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Manufacturers Face Evolving COVID-19 Legal Challenges

By **Stephanie Laws** (October 4, 2021, 6:03 PM EDT)


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The manufacturing industry faces unique challenges as a result of the COVID-19 pandemic. When many Americans began working from home, manufacturing companies worked to keep line and other on-site workers safe, resolve supply chain shortages threatening to close down plants, and respond to tremendous upheavals in consumer spending habits and product demand.

COVID-19 has thrust certain categories of products — like air filtration systems, hand sanitizer and the now-ubiquitous face masks — into the spotlight regarding their debated ability to reduce the spread of the virus.

The pandemic has also affected the legal landscape, presenting manufacturing companies with new legal challenges and potential areas of exposure, as well as new risk management and litigation strategies.

This article provides a high-level overview of some of the potential legal claims and issues facing manufacturing companies as a result of the pandemic.

COVID-19's Impact to Date

In early 2020, federal and state courts across the country modified court procedures, scheduling orders and deadlines to accommodate delays caused by COVID-19.

Approaches have varied widely by jurisdiction — seemingly based both on COVID-19 spread and the political climate — and have included measures like closing courthouses, postponing proceedings and trials, and conducting hearings and other appearances remotely.[1]

Some of these pandemic-generated rules specifically affect manufacturing companies facing product liability claims. In early 2020, several jurisdictions imposed limitations on obtaining discovery from health care providers who could demonstrate that the requests affected their ability to respond to the pandemic.

For example, the New Jersey Supreme Court issued an order suspending all depositions and appearances of doctors, nurses and other health care professionals involved in responding to COVID-19 unless requested by the health care provider or for matters related to virus.[2]

Likewise, individual courts across the country have issued orders requiring leave of court be obtained before conducting discovery on health care providers.[3] Product liability defendants should continue to anticipate hurdles and delays in obtaining health care provider discovery, particularly from those who are directly involved in treating persons with the virus.

Anticipated Claims and Actions

Product manufacturers face a variety of claims and legal challenges related to COVID-19, including product liability litigation, consumer protection claims, government enforcement actions, unsafe workplace claims, supply chain disputes and more.

Product Liability

Despite the pandemic, 2020 saw an overall increase in product liability claims filed in federal district courts.[4] But manufacturing companies have yet to see an influx of claims alleging that products were defective in preventing, diagnosing or treating the COVID-19 virus.

As statutes of limitation begin to expire, manufacturers can expect to see the full gamut of product liability

claims filed against them — including claims alleging that products were defectively designed, manufactured and/or accompanied by faulty warnings and instructions; that manufacturers acted with negligence in preparing and marketing products; and that manufacturers breached their warranties surrounding, or intentionally misrepresented, products' characteristics and abilities.

Claims that products were defective in preventing, diagnosing or treating COVID-19 face a variety of legal hurdles. Importantly, given the extremely contagious and widespread nature of the virus, it will be difficult to establish that any alleged product defect resulted in a positive COVID-19 diagnosis.

Additionally, the medical and scientific communities' understanding of COVID-19, its treatment, and its short- and long-term health effects is quickly evolving, complicating the analysis of whether any alleged defect caused or contributed to a specific injury or adverse outcome.

COVID-19 may even affect the causation analysis in claims unrelated to the virus where, for example, a plaintiff alleges he or she suffered injuries that may also be attributed to the illness.

Manufacturers facing product liability claims may also be able to avail themselves of the various statutory defenses aimed at limiting liability for COVID-19-related products. The Public Readiness and Emergency Preparedness Act broadly preempts COVID-19-related claims against manufacturers of "covered countermeasures."

These include U.S. Food and Drug Administration-approved products designed "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" and drugs, biological products and devices that the FDA has authorized for use to combat the pandemic via an emergency use authorization.[5] The immunity provided to qualifying manufacturers under the PREP Act is sweeping, but does not apply to claims of death or serious physical injury caused by willful misconduct.[6]

Additionally, many state and local governments are enacting their own COVID-19 safe harbor laws shielding businesses from COVID-19-related claims. Although the specifics of the defense vary by statute, at least some explicitly apply to product manufacturers, and shield them from product liability claims under certain circumstances.

