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Defending Against A Wave Of Hand Sanitizer Class Actions

By **Alex Smith** (April 2, 2020, 5:10 PM EDT)


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Amid the COVID-19 pandemic, consumers have increasingly turned to a familiar and convenient hygiene measure: hand sanitizer.

The Centers for Disease Control and Prevention advises that alcohol-based hand sanitizers inactivate "viruses that are genetically related to, and with similar properties as, the 2019-nCoV" and recommends them in health care settings as part of their hand hygiene guidelines. The CDC also recommends hand sanitizers — albeit somewhat less enthusiastically — for consumer use. And consistent with those recommendations, consumer demand for hand sanitizer is so high that it is unavailable at many stores throughout the country.

In stark contrast to the CDC guidance, however, the U.S. Food and Drug Administration sent a warning letter earlier this year to Gojo Industries, the manufacturer of Purell, in which it asserted that Purell's labeling claims — including the claim that Purell "kills 99.99% of most common germs" — were insufficiently substantiated and that they violated federal law.

And in the wake of that warning letter, many plaintiffs have filed putative consumer class actions against Gojo and other manufacturers of hand sanitizer, in which they accuse these manufacturers of false advertising and characterize hand sanitizers as unapproved new drugs. While these claims are unlikely to discourage consumers from using hand sanitizer, they present serious risks to manufacturers of hand sanitizer and are likely to proliferate as the COVID-19 pandemic continues.

The FDA Warning Letter to Gojo

In its Jan. 17 warning letter to Gojo, the FDA asserted that "[a]s currently formulated and labeled, PURELL Healthcare Advanced Hand Sanitizers are unapproved new drugs in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act." The FDA noted that Gojo's website and social media accounts made a variety of claims about the intended uses of Purell hand sanitizers, including by claiming that Purell:

- Kills more than 99% of most common germs that may cause illness in a health care setting, including methicillin-resistant Staphylococcus aureus, or MRSA, and vancomycin-resistant enterococcus, or VRE;

- Demonstrated effectiveness against a drug resistant clinical strain of Candida auris in lab testing; and

- Can reduce MRSA and VRE by 100%.

The FDA also noted that Gojo had claimed that Purell was effective against various enveloped viruses, such as influenza, norovirus and Ebola, which are "easily killed or inactivated by alcohol." While the FDA did not mention COVID-19 in this warning letter, it is worth noting that COVID-19 is also an enveloped virus.

The FDA took issue with all of these claims. It noted that it was "not currently 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 any such bacteria or virus."

The FDA also viewed these claims as evidence that Purell hand sanitizer was a drug under Title 21 of U.S. Code Section 321(g)(1), either because it is "intended for the diagnosis, cure, mitigation, or prevention of disease" or because it is "intended to affect the structure or any function of the body." And the FDA concluded that Purell was an unapproved new drug, as it was sold without FDA approval and was not "generally recognized as safe or effective under the conditions prescribed, recommended, or suggested in [the] labeling."

The FDA also disagreed with Gojo's assertion that Purell hand sanitizers were marketed under the FDA's over-the-counter drug review because they were formulated with ethyl alcohol. The FDA noted that it had deferred rulemaking on the use of ethyl alcohol, isopropyl alcohol and benzalkonium chloride in consumer antiseptic rubs (i.e., hand sanitizers) and did not intend to object to the marketing of hand sanitizer products provided that they comply with the formulation and labeling conditions set forth in the FDA's tentative final monograph for such products.

But the FDA nonetheless concluded that Purell's claims of being "effective in preventing disease or infection from pathogens such as Ebola, MRSA, VRE, norovirus, flu, and Candida auris, and in preventing the spread of infection," were unlawful because they "go beyond merely describing the general intended use of a topical antiseptic."

