

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF FLORIDA  
PENSACOLA DIVISION**

IN RE: 3M COMBAT ARMS  
EARPLUG PRODUCTS  
LIABILITY LITIGATION

Case No. 3:19md2885

This Document Relates to:  
*Estes*, 7:20cv137  
*Keefer*, 7:20cv104  
*Hacker*, 7:20cv131

Judge M. Casey Rodgers  
Magistrate Judge Gary R. Jones

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**ORDER**

This matter is before the Court on Plaintiffs’ Motion for Judgment as a Matter of Law under Federal Rule of Civil Procedure 50(a) on the applicability of the sophisticated intermediary defense under Georgia and Kentucky law, respectively.<sup>1</sup> Both sides submitted briefs on the issue and oral argument was heard on April 26, 2021. Having now fully considered the parties’ arguments and the applicable law, the Court concludes the sophisticated intermediary defense is not a legally viable defense in these cases.

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<sup>1</sup> Contrary to Defendants’ assertions during oral argument, the intermediary doctrine is an affirmative defense—and not merely an evidentiary standard—in Georgia. *See Freeman v. United Cities Propane Gas of Ga., Inc.*, 807 F. Supp. 1533 (M.D. Ga. 1992) (“The suppliers have the burden of proof on [the intermediary doctrine]. It is, after all, an affirmative defense to the assertion that [they] failed to warn [plaintiff].”). Kentucky does not appear to have taken a position on the issue. Of note, Defendants pled the sophisticated intermediary doctrine as an affirmative defense in their Amended Answer to Master Long Form Complaint. *See* ECF No. 959 at 99-100.

## **I. Legal Standard**

Judgment as a matter of law is appropriate where a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for the party on that issue. *Ledbetter v. Goodyear Tire & Rubber Co., Inc.*, 421 F.3d 1169, 1177 (11th Cir. 2005) (citing Fed. R. Civ. P. 50(a)). When considering such a motion, a court must “review the entire record, examining all the evidence, by whomever presented, in the light most favorable to the nonmoving party, and drawing all reasonable inferences in the nonmovant’s favor.” *Id.* In doing so, the court may not make credibility determinations or weigh the evidence, as those are solely functions of the jury. *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000). A motion for judgment as a matter of law should be granted “only if the facts and inferences point so overwhelmingly in favor of the [moving party] that [a] reasonable [jury] could not arrive at a contrary verdict.” *Bogle v. Orange County Bd. of County Comm’rs*, 162 F.3d 653, 656 (11th Cir. 1998).

## **II. Discussion**

Manufacturers generally owe a “non-delegable” duty to warn foreseeable users of known dangers inherent in their products. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 768 (Ky. 2004). Most jurisdictions have carved out one or more limited exceptions to the rule, which allow a manufacturer to “discharge” its duty to warn by adequately warning a sufficiently knowledgeable or sophisticated intermediary who purchases the

product and/or controls its availability to the ultimate users. *See, e.g., Webb v. Special Elec. Co., Inc.*, 370 P.3d 1022, 1027 (Cal. 2016) (discussing various intermediary defenses). Georgia and Kentucky have explicitly adopted the most commonly invoked intermediary exception—the learned intermediary doctrine—which enables manufacturers of prescription drugs and medical devices to adequately inform prescribing physicians, as opposed to patients directly, of any risks associated with their drugs and devices. *See McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003); *Larkin*, 153 S.W.3d at 761-63. Physicians serve as “learned intermediaries” between manufacturers and patients, as patients can only obtain prescription products through their physicians, and physicians, through specialized education and experience, are generally in the best position to evaluate the potential risks and benefits of a particular drug or medical device, and to advise their patients accordingly. *See McCombs*, 587 S.E.2d at 595; *Larkin*, 153 S.W.3d at 763-64.

A small number of states—at least nine, according to Defendants—have also adopted another variant of the intermediary exception, the so-called “sophisticated intermediary” doctrine, which enables a manufacturer to warn certain intermediate purchasers of its product of the known and knowable hazards in the product’s use, and to rely on those purchasers to pass on adequate warnings to end users. *See, e.g., Webb*, 370 P.3d at 1027. Where available, the sophisticated intermediary doctrine generally has been extended in circumstances where: (1) the manufacturer lacked knowledge

and/or control over how their product would be used or what the product might ultimately become; (2) the manufacturer had little ability to reasonably predict who potential end-users would be; and/or (3) the form or nature of the product—particularly raw materials and industrial products, such as chemicals, metals or sand—made it impossible or impractical for the manufacturer to provide effective warnings to end-users. *See, e.g., Webb*, 370 P.3d at 1033-38. Significantly, neither Georgia nor Kentucky has expressly adopted or applied the sophisticated intermediary doctrine. Nevertheless, Defendants insist “there is no doubt they would do so in an appropriate case” and, in their view, the instant cases are precisely that. The Court disagrees.