For example, South Carolina's COVID-19 Liability Immunity Act precludes liability for claims pertaining to the "the manufacturing or donating of precautionary equipment or supplies, including personal protective equipment, due to shortages that occurred during the coronavirus pandemic."[7]

Generally, these statutory defenses only apply where, as the South Carolina law specifies, the defendant "reasonably adheres to public health guidance applicable at the time the conduct giving rise to a coronavirus claim occurs" and, like the PREP Act, the statutes do not preclude liability for willful misconduct.[8]

Consumer Protection Claims

Although product liability claims related to COVID-19 have yet to materialize, manufacturing companies have already faced lawsuits alleging their marketing statements violated state consumer protection statutes.

In early 2020, plaintiffs lawyers filed a slew of putative class actions against manufacturers and sellers of hand sanitizers nationwide, including GOJO Industries Inc., the maker of Purell.[9] These lawsuits, which brought claims for misrepresentation, fraud and violation of various state consumer protection statutes, alleged that the defendants had falsely represented that their alcohol-based hand sanitizer products could "kill 99.99% of germs" and thus could "could prevent the flu and other viruses," including the coronavirus.[10]

In support of these claims, plaintiffs in Taslakian v. Target Corp., filed in March 2020 in the U.S. District Court for the Central District of California, cited a Jan. 17, 2020, FDA warning letter to GOJO that characterized similar marketing claims as unfounded, stating that agency was:

> currently not aware of any adequate and well-controlled studies demonstrating that killing or decreasing the number of bacteria or viruses on the skin by a certain magnitude produces a corresponding clinical reduction in infection or disease caused by such bacteria or virus.[11]

Importantly, the plaintiffs did not allege to have suffered any personal injury. Rather, they claimed they would have purchased other hand sanitizer products in lieu of the defendants' products, or would not have paid as high a price but for these purported misrepresentations.[12]

Several such proposed class actions were consolidated in the U.S. District Court for the Northern District of Ohio in Aleisa v. GOJO Industries Inc., where they were ultimately dismissed with prejudice in May of this year for lack of standing to bring suit.[13]

Specifically, the court reasoned that the plaintiffs' claims that they would have purchased different hand sanitizer products but for the defendant's alleged misrepresentations lacked standing, because, by their own allegations, the plaintiffs paid for and received hand sanitizer that accomplished its intended purpose — killing germs — to some material degree, and the plaintiffs could not identify any alternative product they purportedly would have purchased but for the alleged misrepresentations.[14]

Regarding the plaintiffs' overpayment claims, the court found that the plaintiffs had not alleged facts plausibly suggesting that any alleged misrepresentations increased the product's market price.[15]

Significantly, the court found that consumers' fear that "they may have a greater exposure to germs than they wanted ... does not amount to an injury that is concrete, particularized, actual, or imminent," as required for standing under Article III.[16]

The court repeatedly criticized the plaintiffs' allegations as an attempt to "transform meritless product liability claims into a consumer class action."[17] The impact of the Aleisa court's ruling will soon be seen, as putative consumer protection class actions continue to be filed against manufacturers of other products in different jurisdictions.

In May, a plaintiff in the U.S. District Court for the District of Delaware filed Garner v. Global Plasma Solutions Inc., a putative class action against the manufacturer of ionization products and systems intended to clean indoor air, alleging those products failed to prevent exposure to COVID-19 as represented by the defendant.[18]

The plaintiff's 108-page complaint set forth similar themes to those used by the Aleisa plaintiffs — namely, that the defendant misrepresented its product's ability to reduce the virus's spread, in "an effort to capture dollars from COVID-19 fear,"[19] and also "prey[ed] on people desperate to cleanse the air and protect themselves from ... the COVID-19 virus."[20]

As in Aleisa, the Global Plasma plaintiff did not allege that any individual was actually exposed to or contracted COVID-19 due to reliance on the defendant's alleged misrepresentations.[21] Rather, the plaintiff claimed that he and other putative class members would not have purchased the products but for the alleged misrepresentations about their ability to prevent COVID-19,[22] and "fear[ed] future injury and physical harm for himself, family members, friends, and other people that may have been exposed as a result of his use of Defendant's Product."[23]

The defendant filed a motion to dismiss on May 24, arguing, among other things, that the plaintiff failed to allege an actionable injury because "[f]ear of future potential negative health effects is too speculative to state a claim."[24] The court has not yet ruled on the motion.

