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New Criminal Enforcement Risks to Dietary Supplement Industry

Patrick Linehan, Christopher Niewoehner, David Fragale, and Galen Kast, Steptoe & Johnson LLP

New Criminal Enforcement Risks to Dietary Supplement Industry Litigations

Contributed by Patrick Linehan, Christopher Niewoehner, David Fragale, and Galen Kast, Steptoe & Johnson LLP

Health concerns raised by the Covid-19 pandemic have prompted consumers to seek prevention and treatment in the absence of any therapies approved by the Food and Drug Administration. In this environment, government agencies and law enforcement will monitor the dietary supplement industry in search of claims by supplement companies that their products offer benefits related to Covid-19.

Indeed, the FDA has already launched its first salvo of Covid-19 related warning letters, which offer a glimpse into the areas where it will be focusing its enforcement efforts. Criminal enforcement actions are sure to follow, in these areas and beyond. This article looks at the likely areas where the FDA and criminal prosecutors will focus their attention in an effort to stave off consumer harm during this pandemic.

Dietary Supplement Regulation

Dietary supplements are subject to both the general criminal prohibitions against misbranded and adulterated "foods" under the Food Drug & Cosmetic Act (FDCA) as well as the more supplement-specific rules enacted under the Dietary Supplement Health and Education Act of 1994. DSHEA categorizes dietary supplements as "foods," as opposed to "drugs," as long as certain requirements are met. A "dietary supplement" is a product taken by mouth containing one or more "dietary ingredients."

The statute defines a dietary ingredient as a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of the preceding substances. A product can be marketed and sold as a "dietary supplement" as long as it is taken by mouth, contains a dietary ingredient, and complies with the FDA's labeling requirement. Unlike drugs, the FDA does not approve dietary supplements, meaning that supplement manufacturers and distributors are responsible for the safety and labeling of their products.

DSHEA bifurcates its regulation of dietary supplements between products containing dietary ingredients sold prior to Oct. 15, 1994, and following Oct. 15, 1994–i.e., before DSHEA, and after DSHEA. Manufacturers bringing to market dietary supplements containing ingredients not sold before DSHEA (new dietary ingredients, or NDIs) must notify the FDA at least 75 days prior to sale of the product, and must provide the FDA with the information upon which the manufacturer or distributor has relied to conclude that the product will reasonably be expected to be safe. By contrast, dietary ingredients sold pre-DSHEA do not require pre-market notification to the FDA or the pre-market submission of safety information.

Criminal Liability

Dietary supplement manufacturers and distributors, as well as their executives and officers, and potentially other employees, are subject to criminal liability when their products are "misbranded" or "adulterated," even in the absence of knowledge of or intent to violate the law.

Specifically, 21 U.S.C. § 331 prohibits "[t]he introduction or delivery for introduction into interstate commerce any food, drug, device, tobacco, product, or cosmetic that is adulterated or misbranded." In turn, § 333 renders any violation–regardless of knowledge or intent–a misdemeanor.

Section 333 further provides for felony liability for repeat violators of § 331, or those who violate § 331 with the intent to defraud or mislead. Section 333 thus facially permits felony criminal prosecution for repeat offenders of § 331 even in the absence of proof that the defendant intended, or had knowledge of, the violation.

Criminal liability in the absence of knowledge or intent also extends to executives and officers of the offending institutions. In United States v. Park, 421 U.S. 658 (1975), the president of a national food chain appealed his conviction arising from the chain's distribution of foods exposed to rodent contamination. The court upheld the executive's conviction, explaining that

the government need only show that the defendant had "responsibility and authority either to prevent in the first instance, or promptly correct, the violation complained of, and that he failed to do so."

More recently, in *United States v. Carlson*, 810 F.3d 544 (8th Cir. 2016), a store clerk appealed his misdemeanor conviction for selling misbranded drugs to undercover agents, given his limited responsibilities. The Eighth Circuit explained that "'neither knowledge nor intent is required' for a violation of § 331," and upheld the conviction.

