UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS

Giovanna Bulox, *et al.*,	§	
	§	
Plaintiffs,	§	
	§	
versus	§	Civil Action H-21-2320
	§	
CooperSurgical, Inc., *et al.*,	§	
	§	
Defendants,	§	

Opinion and Order Denying Summary Judgment

1. *Background.*

CooperSurgical distributes birth control devices called Filshie Clips. It is one of three major subsidiaries of its parent corporation, The Cooper Companies, Inc.

In 2010, Bulox had surgery to implant two Filshie Clips across her fallopian tubes. In 2019, the clips were removed after they migrated behind her intestinal wall.

Bulox's sister, Merlo, had the same implants in 2009. In 2020, she began having pain, and doctors attempted to remove the clips from her but were unsuccessful.

On July 16, 2021, Bulox sued CooperSurgical and The Cooper Companies. On October 19, 2021, Bulox added Utah Medical Products, Inc., and Femcare, Ltd., as defendants. CooperSurgical now moves for summary judgment.

2. *Non-Manufacturing Sellers*

Texas law protects a non-manufacturing seller from liability unless Bulox proves that: (a) CooperSurgical exercises substantial control over the product's warning label, and the label's inadequacy results in injury; (b) if it incorrectly

represents a fact which causes harm to the claimant; or (c) if it knew of a product defect at the time of sale and the claimant was harmed as a result.[1]

CooperSurgical says that it is a non-manufacturing seller and does not fall into these exceptions. It says that it is not liable because it did not modify, manufacture, design, or alter the product.

Bulox says that CooperSurgical meets these exceptions because it knew about the defect and made false representations about the device that caused her injuries.

3. *Analysis.*

In 2003, CooperSurgical acquired distribution rights from Avalon Medical Corporation.[2] It imported clips from Femcare Ltd., the manufacturer, and distributed them in 2009. Although CooperSurgical does not design or manufacture these clips, it is heavily involved in the advertising and marketing of them.

CooperSurgical printed an informational brochure about the Filshie Clip. In the brochure, the clip is advertised as "safe and effective," as well as "expertly designed." Along with informational brochures, CooperSurgical has "Key Opinion Leaders" promote and recommend the Filshie Clip to prospective patients. One such leader was Doctor Jeannie Pflum, who said that the clips were "safe, quick, and effective." In that material, she says that patients usually have minimal pain after surgery, but "no pain specific to the Filshie Clip itself." She says, "They're simple and they have a low complication rate!" Nowhere in the promotional material does she mention the risk, possibility, or likelihood of clip migration.

CooperSurgical also has a "Care, Maintenance, and Sterilization Manual." Section 4.3 of CooperSurgical's Care, Maintenance, and Sterilization Manual says that, "Trauma to pelvic organs, though infrequent, may occur during Filshie Clip application." Section 4.7 says, "Three instances of apparently asymptomatic

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[1] Tex. Civ. Prac. & Rem. Code § 82.003

[2] Plaintiff's Exhibit B (50).

migration of the Clip were observed as incidental findings, but the frequency of this event is not known." The manual says that clip migration or expulsion was reported at a rate of 0.13%. Dr. Filshie, however, reported a 20% risk of migration.

CooperSurgical listed complaints relating to the Filshie Clip. It contains at least 26 instances where patients reported that their clips had migrated between 2013 and 2019. During this time, CooperSurgical had actual knowledge of the reports and continued to advertise and market Filshie Clips without any substantial change in their material.

The record shows that the brochures and manual raise an issue of fact for whether CooperSurgical gave adequate warnings or made false representations. The information presented by CooperSurgical gives little, if any, serious warnings about the risk of migration, and characterizes the clips as safe and effective. These materials on their face downplay potential harms posed by the tendency of these clips to migrate. If Bulox had known of the rate of migration, she may have decided against the medical procedure. Because it is possible that Bulox's injuries were caused by inadequate warnings and potentially false representations, it survives summary judgment.

The record further shows CooperSurgical could have known that the clips were defective when it sold them. Their listing of complaints spans only eight years from 2013-2019. CooperSurgical has had distribution rights since 2003, and the imported clips have been subject to FDA approval and regulation since 1996. Although the listing logs injuries from years after the surgeries of Bulox and Merlo, it may be reasonable to infer that those injuries reported on the listing may have been late onset like Bulox and Merlo. When viewed in the light most favorable to Bulox, she has demonstrated that CooperSurgical was substantially involved in the warning labels and falls under the non-manufacturing seller exception.

4. *Learned Intermediary.*

The learned intermediary doctrine says that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers.[3] In some contexts, however, the manufacturer's or supplier's duty to warn doctors of the dangerous propensities of its product is limited to providing an adequate warning to an intermediary, who then has a duty to pass the necessary warnings to the end users.[4]

CooperSurgical says that it is not liable because of the learned intermediary doctrine. CooperSurgical says that it satisfied its duty to warn and is immune from liability.

The Texas Supreme Court usually applies this doctrine in prescription drug cases, but the logic still follows.[5] If the doctrine applies in this case, a genuine issue of fact remains whether CooperSurgical gave adequate and informed warnings to intermediary doctors about the risk of clip migration. CooperSurgical advertised that the clip migration percentage was 0.13%, but was reported at a much higher rate. By representing the lower percentage to intermediary doctors, it would not have adequately informed them of the potential risk to their patients.

5. *Conclusion.*

CooperSurgical's motion for summary judgment is denied. (47)

Signed on July 11, 2022, at Houston, Texas

Lynn N. Hughes
United States District Judge

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[3] *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986).

[4] *Centocor, Inc., v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012).

[5] *Id.* at 164.