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Teva, Cooper Cos. Argue FDA Approval Barred IUD Update

By **Chart Riggall**

Law360, Atlanta (November 20, 2025, 7:14 PM EST) -- Teva Pharmaceuticals on Thursday urged a Georgia federal judge to hand it a summary judgment win ahead of a bellwether trial in multidistrict litigation over an IUD's alleged propensity for breakage, arguing a U.S. Food and Drug Administration approval blocks claims over the product's design and warning labels.

Counsel for Teva and Cooper Companies, which are facing an avalanche of claims that the brittle material of their Paragard contraceptive is prone to breaking off inside the uterus, told U.S. District Judge Leigh Martin May that the changes sought by consumers would have conflicted with the device's parameters as approved by the FDA.

While such changes to its design are permissible with the introduction of new information about the product, the companies added, the mere fact that Paragard devices can break has been known and doesn't qualify as new information.

But Judge May, weighing Teva's preemption argument, said she was concerned by plaintiffs Alisa Robere, Pauline Rickard and Melody Braxton's arguments that Teva took five years to comply with an FDA requirement that the manufacturer update its warning labels in 2010.

"That seems troubling to me. It looks like they purposely didn't," Judge May said, adding that it appeared Teva was trying to "use the fact that it wasn't done as a shield."

Counsel for the plaintiffs warned that granting Teva summary judgment would allow medical manufacturers to ignore data they receive about potential dangers of their products.

"They can't just simply not comply with their obligations," said Keller Postman LLC's Nicole Berg.

Thursday's hearing in Georgia federal court comes amid years of litigation against Teva and Cooper Companies over the alleged dangers of the Paragard IUD, which hundreds of plaintiffs said broke inside their bodies without warning. The device — a small, T-shaped piece of plastic wrapped in copper wire — was developed by Teva but sold to Cooper Companies in 2017.

After **dismissing** the defendants' initial motion to dismiss, Judge May announced earlier this year that claims from Rickard, Robere, and Braxton would proceed to bellwether trials, in that order, court records show. Rickard, who received her Paragard device from a Florida doctor in 2012, said she required "complicated medical interventions" to remove the broken device.

In their summary judgment bids, however, Teva and Cooper Companies said all of the plaintiffs' state law claims should be preempted because they would conflict with how the FDA approves changes to medical device labels and design.

"The changes plaintiffs suggest to cure the perceived defect — modifications to Paragard's materials and shape/size — are precisely the kind of major changes that must be approved by FDA," Teva argued in a brief last month.

Cooper Companies, meanwhile, said it should be let out of the trial since it acquired the Paragard label well after the three bellwether plaintiffs received their devices.

On Thursday, defense counsel Shayna Cook of Goldman Ismail Tomaselli Brennan & Baum LLP said the record shows that doctors who prescribed Paragard devices said they weren't routinely checking the product's warning label, undermining the causation element of the plaintiffs' failure to warn claims.

Attorney Bridget Wholey of Goldman Ismail, counsel for Teva and Cooper Companies, argued that while it was "narratively appealing" to argue that Paragard breakages were a systemic defect, that wasn't the same thing as a "known but rare side effect."

"Bad things can happen to any product," she said.

But Judge May again appeared skeptical, opining, "I don't think that's the same thing," and asking Wholey if she was "saying that a known risk can't be a defect."

The plaintiffs are represented by Nicole C. Berg and Ashley Barriere of Keller Postman LLC, Erin K. Copeland of Fibich Leebron Copeland Briggs, and C. Andrew Childers of Childers Schlueter & Smith LLC.

Teva and Cooper Companies are represented by Christopher D. Morris and Pamela L. Ferrell of Butler Snow LLP, Allison Ng and Lori G. Cohen of Greenberg Traurig LLP, and Bridget M. Wholey, Shayna S. Cook, Nia C. Vogel and Rami N. Fakhouri of Goldman Ismail Tomaselli Brennan & Baum LLP.

The case is Rickard v. Teva Pharmaceuticals USA Inc. et al., case number 1:21-cv-03861, in the U.S. District Court for the Northern District of Georgia.

--Editing by Lakshna Mehta.

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