Lawsuits Based on the FDA Warning Letter

Soon after the FDA sent its warning letter to Gojo, plaintiffs began filing consumer class actions against Gojo. Two sets of plaintiffs filed separate lawsuits in the U.S. District Court for the Central District of

California on Jan. 31.[1] The next day, another plaintiff brought a parallel lawsuit, Gonzalez v. Gojo Industries Inc., in the U.S. District Court for the Southern District of New York.[2] And at least two other sets of plaintiffs have filed similar lawsuits in the Northern District of Ohio, where Gojo is headquartered.[3]

Although these lawsuits assert slightly different causes of action, they are premised on the same basic theory of deception. They allege that Purell touts its ability to kill 99.99% of germs and to prevent a variety of viral diseases (including influenza, Ebola and norovirus), and they assert — like the FDA — that Gojo illegally markets Purell as an unapproved new drug. They also allege that the labeling of Purell is independently deceptive, as they suggest that they prevent disease — even though there is allegedly no reliable scientific support for this claim.

While Purell's labeling does not specifically represent that it is effective at preventing COVID-19, there is no doubt that the COVID-19 pandemic lurks in the background of these lawsuits. For example, the Gonzalez complaint notes that the "recent outbreak of the fatal Coronavirus has prompted increased demand for the Products" and that "[a]ccording to some reports, defendant has promoted the Products as a viable means of preventing transmission of Coronavirus."

Likewise, the Miller complaint notes in passing that the "recent outbreak of the coronavirus has greatly increased demand for the Product." And the COVID-19 pandemic may also have prompted plaintiffs to begin filing similar lawsuits against other manufacturers of hand sanitizer, such as Vi-Jon Inc. (the manufacturer of Germ-X) and Target.[4] As the COVID-19 pandemic continues to spread, it is inevitable that plaintiffs will continue to file these lawsuits against hand sanitizer manufacturers around the country.

Strategies for Defending Against Hand Sanitizer Claims

While plaintiffs lawyers may claim that these lawsuits seek to prevent unscrupulous manufacturers from exploiting the COVID-19 pandemic by making unsubstantiated claims on their labeling, defendants may claim that these lawsuits simply prove that no good deed goes unpunished.

Indeed, while the plaintiffs in these cases accuse manufacturers of making false claims about the disease prevention properties of hand sanitizer, these lawsuits generally do not allege that hand sanitizer is ineffective at preventing disease — because there is little evidence showing that this is the case. Instead, they allege that claims about the effectiveness of hand sanitizer are not scientifically substantiated, which shifts the burden to the defendants to identify adequate scientific support for their disease-prevention claims.

Defendants in these lawsuits should be aware that many state consumer fraud statutes do not authorize private plaintiffs to assert lack-of-substantiation claims. Under California law, for example, "[p]rivate plaintiffs are not authorized to demand substantiation for advertising claims.[5] New York courts have likewise distinguished between claims that a defendant's "statements are not substantiated by science" and claims that those statements are "affirmatively untrue."[6]

As one court explained, it "is one thing for plaintiff to say that a certain representation is actually untrue or misleading," but "another thing ... for a plaintiff to say that a certain representation hasn't been shown to be true; that case does not pass go."[7]

Defendants also have several viable responses to plaintiffs' claims that a hand sanitizer is an unapproved new drug. Many courts have held that courts are not appropriately situated to determine that a product is an unapproved new drug and have stayed or dismissed these claims under the doctrine of primary jurisdiction.[8]

While many of these cases concern cosmetic products (such as anti-wrinkle lotions), manufacturers of hand sanitizers may be able to argue that the doctrine of primary jurisdiction should also apply here, as courts are similarly not situated to determine whether hand sanitizers are drugs or whether their labeling complies with the FDA's monograph for topical antiseptics.

Additionally, because plaintiffs' unapproved new drug claims are premised on alleged violations of the Federal Food, Drug, and Cosmetic Act or FDA regulations, and not on allegations that the challenged labeling claims are deceptive, defendants should consider whether the relevant state consumer protection laws permit plaintiffs to assert claims premised on violations of FDA regulations.