Government Enforcement Actions

Manufacturing companies should also anticipate potential governmental actions aimed at representations regarding the ability of products to prevent, diagnose or treat COVID-19. As of September, the Federal Trade Commission had received over 365,000 COVID-19-related fraud reports, totaling a reported $564 million in fraud.[25]

For its part, the FDA had received nearly 1,500 reports of fraudulent products related to COVID-19 as of July, the last date for which data was published.[26] The FDA has also initiated its own proactive review of online marketplace activities — known as Operation Quack Hack — to identify and stop potential fraud.[27] Collectively, the FTC and the FDA have issued hundreds of warning letters to companies regarding products related to COVID-19.[28]

Additionally, to help combat COVID-19-related fraud, the U.S. Congress passed the COVID-19 Consumer Protection Act in December 2020, which "makes it unlawful ... to engage in a deceptive act or practice in or affecting commerce associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19 or a government benefit related to COVID-19."[29]

Persons, including corporations, who violate the COVID-19 Consumer Protection Act are subject to the remedies available under the Federal Trade Commission Act, including injunctive relief and civil penalties.

[30]

The U.S. Department of Justice, together with the FTC, brought the first enforcement action under the COVID-19 Consumer Protection Act in April.[31] The civil complaint in that action — brought against chiropractor Eric Nepute and his company, Quickwork LLC — alleged that the defendants falsely marketed nutritional supplements containing vitamin D and zinc as preventing and treating the COVID-19 virus, even claiming certain products were more effective than the COVID-19 vaccines authorized for use by the FDA.[32]

According to the government's complaint, these claims were either not based on published studies or were based on observational studies or other flawed study designs, like observational studies, that "failed to conform to FDA guidelines for scientific studies investigating the efficacy of treatments for COVID-19."[33]

As a result, the defendants allegedly "disseminat[ed] misinformation, exploit[ed] fears in the midst of a pandemic, and pos[ed] a significant risk to public health and safety."[34]

Because this action is in its early stages, it is not yet known what its impact will be on the marketing of COVID-19 related products going forward. But manufacturing companies should be mindful of the COVID-19 Consumer Protection Act as a potential source of liability, take extra care when making any representations related to their products and the COVID-19 virus, and be sure all representations are based on reliable scientific data, like controlled studies.

Additional government enforcement actions are occurring at the state level. For example, in March 2020, the Missouri Attorney General's Office filed suit against televangelist Jim Bakker and his production company, Morningside Church Productions Inc., alleging they had violated the Missouri Merchandising Practices Act by soliciting donations for various colloidal silver products after a guest on Bakker's television show — allegedly a naturopathic doctor and natural health expert — implied the products could prevent and treat COVID-19.[35]

The action was ultimately resolved on June 22 of this year, with defendants agreeing to pay $156,000 in restitution.[36] Other state attorneys general have issued cease-and-desist notices to companies claiming their products — from air purifiers to toothpaste — can prevent, diagnose or treat COVID-19.[37]

Although, to date, government enforcement actions generally have been focused on snake oil-type scams, their scope could expand, as increasing resources are directed toward stopping COVID-19-related fraud.

Unsafe Work Environment Claims

Because manufacturing facilities generally require workers to be physically present on-site, the companies that operate those facilities also face potential unsafe work environment claims. Workers across the country have filed claims in similar contexts — mostly against food companies — alleging they and/or their loved ones at home contracted COVID-19 as a result of unsafe working conditions.[38]

In one notable case, Ek v. See's Candies Inc., filed in California Superior Court in December 2020, a worker sued the candy maker for allegedly requiring her to work on its packing line without proper social distancing and in close proximity to other workers, while some workers were exhibiting COVID-19 symptoms, like coughing and sneezing.[39] As a result, the worker alleged she both contracted COVID-19 and brought the virus home to her husband, who died.[40]

In that matter, a California Superior Court judge denied See's Candies demurrer arguing that the plaintiff's claims regarding her husband's death were barred by the state's Workers' Compensation Act — the exclusive remedy for workplace injuries — allowing those claims to go forward.[41]

Supply Chain Disputes

As COVID-19 continues to cause shutdowns and travel embargoes affecting manufacturing facilities worldwide, many companies face shortages and other supply chain disruptions that dramatically affect their bottom line. Who is responsible for bearing those losses depends heavily on the facts of each case, and the nature and language of the relevant agreement.

