to the vendor requesting corrective action within 48 hours, leading the website to be taken down

FDA Logo, “FDA approved”, or “FDA cleared” Claims

- **Use of FDA Logo:** FDA takes the position that use of the logo will render the product misbranded **in violation of law** under Section 502(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. SS 352(a)). FDA has issued numerous warning letters on this topic.
- **“FDA approved” claims:** Only for a product that has undergone full premarket approval application (PMA) for a medical device, or a new drug approval (NDA). Simply because a product is marketed in compliance with FDA requirements does not mean it is FDA approved.
- **“FDA Cleared” claims:** This term is specific to certain medical devices that have undergone the 510(k) premarket clearance process. It should not be used on products other than cleared devices.



Platform Monitoring/Compliance

- Companies should be aware of social media, consumer testimonials, website claims, “linking” to third-party websites & clinical trials as FDA generally views these claims to be adopted as the company’s own claims.
- In March 2020, FDA launched Operation “Quack Hack”. This team has reviewed thousands of websites, social media posts, and online marketplace listings, resulting in over 100 warning letters to sellers, more than 200 reports sent to online marketplaces, and more than 250 abuse complaints sent to domain registrars.
 - This initiative has led domain registrars to take down numerous websites illegally selling unapproved products and retailers to remove unlawful products from the marketplace.
- Issued warning letters are evidence of platform monitoring as letters not only mention company websites but also false and misleading claims made on social media websites like Facebook and Twitter.

Recommendations

- Check FDA's "Fraudulent Coronavirus Disease 2019 (COVID-19) Products" page for up to date FDA enforcement including warning letters
- Refer to FDA Guidance documents and other policies for labeling/advertising requirements for regulated products
- Check FDA's Frequently Asked Questions (FAQs) for labeling/advertising guidance on specific topics including hand sanitizers, face masks and other products
- Ensure accuracy of information/claims made on all advertising and promotional platforms

Resources

Fraudulent Coronavirus Disease 2019 (COVID-19) Products

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Health Fraud Scams

El Fraude en la Salud

The U.S. Food and Drug Administration is issuing **warning letters** to firms for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure coronavirus disease 2019 (COVID-19). We are actively monitoring for any firms marketing products with fraudulent COVID-19 prevention and treatment claims. The FDA 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.

Content current as of:
09/15/2020

<https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-diseases-2019-covid-19-products>

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>

COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders

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Coronavirus Disease 2019 (COVID-19)

COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders

COVID-19 Frequently Asked Questions

The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid coronavirus disease 2019 (COVID-19) response efforts.

Content current as of:
09/14/2020

Process for COVID-19 Related Guidances

In the *Federal Register* of March 25, 2020, FDA published a [Notice announcing the process for making COVID-19 related guidance documents available to the public](#). The process is in accordance with FDA's established good guidance practices regulations and will enable FDA to more rapidly disseminate and implement agency recommendations and policies related to COVID-19.

Questions?



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Upcoming Events:

Session 3: A Fireside Chat and Crystal Ball Reading with FTC Attorney Advisors
Thursday, October 1, 2020 | 12:00 p.m. - 1:30 p.m. ET

Resources:

- **Venable's Advertising and Marketing Practice:** www.Venable.com/adlaw
- **Advertising Law Toolkit:** www.Venable.com/AdlawToolkit
- **Blog:** www.AllAboutAdvertisingLaw.com



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