For example, New York typically does not permit private plaintiffs to assert claims based on alleged violations of FDA regulations absent a showing that the labeling statement at issue is independently deceptive.[9] Courts in New Jersey have likewise expressed skepticism about whether plaintiffs can use state consumer fraud statutes to "bootstrap a FDCA claim they could not otherwise bring."[10]

In light of the difficulties of asserting a lack-of-substantiation or an unapproved new drug claim, plaintiffs may attempt to characterize these lawsuits as garden-variety actual falsity claims — i.e., that manufacturers assert that hand sanitizers prevent the transmission of disease, even though they do not. That theory, while potentially more viable as a matter of law, defies the common sense wisdom — and the recommendations of public health authorities — that using hand sanitizer reduces the risk of infection.

Moreover, while the plaintiffs suing hand sanitizer manufacturers have brought their lawsuits as putative class actions, it is far from clear that an actual falsity claim is susceptible to classwide resolution. Courts have made clear that, in a false advertising case, class certification is inappropriate unless "the challenged statements were actually false as applied to all (or even most) class members."[11]

If the plaintiffs' theory is that hand sanitizer is not effective, defendants may be able to point to a variety of individualized factors — such as exposure to germs, compliance with social distancing recommendations and other hygiene practices — that preclude a court from determining on a classwide basis whether the hand sanitizer was ineffective (and the challenged labeling claims false) as to any given consumer.

These cases are still in their early stages, and no court has yet addressed the merits of the plaintiffs' claims in these lawsuits. Nonetheless, while these lawsuits will continue to percolate through the courts for foreseeable future, it is unlikely that they will — or should — dissuade consumers from applying hand sanitizer.

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[1] Marinovich v. Gojo Indus., Inc., Case No. 3:20-cv-747 (N.D. Cal.); Aleisa v. Gojo Indus., Inc., Case No. 2:20-cv-1045 (C.D. Cal.).

[2] Gonzalez v. Gojo Indus., Inc., Case No. 1:20-cv-888 (S.D.N.Y.).

[3] Jurkiewicz v. Gojo Indus., Inc., Case No. 5:20-cv-279 (N.D. Ohio); Miller v. Gojo Indus., Inc., Case No. 4:20-cv-562 (N.D. Ohio).

[4] See David v. Vi-Jon, Inc., 3:20-cv-424 (S.D. Cal.); Taslakian v. Target Co., 2:20-cv-2667 (C.D. Cal.).

[5] Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc., 107 Cal. App. 4th 1336, 1345 (2003).

[6] Tomasino v. Estee Lauder Cos. 44 F. Supp. 3d 251, 259 n.4 (E.D.N.Y. 2014).

[7] Nilon v. Natural-Immunogenics Corp., No. 12-930, 2013 WL 5462288, at *1 (S.D. Cal. Sept. 30, 2013).

[8] See, e.g., Mollicone v. Universal Handicraft, Inc., No. 16-7322, 2017 WL 440257, at *13 (C.D. Cal. Jan. 30, 2017); Imaginetix v. Frutarom USA, Inc., No. 12-2823, 2013 WL 6419674, at *1 (S.D. Cal. Dec. 9, 2013).

[9] See e.g., Verzani v. Costco Wholesale Corp., No. 09-2117, 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010), aff'd, 432 F. App'x 29 (2d Cir. 2011); Quiroz v. Beaverton Foods, Inc., No. 17-7348, 2019 WL 1473088, at *6 (E.D.N.Y. Mar. 31, 2019).

[10] Mladenov v. Wegmans Food Mkts., Inc., 124 F. Supp. 3d 360, 380 (D.N.J. 2015).

[11] Konik v. Time Warner Cable, No. 07-763, 2010 WL 8471923, at *9 (C.D. Cal. Nov. 24, 2010).