Taken together, these cases suggest that individual employees—from president to store clerk—have civil and potentially criminal exposure for violations of § 331 even in the absence of knowledge of or intent to commit the underlying crime.

Likely Areas of Criminal Enforcement

The pandemic has set the stage for a more aggressive law enforcement push against dietary supplement companies in at least three areas: misbranded products making unsubstantiated claims regarding prevention of COVID-19, adulteration based on material cGMP violations, and adulteration based on products that pose a "significant and unreasonable risk of harm to consumers."

Unsubstantiated Covid-19-Related Claims

The FDA's first tool is its authority to regulate the language that can be used in a dietary supplement's labeling, defined broadly under 21 U.S.C. § 321(m) as "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The term encompasses not only written matter that physically accompanies articles of food or drugs, but any written matter that bears a "textual relationship" to the article, such as magazine advertisements or web pages. Where that labeling does not comply with FDA regulations, such as the requirement that the product include a statement that it is a dietary supplement, the FDA can declare a product "misbranded," resulting in liability for the manufacturer or distributor.

Dietary supplement manufacturers are broadly permitted to make "structure or function" claims on the labeling, which can describe the role of or mechanism by which nutrients or dietary ingredients affect structure or function in humans, as well as benefits related to nutrient deficiency diseases, with certain restrictions. Unlike the FDA's drug authority, structure or function claims do not require pre-market approval, although dietary supplement manufacturers must have substantiation that the structure or function claims are truthful and not misleading, and comply with related labeling requirements, including a statement that the product is not "intended to diagnose, treat, cure, or prevent any disease."

As the required disclaimer makes clear, dietary supplements can run afoul of the FDA when its labeling contains explicit or implicit claims related to a specific disease, such as Covid-19. For example, with proper substantiation, a dietary supplement could include a structure or function claim such as "promotes respiratory health," but is not permitted to tie those health benefits to a particular disease statement through a claim such as "prevents Covid-19" or "alleviates the symptoms of Covid-19," or via a product name, such as "Covid-19 Immune Booster." Such claims are particularly susceptible to enforcement action where they are likely to induce a customer to engage in risky behavior. For instance, products tied to Covid-19 might provide consumers with a false sense of security that results in reduced handwashing or mask wearing.

Explicit Covid-19-related labeling claims are at the center of at least 50 warning letters issued by the FDA, and at least five indictments since the beginning of the pandemic. Examples of such claims include:

- "Chinese Herbal Solutions … reported with success in China for the prevention and treatment of Covid-19"
- "The FDA established [ImunStem] as safe and effective to treat … Covid-19 virus"

Such disease-related claims not only expose manufacturers and distributors to criminal exposure arising from misbranding of a dietary supplement, but also render the underlying products unapproved new drugs in violation of 21 U.S.C. § 355(a), and misbranded drugs under 21 U.S.C. § 352, compounding the potential liability for a violation.

Where disease claims or false assertions of FDA approval are made to customers or insurers, manufacturers and distributors are also exposed to mail or wire fraud charges. For example, on July 9, 2020, the chief executive of Golden Sunrise Pharmaceutical, Inc. and Golden Sunrise Nutraceutical, Inc. was indicted on two counts of mail fraud and three counts of misbranding for the allegedly false claim that the Golden Sunrise Companies' product, "ImunStem," was

approved by the FDA for the treatment of Covid-19, and the Golden Companies' subsequent submission of claims to customers' insurers.

Perhaps more dangerous to manufacturers cognizant of the need to avoid disease claims is the risk of labeling that implies that a dietary supplement can treat or prevent Covid-19. For example, at the height of the coronavirus outbreak, football quarterback Tom Brady's health and wellness company, TB12, released a new product called "Protect" that comes perilously close to making claims an (over)aggressive prosecutor might allege relates to Covid-19. The online marketing for Protect states, "It's more important than ever to give your body everything it needs to help support your #immune system."