At least one court, however, has given credence to the idea that the COVID-19 pandemic may excuse a supplier's failure to supply goods or parts under the defense of commercial impracticability.[42] In JVIS-USA LLC v. NXP Semiconductors USA Inc., filed in the U.S. District Court for the Eastern District of Michigan, the court considered the impact of the COVID-19 pandemic on a suppliers' failure to deliver

semiconductor chips pursuant to its agreement with a manufacturer of components used in automobile manufacturing.

The court ultimately recognized in a written order in April that "global supply chains suffered tremendous upheavals as a result of the Covid-19 pandemic," and described the parties as "sparrows in a hurricane" dealing with factors beyond their control.[43]

Although the JVIS opinion was in the context of a plaintiff's request for injunctive relief to obtain the missing semiconductor chips, this language suggests that any manufacturing companies seeking to enforce supply chain obligations through civil litigation will need to overcome sympathy toward the widespread effects of the pandemic on global operations.

Conclusion

Manufacturing companies are facing a new era of risk management amid COVID-19. In-house counsel, and the outside counsel working with them, should monitor the litigation landscape surrounding product manufacturing, and continually reassess the status quo when determining legal strategy.

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[1] See, e.g., Roberson v. Respironics Inc. , No. 4:20-CV-174-DMB-JMV, 2021 WL 2179265, at *1, 4 (N.D. Miss. May 28, 2021) (deadlines set forth in scheduling order modified because COVID-19 inhibited depositions); Kieffaber v. Ethicon Inc. , No. CV 20-1177-KHV, 2021 WL 425822, at *1–2 (D. Kan. Feb. 8, 2021) (ordering parties to proceed to a jury trial by videoconference due to COVID-19-related safety concerns over medical device manufacturer defendant's objections); Rouviere v. DePuy Orthopaedics Inc. , 471 F. Supp. 3d 571, 572–74 (S.D.N.Y. 2020) (denying plaintiffs' request to conduct in-person depositions because of COVID-19 risks, despite plaintiffs' counsel's plan to "rent[] a recreational vehicle and ... drive it from their home state of Florida to New Jersey").

[2] N.J. Supreme Ct., Omnibus Order on COVID-19 Issues (March 27, 2020) (Rabner, C.J.), https://www.njcourts.gov/notices/2020/n200327a.pdf?c=Z6C.

[3] See, e.g., Standing Order for Civil Cases Pending Before Judge Cornelius with Consent Pursuant to 28 U.S.C. § 636(c), Voss v. State Farm Mutual Auto. Ins., 1:17-cv-1465-SGC (N.D. Al. March 31, 2020), ECF No. 68 (implementing a standing order requiring parties to obtain leave of court before seeking any discovery from health care providers in pending civil cases, with certain limited exceptions); Lipsey v. Walmart Inc. , No. 19 C 7681, 2020 WL 1322850, at *4 (N.D. Ill. March 20, 2020) (implementing a protocol prohibiting service of a subpoena on a medical provider without a court order, and requiring, among other things, that a party seeking to depose a medical provider submit information to the court regarding the proposed deponent's involvement in responding to COVID-19 and the availability of alternative methods of obtaining the evidence); DeVine v. XPO Logistics Freight , No. 18 C 1264, 446 F. Supp. 3d 332, 335 (N.D. Ill. March 17, 2020) (same).

[4] Rachel Bailey, Summary: Impacts of the Coronavirus Pandemic on Litigation Activity in Federal District Court, Lex Machina (May 18, 2021), https://lexmachina.com/blog/2020-impact-of-coronavirus-pandemic-on-litigation-activity/.

[5] 42 U.S.C. § 247d–6d(i)(7).

[6] Id. § 247d–6d(d).

