Warning: Additional Warnings May Be Required

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MANUFACTURERS face a fractured landscape of increasingly stringent, overlapping, and conflicting rules and rulings governing how they must warn against the risks associated with their products. This is true of manufacturers of various consumer products, commercial products, food, pharmaceuticals, and other products who produce for a national or global marketplace and find themselves subject to different regulatory schemes depending on where their products are offered, sold and/or used. Rules born from case law impose additional, and varying, obligations upon them. Because it is not generally feasible to create different warning labels for different areas of the country or world, such varying laws impose a high burden on manufacturers across industries. And where laws conflict, it is not always possible to standardize warnings at the strictest standards. As a result, a bad rule or case can impact how the manufacturer addresses warnings across the globe.

This article sets forth recent developments and notable lawsuits across certain industries with regard to warning labels, focusing particularly on the sometimes conflicting requirements imposed on manufacturers by inconsistent regulations and/or court rulings.

I. Increased Warning Requirements

A. The Risks of Products Manufactured by Other Companies: Do Jelly Makers Have to Warn About Peanut Allergies?

Manufacturers may be liable for warning consumers against the risks associated not only with their own products, or even with products that are required for use of their products, but even with products that *could foreseeably* be

used with their own products. At least that is the law in Tennessee right now.

Last year, the United States Supreme Court recognized in a maritime case that "[t]hree approaches have emerged" on how to apply a 'duty to warn' principle "when the manufacturer's product requires later incorporation of a dangerous part . . . in order for the integrated product to function as intended."[1] The first, which the Court dubbed "the foreseeability rule" states that "[a] manufacturer may be liable when it was foreseeable that [it]s product would be used with another product or part, even if [it]s product did not require use or incorporation of that other product or part."[2] The second, the "bare metal defense," shields any manufacturer that "did not itself make, sell, or distribute the part or incorporate the part into the product … even if the product required incorporation of the part and the manufacturer knew that the integrated product was likely to be dangerous for its intended uses."[3] The third approach, imposes a duty to warn when a product "requires incorporation of a part . . . the manufacturer knows or has reason to know that the integrated product is likely to be dangerous for its intended uses."[4]

The United States Supreme Court adopted the third approach, holding that a manufacturer can be liable if a court finds "it should have known" that its product would be used with another product. This rule requires a manufacturer to find all the products that are likely to be used with its product and determine what risks those products might pose, but the Court noted it was "most appropriate" for the maritime context, because maritime law "has always recognized a special solicitude for the welfare" of sailors.[5] The Court rejected the foreseeability rule even in this special context, finding it "would sweep too broadly," imposing "a difficult and costly burden on manufacturers, while simultaneously overwarning users."[6]

The application of these three approaches in different jurisdictions shows the challenge that manufacturers face. The *Air & Liquid Systems* case arose in the asbestos context, but it could be applied to a variety of component products. The Court's holding could have standardized the moderately stringent third approach, or led courts to adopt the bare metal defense, recognizing the third approach as appropriate only in contexts necessarily more

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[1] Air & Liquid Sys. Corp. v. Devries, 139 S. Ct. 986, 993 (2019).
[2] *Id*.
[3] *Id*.
[4] *Id.* at 993-994.
[5] *Id*. at 994, 995 (internal citations omitted).
[6] *Id*. at 203.

protective – like maritime law. Instead, at least in one jurisdiction, a state appellate court has adopted the *most* restrictive rule, and its language seems to apply broadly across the product liability landscape.