To begin with, it is not at all clear that either Georgia or Kentucky would adopt the sophisticated intermediary doctrine as a general proposition. As Defendants themselves observe, “the Restatement of Torts has recognized the defense for nearly sixty years.” *See* Def. Brief, ECF No. 100 at 6. However, in that time, there has not been a single reported decision in either jurisdiction doing the same. As already discussed, both states have explicitly adopted the learned intermediary doctrine with respect to prescription drugs and medical devices. *See McCombs*, 587 S.E.2d at 595; *Larkin*, 153 S.W.3d at 761. Notably, Kentucky has never applied that doctrine outside of prescription products. *See Roberts v. Stryker Corp.*, 2014 WL 12911070, \*10 (W.D. Ky. Aug. 7, 2014) (“[T]he Court can find no instance in which Kentucky courts have described [the intermediary] doctrine with regard to anyone other than physicians.”);

*id.* (“Not once does *Larkin* mention a potential application to a third party who is not a medical provider.”); *see also Larkin*, 153 S.W.3d at 761-63. And Georgia has declined to extend the learned intermediary doctrine beyond the prescription context except in very limited circumstances involving specialized industrial products supplied to members of a “particular trade or profession” charged with knowledge of the dangers associated with such products. *Compare Eyster v. Borg-Warner Corp.*, 206 S.E.2d 668, 670 (Ga. App. 1974) (doctrine applied for home air conditioner with copper terminal connected using aluminum wire by distributor charged with generally accepted trade knowledge of the dangers of copper-aluminum connections, and with installing in accordance with electrical codes that warned against improper copper-aluminum connections), and *Stiltjes v. Ridco Exterminating Co.*, 343 S.E.2d 715 (Ga. App. 1986) (doctrine applied for pesticides sold only to licensed commercial applicators and not to individuals, and all commercial applicators were charged by federal law with knowledge of the dangers of the use of pesticides), *with Dozier Crane & Mach., Inc. v. Gibson*, 644 S.E.2d 333 (Ga. App. 2007) (declining to treat crane and rigging company that purchased used crane as a learned intermediary in case against seller and refurbisher of the crane for injuries resulting from accident involving the crane), *Hill v. Konecranes, Inc.*, 2020 WL 3259178 (S.D. Ga. June 16, 2020) (declining to treat crane owner as learned intermediary in case against manufacturers and servicers contracted to inspect, repair, and maintain the crane), and *Long v. Amada Mfg. Am.*,

*Inc.*, 2004 WL 5492705 (N.D. Ga. Mar. 31, 2004) (declining to extend intermediary doctrine to equipment manufacturing cases). These authorities, which explicitly and narrowly cabin the bounds of the intermediary rule in Kentucky and Georgia, do not support a conclusion that either jurisdiction would recognize a variant of that rule, like the sophisticated intermediary doctrine, which greatly expands those bounds.<sup>2</sup> See *Combs v. Int’l Ins. Co.*, 354 F.3d 568, 578 (6th Cir. 2004) (“Federal courts hearing diversity matters should be extremely cautious about adopting ‘substantive innovation’ in state law.”); *Pincus v. Am. Traffic Solutions, Inc.*, 986 F.3d 1305, 1310 (11th Cir. 2021) (federal courts in diversity cases must determine issues of state law in “the way it appears the state’s highest court would” decide them based on relevant state law precedents).

Even assuming theoretically that Kentucky and Georgia would adopt the sophisticated intermediary doctrine, it would not be available here. Indeed, the Court has not found a single case—anywhere—in which the doctrine was applied to an ordinary consumer product marketed and sold directly to the general public, like the CAEv2.<sup>3</sup> None of the sophisticated intermediary cases identified by Defendants

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<sup>2</sup> Perhaps the Eleventh Circuit, in its discretion, will find it appropriate to certify this question to the Kentucky and Georgia Supreme Courts. However, there being no indication in these states’ jurisprudence that either would adopt the sophisticated intermediary doctrine and, in fact, undeniable indications that both would reject the doctrine, this Court will not certify the question.