Protect is a dietary supplement that TB12 markets for its "immune-supporting benefits" to help the immune system respond to "outside threats." TB12's website also makes a number of structure or function claims related to Protect, including: "Protect helps to 'close the window' where your body is susceptible to bacteria and viruses after strenuous exercise"; "Protect helps support improved NK cell function so they can better fight off outside threats"; and "improves microphage function … to quickly recognize and kill threats while alarming other cells."

While Protect's claims do not reference Covid-19, an enterprising prosecutor could attempt to draw a connection. For example, on the day TB12 announced its new product, one of its Instagram posts stated that Protect contained the "right combination to protect and shield your body, they work together to prime key immune cells, counter free-radical damage, and alleviate exercise-induced immune suppression and daily stress," and then emphasized, "It's more important than ever to give your body everything it needs to help support your #immune system." Such a claim runs the risk that the FDA interprets the labeling to imply that Protect was referencing the coronavirus pandemic as the reason it was more important than ever to support the immune system and that Protect was able to protect and shield the body from the virus during this time.

In addition to liability stemming from disease claims, the ongoing crisis is also likely to draw consumers to direct sales from dietary supplement manufacturers and distributors as retail outlets like GNC and The Vitamin Shoppe remain closed or operate with reduced capacity. Such direct-to-consumer sales eliminates the vetting of claims and labeling traditional retailers undertake before marketing a product, thus placing greater compliance and liability risks on the manufacturers and distributors conducting direct sales.

Material Non-Compliance With cGMP

Current Good Manufacturing Practices, or cGMP, are FDA regulations that provide for "proper design, monitoring, and control of manufacturing processes and facilities" for dietary supplements sold in the U.S. Discussion of all cGMP requirements is beyond the scope of this article, but as relevant to the ongoing pandemic, require the establishment of processes for the prevention of microbial contamination.

In particular, cGMP regulations require manufacturers to exclude from working any person who "by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have" an abnormal source of microbial contamination "that could result in the microbial contamination of components, dietary supplements, or contact surfaces." The regulation further requires manufacturers to instruct employees to notify supervisors if they have, or if there is a reasonable possibly that they have a qualifying health condition (such as Covid-19).

Finally, the regulation requires the use of "hygienic practices to the extent necessary to protect against such contamination" around components, dietary supplements, or contact surfaces, including use of protective garments, gloves, and hair nets, adequate personal cleanliness, handwashing, removal of unsecured objects like jewelry, avoidance of clothing storage, avoidance of consumption of food, gum, beverages, or tobacco products, and any other precautions necessary to protect against the contamination of components, dietary supplements, or contact surfaces.

These requirements pose unique enforcement risks to dietary supplement manufacturers or distributors operating during the pandemic given the rapid spread of the contagion and challenges in virus carrier identification. For instance, employees may not always know when they have a "reasonable possibility" of a Covid-19 infection, and identifying employees who "appear to have" Covid-19 relies on an evolving set of diagnostic criteria.

While Covid-19 transmission via a contaminated product is likely to be rare or impossible given the time between production and purchase, such practicalities will not stop overzealous plaintiff's lawyers or prosecutors searching for a

violation. And many dietary supplement companies, which are often smaller and less sophisticated, may not have the technology or infrastructure to address these issues as effectively as pharmaceutical companies.

At a higher level, the Covid-19 pandemic is also likely to affect manufacturer, distributor, and packer staffing, as employees are excluded for Covid-19-related reasons as required under cGMP. These unpredictable factors may result in shipment delays, reliance on alternative suppliers, and in some instances, reductions in compliance and other corner-cutting to make up for revenue or time lost due to Covid-19.

In addition, the pandemic is likely to reduce the availability of required inspectors and inspections, and has already resulted in an indefinite postponement of domestic and foreign routine surveillance inspections and a "scaled back surveillance inspection program." While infrequent or postponed inspections may offer short-term savings to the inspection recipients, such reductions pose additional risks to manufacturers and distributors that rely on now-uninspected third parties in the supply chain, or whose employees may loosen their focus on cGMP compliance if they perceive that an FDA inspection is less likely.