Last year, the Tennessee Court of Appeals cited *Air & Liquid Systems outside* of the maritime context, and even in this less less-restrictive context, adopted the foreseeability approach rejected by the Supreme Court, holding that manufacturers in Tennessee are liable for the risks of any product that *could foreseeably* be used with its product.[7] This decision could have serious ramifications of manufacturers whose products enter the stream of commerce into Tennessee. Not only does the decision impose an increasingly stringent duty-to-warn standard upon manufacturers without a legislative or regulatory directive, the question remains as to how this jurisdiction-specific rule will affect manufacturers outside the state whose products are used ultimately by Tennessee residents. While the Court of Appeals of Georgia recently limited the application of *Air & Liquid Systems* to the maritime context only,[8] additional courts may interpret and apply the Supreme Court's holding or adopt the Tennessee appellate court decision and expand the breadth of products against which manufacturers must warn.

Tennessee, and any other courts that follow suit, will require manufacturers to determine what products could "foreseeably" be used with their products and then anticipate what the dangers posed by those products would be. The broad language of the court's holding seems to mean that a jelly manufacturer would be required to warn about peanut allergies, since it is reasonably foreseeable that peanut butter will be used with its product. Or, even more complicated, component part manufacturers for parts used in complicated machinery may need to learn and keep apprised of the risks of all the other component parts and products that may foreseeably be used with its component part. Ultimately, the main impact of such laws may be to increase costs to consumers as manufacturers are exposed to unknown liability risks. Another problematic impact is the increased risk of over-warnings—warnings

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[7] *See* Coffman v. Armstrong Int'l, Inc., 2019 WL 3287067, at *20 (Tenn. Ct. App. July 22, 2019); *petition for cert granted*.

[8] *See* Davis v. John Crane, Inc., No. A19A1137, 2019 WL 5558711, at *5 (Ga. Ct. App. Oct. 29, 2019) ("However, we note that the Justices, both in the majority opinion as well as in the dissent, took pains to emphasize that the holding applied only in the maritime tort context due to particular concerns for the welfare of sailors.").

that dilute impact of more important warnings).

B. Monitoring Promotion by Third Parties: He Said, She Said

Manufacturers may also be required to monitor and take action against third parties marketing their products. In 2014, a woman sued Ford for its part in placing "unreasonably and inherently dangerous seat belt extender[s] into the stream of commerce," after the Ford-manufactured seatbelt extender she purchased from a third party to secure her son's booster seat failed upon impact during an automobile accident.[9] The woman alleged that failure of the seatbelt extender left her son unprotected and unrestrained in the vehicle and caused her son to suffer severe traumatic brain injuries.

The complaint alleged that Ford knew an employee at one of its dealerships was reselling Ford-manufactured seatbelt extenders online and marketing them as suitable for buckling children's booster seats, despite the fact that they were intended solely for assisting overweight *adult* passengers with their seatbelts. The complaint further alleged that Ford knew parents were misusing the seatbelt extenders and knew of the associated dangers, but failed to warn against the substantial risks its extenders posed to children when used incorrectly.

The plaintiff noted that had her husband, who died in the same automobile accident, known of the seat-belt extender's danger, he would never has used it to buckle in his son's booster seat. It appears that Ford, whose seatbelt extenders are provided to dealerships at two cents apiece, provides these extenders to be given for free to car buyers who need them. Yet, they were included in the lawsuit against the reseller who made $15 off of each sale, and who claimed that he sold them to whoever wanted one with "no questions asked" about their intended use.

While the case against Ford remains ongoing, the theory of the case threatens to impose liability and additional obligations on product manufacturers whose products are in the "stream of commerce," but later marketed by downstream parties for purposes other than those for which the product was originally intended. Such cases will shape the landscape of oversight requirements for such products. If companies affirmatively scrutinize the practices of resellers, they may be seen as taking on an additional duty,

[9] *See* Complaint, Woodruff v. Spangler, No. 2-486-14 (Cir. Ct Knox County, Tenn., filed July 25, 2014).

which could cause the imposition of additional liability. Global manufacturers cannot employ different policies with regard to resellers of products based on the latest case law in various jurisdictions, but they could be subjected to liability based on the various outcomes of similar cases.