[7] S. Res. 147, 2021 Leg., 124th Sess. (S.C. 2021).

[8] See, e.g., id.

[9] See Miller v. Gojo Indus. Inc., Case No. 4:20-cv-562 (N.D. Ohio March 13, 2020); Taslakian v. Target

Corp., Case No. 2:20-cv-2667 (C.D. Cal. March 20, 2020); David v. Vi-Jon Inc., Case No. 3:20-cv-424 (S.D. Cal. March 5, 2020); Jurkiewicz v. Gojo Indus. Inc., Case No. 5:20-cv-279 (N.D. Ohio Feb. 9, 2020); Gonzalez v. Gojo Indus. Inc., Case No. 1:20-cv-888 (S.D.N.Y. Feb. 1, 2020); Marinovich v. Gojo Indus. Inc., Case No. 3:20-cv-747 (N.D. Cal. Jan. 31, 2020); Aleisa v. Gojo Indus. Inc., Case No. 2:20-cv-1045 (C.D. Cal. Jan. 31, 2020).

[10] See, e.g., Complaint at ¶ 6, Taslakian, Case No. 2:20-cv-2667, ECF No. 1.

[11] Id. at ¶¶ 6, 58; see Warning Letter GOJO Industries Inc., U.S. Food and Drug Admin. (Jan. 17, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gojo-industries-inc-599132-01172020.

[12] Complaint at ¶¶ 107–08, Taslakian, Case No. 2:20-cv-2667, ECF No. 1.

[13] See Aleisa v. GOJO Indus. Inc. , Case No. 5:20-cv-2383, 2021 WL 1893562, at *1 (N.D. Ohio May 11, 2021).

[14] Id. at *6.

[15] Id.

[16] Id.

[17] Id. at *1.

[18] Garner v. Global Plasma Sols. Inc., Case No. 1:21-cv-665-CFC (D. Del. May 7, 2021).

[19] Complaint at ¶ 10, Garner, Case No. 1:21-cv-665-CFC, ECF No. 1.

[20] Id. at ¶ 1.

[21] See id. at ¶¶ 3, 13.

[22] Id. at ¶ 170.

[23] Id. at ¶ 169.

[24] Defendant's Memorandum in Support of Motion to Dismiss at 12, Garner v. Global Plasma Sols. Inc., Case No. 1:21-cv-665-CFC, ECF No. 6.

[25] FTC COVID-19 and Stimulus Reports: Fraud Reports, Fed. Trade Comm'n, https://public.tableau.com/app/profile/federal.trade.commission/viz/COVID-19andStimulusReports/FraudLosses (last visited Sept. 28, 2021).

[26] U.S. Food and Drug Admin., FDA COVID-19 Response: At-A-Glance Summary 1, https://www.fda.gov/media/137005/download.

[27] Id.

[28] For a list of the relevant letters, see Warning Letters, Fed. Trade Comm'n, https://www.ftc.gov/enforcement/warning-letters?title_1=&date_filter%5Bvalue%5D%5Bdate%5D=&field_tags_tid%5B%5D=14297&items_per_page=20 (last visited Aug. 19, 2021), and Fraudulent Coronavirus Disease 2019 (COVID-19) Products, U.S. Food and Drug Admin., https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products#Warning%20Letter%20Table (last visited Aug. 19, 2021).

[29] See COVID-19 Consumer Protection Act, Pub. L. No. 116-260, 134 Stat. 1182, Division FF, Title XIV, § 1401, available at https://www.ftc.gov/enforcement/statutes/covid-19-consumer-protection-act-2021-consolidated-appropriations-act.

[30] Id.

[31] See U.S. v. Nepute, Case No. 4:21-cv-437-RLW (E.D. Mo. April 15, 2021); see also Justice Department and FTC Announce Action to Stop Deceptive Marketing of Purported COVID-19 Treatments,

U.S. Dep't of Justice (April 15, 2021), https://www.justice.gov/opa/pr/justice-department-and-ftc-announce-action-stop-deceptive-marketing-purported-covid-19; In First Action Under COVID-19 Consumer Protection Act, FTC Seeks Monetary Penalties for Deceptive Marketing of Purported Coronavirus Treatments, Fed. Trade Comm'n (April 15, 2021), https://www.ftc.gov/news-events/press-releases/2021/04/first-action-under-covid-19-consumer-protection-act-ftc-seeks.