Liability relating to contaminated ingredients is further amplified by the FDA's increased scrutiny over ingredients sourced from non-United States facilities in China and other countries not subject to the same inspectional requirements as facilities in the U.S. Although international vendors themselves are often beyond the reach of U.S. law, the manufacturers and distributors marketing products containing those ingredients remain liable for the quality and safety of the resulting products.

Adulteration

Finally, the FDA has the ability to declare a product adulterated. For supplements containing dietary ingredients not sold pre-DSHEA, a product is considered adulterated if the manufacturer or distributor failed to provide information demonstrating a reasonable assurance that the ingredient does not present a significant or unreasonable risk of injury. For supplements containing dietary ingredients sold pre-DSHEA, which were thus grandfathered in to the regulatory regime, the FDA may nonetheless declare the product adulterated if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if none were recommended, under ordinary conditions of use.

Because DSHEA does not define the meaning of "significant or unreasonable risk," these definitions have the potential to take on new and costly meanings in the Covid-19 era. For example, consumers and their personal injury lawyers may claim, and report to FDA or federal prosecutors, that they contracted Covid-19 or experienced exacerbated health issues relating to Covid-19 only after consuming a particular dietary supplement.

For example, those claims could be based on theories that the supplement made them more susceptible to the more life-threatening symptoms associated with Covid-19, or that they were somehow exposed to Covid-19 as a result of the supplement company's non-compliance with cGMP. Although such theories are more likely to be pushed by plaintiffs' lawyers, the ability of plaintiffs' lawyers to influence the government's initiation of a criminal investigation or even criminal charges is becoming more and more common.

Contamination-related charges, particularly when rooted in cGMP violations, can result in significant liability, as recently demonstrated by Chipotle Mexican Grill Inc.'s $25 million fine related to an outbreak of foodborne illness between 2015 and 2018, and Blue Bell Creameries' combined $19.35 million fine, forfeiture, and settlement payment relating to a 2015 outbreak of listeriosis.

Practical Steps to Minimize Likelihood of Enforcement

Despite the novel issues that Covid-19 presents, dietary supplement manufacturers and distributors retain a variety of strategies to reduce their criminal and civil exposure, as outlined below.

- Ensure that any new product names or labeling steer clear of claims that the product diagnoses, treats, cures, or prevents any disease, unless it is a qualifying nutritional deficiency claim and disease, such as scurvy and vitamin C. While dietary supplements referencing Covid-19 will undoubtedly be popular in the ensuing months as consumer interest in avoiding infection rises, such products and claims are likely to trigger enforcement action by the FDA.

- Document all procedures used to protect against Covid-19 contamination in cGMP facilities, such as the use of protective equipment like face masks, sanitization policies, instructions to employees and supervisors on the symptoms of Covid-19, and policies to exclude potentially infected employees.
- Communicate with other entities in the production pipeline, such as ingredient suppliers and packing and shipping vendors, to ensure that adequate procedures are in place, and potential delays do not result in compliance or cGMP lapses with the potential to result in significant future liability.
- Keep an internal record of any data clarifying the safety of dietary ingredients and supplements, particularly as related to Covid-19, that forms the basis of the determination that the product is safe for consumers. Such data may include scientific studies on the effects of particular ingredients, the mechanism by which such ingredients affect the body, and any other research or steps taken to ascertain the safety of the product or ingredients used.

  While such documentation may be discoverable in the event of litigation or prosecution, the benefits of being able to demonstrate a robust safety program are likely to outweigh the costs associated with maintaining a strong safety file, and the potential discovery and litigation risks inherent in maintaining additional documentation.

Conclusion

As Covid-19 continues to spread, dietary supplement manufacturers and distributors will face an increased risk of criminal prosecution, FDA civil enforcement, and litigation by plaintiffs based on allegations of misbranding, cGMP violations, or adulteration.

However, adherence to FDA labeling requirements, careful documentation of contamination-prevention procedures (both internally, and by partners and suppliers in the manufacturing and distribution pipeline), the collection and retention of safety-related data, and most importantly, vigorous defense against overaggressive enforcement efforts by the FDA and federal prosecutors, will help limit exposure to these potential risks.