II. Industry Developments and Notable Lawsuits

A. Veggie Burgers: "Meat" is Murder on the Legal Budget

New products require new warnings and promotions, but sometimes a new product line, particularly one that can become politicized, attracts competing lawsuits alleging that marketing either goes too far or not far enough. The Burger King "Impossible" Whopper has faced just such a quandary. A class action suit was recently filed against Burger King for allegations that it misleadingly sold and marketed its "Impossible" Whopper burger as "meat-free" despite cooking the vegan patties on the same grills as Burger King's other meat products.[10] The complaint alleges that Burger King's catchy "0% beef and 100% Whopper" advertisements are misleading, since the outside of the Impossible burger could contain "meat by-product" as a result of being grilled alongside its non-vegan counterparts.[11] These types of lawsuits are familiar to fast food chains and have, in the past, resulted in industry-wide changes. A few examples include the infamous 1992 McDonalds hot coffee case that resulted in the "Caution: Contents Hot" warning, and McDonald's $10 million settlement in 2002 to settle a allegations that it failed to warn customers about the beef fat used to fry its french fries (and resulted in changes to how McDonalds restaurants in India prepare their fries).

While neither the FDA nor USDA currently regulate the use of terms such as "vegan" or "vegetarian" on food labels, the use of such terms to describe food may soon be regulated in the same way as certified organic foods. To carry the certified USDA organic label, meat and produce must meet certain specified standards promulgated by the USDA. For meat products to be certified as organic, the animals must be raised in living conditions accommodating to their nature, fed 100% feed and forage, and be administered no hormones or antibiotics.[12] Produce, on the other hand, must be grown on soil free of synthetic fertilizers and pesticides, with few

[10] *See* Complaint, Williams v. Burger King Corporation, 1:19-cv-24755-UU (S.D. Fla., Nov. 18, 2019).

[11] *Id.*

[12] 7 C.F.R. §§ 205.237 - 205.239.

exceptions.[13] At some point, it is conceivable that the USDA may control the conditions under which certain products can advertise the "vegan" or "vegetarian" label, taking into account the means of production and preparation of such foods.

Alternatively, the FDA could take the position that manufacturers and fast food restaurants must warn consumers about the presence of meat or meat by-products in foods represented as "vegan" or "vegetarian," in the same way that the FDA currently requires manufacturers of packaged goods to warn about the presence, or traces, of certain allergens.[14]

These changes have been pushed by groups advocating a vegetarian or vegan lifestyle, but, on the other side, groups intending to protect the meat industry have pressed for state laws restricting the marketing of vegetarian products as substitutes for specific meat products. An increasing number of states have begun to pass laws restricting the use of certain food-related terms on labels and advertisements – creating the feared regulatory minefield of conflicting rules and regulations. For example, Arkansas passed a law mid-last year banning food manufacturers and grocery stores from representing a product as "meat," "beef" or "pork" if it is not derived from animals, citing to the need to ensure truth in labeling and the potential to confuse or mislead consumers.[15] The Arkansas law even restricts the representation of any product as "rice" if it is not actually "rice or derived from rice."[16] Similar laws have been passed in Missouri, Mississippi, Montana, South Dakota, and Wyoming. Because it is often infeasible for manufacturers to create different labels (or in this case, different names for their products entirely) based on the jurisdiction, manufacturers may adhere to the most stringent and most limiting rules and apply them to their products nationwide.

Because of the conflicting requirements between and among the states and the federal government, manufacturers will need to proactively and continually evaluate how they market and brand their vegetarian alternatives to ensure they are complying with varying state laws and court rulings. These conflicts also risk over-warnings and the dilution of important warnings.