<sup>3</sup> In other words, as Plaintiffs observed during oral argument, if the sophisticated intermediary doctrine were made available here, it would be the first and only case in the country where the doctrine was applied to an ordinary consumer product marketed and sold directly to the general public.

involved such a product. *See, e.g., Parker v. Schmiede Mach. & Tool Corp.*, 445 F. App'x 231 (11th Cir. 2011) (beryllium-containing products supplied to aircraft manufacturing plant); *Freeman v. United Cities Propane Gas of Ga., Inc.*, 807 F. Supp. 1533 (M.D. Ga. 1992) (chemical odorant added to propane gas); *Webb*, 370 P.3d at 176 (crocidolite asbestos used in manufacturing transite pipe); *Gray v. Badger Mining Corp.*, 676 N.W.2d 268 (Minn. 2004) (silica sand supplied to foundry for use in creating molds for shaping metal); *Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155 (Ind. App. 1997) (chemical odorant added to natural gas supply); *Gajewski v. Pavelo*, 670 A.2d 318 (Ct. 1996) (gas fired boiler installed by a licensed plumber); *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588 (Tex. 1986) (closure system for applying aluminum caps to carbonated soft drink bottles); *Jones v. Hittle Serv., Inc.*, 549 P.2d 1383 (Kan. 1976) (chemical odorant added to propane gas supply); *Schmeiser v. Trus Joist Corp.*, 540 P.2d 998 (Or. 1975) (truss joists used in roof construction); *Morris v. Shell Oil Co.*, 467 S.W.2d 39 (Mo. 1971) (industrial use petroleum solvents); *see also Gajewski v. Pavelo*, 670 A.2d 318 (Ct. 1996) (gas fired boiler installed by a licensed plumber); *Persons v. Salomon N. Am.*, 265 Cal. Rptr. 773 (Cal. App. 3d 1990) (ski bindings supplied to shop that selected and rented skis and bindings). And even in cases where an intermediary was implicated—a sophisticated intermediary purchaser of a chemical product, or a learned intermediary physician recommending a nonprescription medical product to a patient—courts have consistently refused to

extend the intermediary doctrine to products available both directly to the intermediary and over-the-counter to ordinary consumers. *See, e.g., Hall v. Ashland Oil Co.*, 625 F. Supp. 1515, 1519 (D. Conn. 1986) (benzene sold both to large industrial purchaser and ordinary consumers); *Mitchell v. VLI Corp.*, 786 F. Supp. 966, 970 (M.D. Fla. 1992) (nonprescription contraceptive sponge given to patient by her physician); *Prager v. Allergan, Inc.*, 1990 WL 70875 (N.D. Ill. 1990) (contact lens solution recommended by physician but available over-the-counter without prescription); *Torsiello v. Whitehall Lab'ys, Div. of Home Prods. Corp.*, 398 A.2d 132 (N.J. Super. Jan. 23, 1979) (over-the-counter drug containing aspirin recommended by physician). Georgia and Kentucky jurisprudence reflect a similarly unequivocal stance that the learned intermediary doctrine “obviously” does not apply “to over-the-counter products” and “normal consumer item[s].” *See Larkin*, 153 S.W.3d at 762-63; *Hawkins v. Greenberg*, 283 S.E.2d 301, 307 (Ga. App. 1981) (learned intermediary does not apply to “drugs sold over the counter”). Reading these authorities together, the basis for distinguishing ordinary consumer products is clear—“the underlying rationale for the *intermediary* defense is lost where . . . users could purchase and use the product *without* an *intermediary*.” *See* Pl. Brief, ECF No. 102 at 7; *see also Hall*, 625 F. Supp. at 1519; *Mitchell*, 786 F. Supp. at 970 (“Considering that [plaintiff] could have obtained the [product] over-the-counter, it would be illogical to treat her differently based on the mere fortuity that she obtained a sample of the [product] from her physician.”). No



authority has been cited or found that would support a different conclusion. Consistent with that conclusion, the Court finds that neither Georgia nor Kentucky would extend the sophisticated intermediary doctrine to a product like the CAEv2, which was marketed and sold both to the military and directly to the general public, and declines to extend the doctrine here.<sup>4</sup>

For these reasons, the Court concludes as a matter of law that the sophisticated intermediary doctrine does not apply in these cases. Neither Georgia nor Kentucky recognizes the doctrine, and even if they did, it would not be available in this context. Accordingly, Plaintiffs' motion for judgment as a matter of law on the sophisticated intermediary defense is **GRANTED**.

**SO ORDERED**, on this 27th day of April, 2021.

*M. Casey Rodgers*

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**M. CASEY RODGERS**  
**UNITED STATES DISTRICT JUDGE**

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<sup>4</sup> It is worth noting that even within the military, the CAEv2 was but one of numerous hearing protector options approved for use by service members, who could (and, sometimes, did) obtain the CAEv2 either directly from the military or by purchasing it in a retail store.