[32] Complaint at ¶ 1, Nepute, Case No. 4:21-cv-437-RLW, ECF No. 1.

[33] Id. at ¶¶ 27, 31.

[34] Id. at ¶ 1.

[35] See Application for Temporary Restraining Order, State of Missouri v. Jim Bakker, Case No. 20SN-CC00084 (Mo. Cir. Ct. March 10, 2020); Matthew S. Schwartz, Missouri Sues Televangelist Jim Bakker For Selling Fake Coronavirus Cure, NPR (March 11, 2020), https://www.npr.org/2020/03/11/814550474/missouri-sues-televangelist-jim-bakker-for-selling-fake-coronavirus-cure.

[36] Missouri Attorney General Recoups $156,000 in Restitution, Settles Case Against Jim Bakker and Morningside Church, Office of the Mo. Attorney Gen. (June 23, 2021), https://ago.mo.gov/home/news/2021/06/23/missouri-attorney-general-recoups-$156-000-in-restitution-settles-case-against-jim-bakker-and-morningside-church.

[37] See AG James Orders Companies to Stop Selling Bogus "Coronavirus-Killing" Devices, N.Y. State Office of the Attorney Gen. (March 26, 2020), https://ag.ny.gov/press-release/2020/ag-james-orders-companies-stop-selling-bogus-coronavirus-killing-devices; Attorney General James Orders Craigslist to Remove Posts Selling Fake Coronavirus Treatments and Exorbitantly-Priced Items, N.Y. State Office of the Attorney Gen. (March 20, 2020), https://ag.ny.gov/press-release/2020/attorney-general-james-orders-craigslist-remove-posts-selling-fake-coronavirus; Attorney General James Orders Alex Jones to Stop Selling Fake Coronavirus Treatments, N.Y. State Office of the Attorney Gen. (March 12, 2020), https://ag.ny.gov/press-release/2020/attorney-general-james-orders-alex-jones-stop-selling-fake-coronavirus-treatments; Attorney General James Orders Companies to Stop Selling Fake Treatments for Coronavirus, N.Y. State Office of the Attorney Gen. (March 11, 2020), https://ag.ny.gov/press-release/2020/attorney-general-james-orders-companies-stop-selling-fake-treatments-coronavirus.

[38] See, e.g., Elijah v. Pilgrim's Pride Corp., Case No. 5:21-cv-47, 2021 WL 1570138 (E.D. Tex. April 21, 2021); Petition, Fernandez v. Tyson Foods Inc., Case No. 6:20-cv-2079-LRR-KEM (N.D. Iowa Oct. 5, 2020), ECF No. 2; State of New York v. Amazon.com Inc., Case No. 45362/2021, 2021 WL 678693 (N.Y. Sup. Ct. Feb. 16, 2021); Complaint, Ek v. See's Candies Inc., Case No. 20STCV49673 (Cal. Super. Ct. Dec. 30, 2020); Iniguez v. Aurora Packing Co. Inc., Case No. 20-L-372, 2020 WL 4734941 (Ill. Cir. Ct. Aug. 5, 2020).

[39] Complaint at 4, Ek, Case No. 20STCV49673.

[40] Id.

[41] Notice of Ruling Regarding Demurrer of Defendants to Plaintiffs' Complaint, Ek, Case No. 20STCV49673.

[42] The commercial impracticability defense, "[d]elay in delivery or non-delivery in whole or in part by a seller ... is not a breach of his duty under a contract for sale if performance as agreed has been made impracticable by the occurrence of a contingency the non-occurrence of which was a basic assumption on which the contract was made." U.C.C. § 2-615(a).

[43] Order Granting Plaintiff's Emergency Motion to Expedite Hearing and Denying Plaintiff's Emergency Motion for Temporary Restraining Order at 6–7, 10, JVIS-USA, LLC v. NXP Semiconductors USA Inc., Case No. 4:21-cv-10801-SDD-APP (E.D. Mich. April 16, 2021), ECF No. 24.