B. Connected Devices: How Connected is Too Connected?

Under a new California law, effective January 1, 2020, businesses who 1) have gross

[13] 7 C.F.R. § 205.203(e)(1).
[14] 21 U. S. C. § 343(w).
[15] *See* ARK. CODE ANN. § 2-1-305(6-9).
[16] *See* ARK. CODE ANN. § 2-1-305(11).

annual revenues exceeding $25 million, 2) which buy, receive, or sell the personal information of 50,000 or more consumers, households, or devices, or 3) derive 50% or more of their annual revenue from selling consumers' personal information, will be required, among various other requirements, to inform users of what data it collects and with whom the data may be shared.[17] Additionally, some businesses are required to provide users an opportunity to "opt out" of having to share their data with the product manufacturer in the first place.

While the law quite obviously applies to internet giants such as Facebook and Google, the manufacturers of what California has defined "connected devices" (also referred to as "Internet of Things" or IoT products) may also find themselves subject to the new requirements. California has taken a particular interest in defining these new waves of products, and broadly a connected device, to include "any device, or other physical object that is capable of connecting to the internet, directly or indirectly, and that is assigned an Internet Protocol address or Bluetooth address."[18] The law likewise includes industrial IoT devices, retail-point-of-sale device, and health-related devices with components that connect to the internet and that are allocated an IP or Bluetooth address. Accordingly, devices subject to these regulations include popular devices such as smart watches, Bluetooth speakers, Google Home, and Bluetooth headphones; but it could even include medical devices that send data to an internet-based patient portal.

Most relevant here, however, is that the California law can be read to impose a new type of "data warning" on a broad range of IoT manufacturers who meet one of the three statutory thresholds. Because many of these manufacturers have components connected to the internet (such as internet websites which buy, receive, or sell personal information) with a global reach that likely includes California, manufacturers may have to add a "data warning" to its product-related websites, based solely on the laws of one state.

C. Pharmaceuticals: Sued if You Do and Sued if You Don't

State laws requiring pharmaceutical companies to warn patients of known risks associated with its drugs often conflict with federal FDA standards and

[17] CAL. CIV. CODE § 1798.140; *see also* CAL. CIV. CODE § 1798.130; CAL. CIV. CODE § 1798.135.
[18] CAL. CIV. CODE § 1798.91.05(b).

regulations controlling the content of warning labels, leaving manufacturers with little recourse. This was the central issue in the Supreme Court's recent decision in *Merck Sharp & Dohme v. Albrecht*. *Albrecht* involved allegations that Merck failed to adequately warn consumers that Merck's drug Fosamax (intended for the treatment of osteoporosis in postmenopausal woman) carried an increased risk of "atypical femoral fractures."[19] Fosamax's original label when it was first approved by the FDA for sale in 1995 did not warn against this risk of fracture since, at the time, the associated risk was speculative at best. However, additional evidence linking Fosamax to fractures developed in the following years, and Merck applied to the FDA to add a fracture warning to its Fosamax label in 2008. Nonetheless, a warning about atypical femoral fractures was not added to the label until 2011, after FDA had conducted its own analysis pursuant to FDA rules and regulations. While state law required Merck to include a label warning of the risks associated with Fosamax, Merck maintained that it could not do so until FDA approved a change to its label.

The Court ultimately held that a judge, and not a jury, should interpret federal regulations, specifically referring to FDA regulations with respect to when and how drug labels may be amended. *Albrecht* set forth a two-part test for what satisfies as "clear evidence" that the FDA would not have approved a change to a drug's label to include the type of warning required under state law.[20] Specifically, a pharmaceutical defendant must show that: (1) FDA was kept fully informed of the justifications for adding the warning required by state law, and (2) FDA declined the company's request to change the labels to include the warning required by state law.[21]

In light of the Supreme Court's decision, the Third Circuit has sent back to the district court hundreds of suits against Merck for the same allegations that it failed to warn consumers about the risk of fracture associated Fosamax. Pharmaceutical companies, and manufacturers generally, should closely monitor these lower court decisions for their impact on state-based failure-to-warn claims that may in fact be pre-empted by federal authority.

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[19] *See* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 203 L. Ed. 2d 822 (2019) (Atypical femoral fractures was described by the Court as "a rare type of complete, low-energy fracture that affects the thigh bone.").

