

Polsinelli Secures Appellate Victory for MSN Pharmaceuticals in Challenge to FDA Approval of Entresto Generic

(Oct. 10, 2025) In a widely followed appellate battle, a team of Polsinelli attorneys secured a victory for MSN Pharmaceuticals at the D.C. Circuit Court of Appeals, affirming approval of MSN's generic version of the multibillion-dollar Entresto to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with chronic heart failure and reduced ejection fraction. The court upheld the U.S. Food and Drug Administration's (FDA) decision, confirming MSN's ability to market its generic product.

The case centered on complex issues involving so-called "skinny labels," where certain patented uses are carved out of a generic label. The D.C. Circuit agreed that MSN's label complied with regulatory requirements and upheld FDA's determination that the changes to MSN's label did not render the product less safe or effective than Novartis' Entresto. The court also upheld FDA's determination that MSN's product had the same active ingredient as Entresto.

The appeal stems from Novartis suing the U.S. Department of Health and Human Services and FDA under the Administrative Procedure Act, attempting to undo FDA's approval of MSN's product, and it was one of the first court challenges to an FDA decision following the Supreme Court's decision in *Loper Bright* in 2024, which overturned decades of law applying deference to federal agency decisions under the *Chevron* line of cases. The Polsinelli team intervened in the lawsuit on MSN's behalf, successfully opposing Novartis's motion for a temporary restraining order within days of the suit being filed and later obtaining summary judgment from the district court maintaining MSN's FDA approval. The D.C. Circuit Court heard oral arguments in April 2025.

Hatch-Waxman & Biologics Chair Chad A. Landmon led the Polsinelli team, which also included Associates Kendall K. Gurule and Suzanne E. Bassett. The team was also assisted by Shareholder Corey M. Casey, Counsel E. Benton Keatley and Associates Dominique E. Smith and Melenie Van at earlier stages of the case.

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