[20] *See id*. at 1678-1679.

[21] *Id.*

D. Medical Marijuana: Don't Take across State Lines

The term "marijuana" typically conjures one of two images: an illicit drug or a medicine. This conflict is reflected in the rising tension between states and the federal government with regard to the regulation and legality of marijuana and some of its derivatives. Currently, thirty-three states and the District of Columbia have passed varying laws and regulations relating to the legalization of marijuana, both for recreational and/or medicinal purposes.[22] These states' treatment of marijuana is a marked departure from how marijuana is treated by the federal government, under which it remains largely illegal and is considered a Schedule 1 controlled substance.[23]

Nonetheless, states where legal restrictions surrounding marijuana have been lifted have been quick to regulate the manufacture, production, and sale of marijuana, including with respect to warning labels. Effective January 3, 2020, marijuana smoke and Tetrahydrocannabinol (or THC) have been added to California's Proposition 65 list as toxic chemicals for the associated risks posed to pregnant woman and their developing fetuses.[24] As such, manufacturers in the marijuana industry seeking to reach the California market will be required to bear the specific warning label required by Proposition 65,[25] even though state law already required marijuana packaging to note that marijuana use while pregnant or breast feeding "may be harmful." Critics in the cannabis industry reportedly fear that the lack of sound research supporting the inclusion of marijuana smoke and THC on Proposition 65 opens up manufacturers and producers to frivolous retroactive claims of injury from use during pregnancy.

Developments in California further demonstrate the administrative burdens faced by manufacturers in the marijuana industry to comply with a fragmented regulatory scheme. As it stands, manufacturers must develop labels and warnings adhering to the requirements of each state in which they sell and market their products, while being careful to avoid federal jurisdiction. In practice, this may be impossible.

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[22] *See* National Conference of State Legislatures, *State Medical Marijuana Laws*, available at https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last updated October 6, 2019).

[23] 21 C.F.R. § 1308.11(d); *see also* United States Drug Enforcement Administration, *Drug Scheduling*, available at https://www.dea.gov/drug-scheduling (last accessed on February 22, 2020).

[24] California's Office of Environmental Health Hazard Assessment, *Marijuana (Cannabis) Smoke* (June 19, 2019), available at https://oehha.ca.gov/proposition-65/chemicals/marijuana-cannabis-smoke.

[25] CAL. CODE REGS. Tit. 27, §§ 25102 et al.

For instance, in Illinois, state laws governing cannabis both cite to and conflict with federal labeling laws. Illinois' "Compassionate Use of Medical Cannabis Pilot Program Act" (CUMCPPA) governs edible cannabis-containing products in part by reference to the Illinois Food, Drug and Cosmetics Act— incorporating food labeling requirements of the federal Food, Drug and Cosmetics Act— even though marijuana is illegal under federal law.[26] CUMCPPA also contains internal inconsistencies, such as describing such products as "food" but requiring that each be labeled as "Not a Food."[27]

III. Conclusion

Manufacturers face complex and conflicting laws concerning what qualifies as an adequate warning sufficient to protect them from liability for failure-to-warn. While the trend increasingly appears to favor more and more warnings, the end result is a regulatory minefield in which manufacturers will simply choose the most demanding standard in order to minimize the burden of complying with different sets of rules for different jurisdictions. This trend can be seen across many industries, from consumer products to pharmaceuticals. As manufacturers increasingly must track legal developments on warnings across the globe and make necessary changes, consumers will face an array of over-warnings and higher product prices.

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[26] *See* 410 ILL. COMP. STAT. 130/80.

[27] *Id.* at § a(3)(G) (All items "shall conform to the labeling requirements of the Illinois Food, Drug and Cosmetic Act and shall include….a warning that the item is a medical cannabis infused product and not a food must be distinctly and clearly legible on the front of the package").