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Debevoise & Plimpton

U.S. Regulatory, Political, & Case Law Developments

PTMG Autumn Conference
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David H. Bernstein
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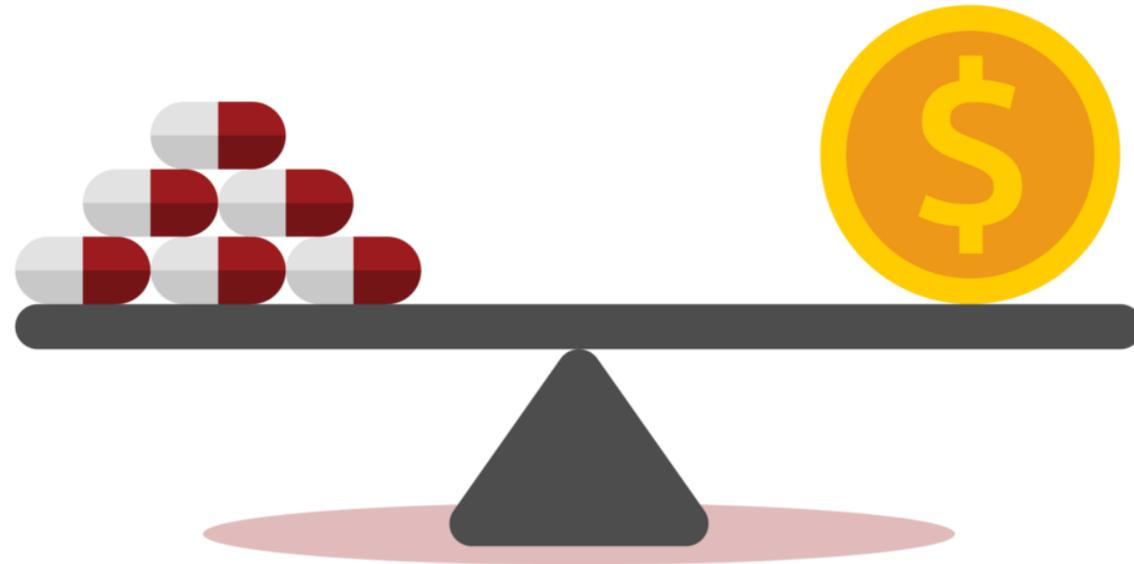
Agenda

- U.S. Regulatory and Political Developments
 - Prescription Drug Pricing
 - Tariffs & Domestic Manufacturing
 - U.S. Food and Drug Administration (FDA)
 - Centers for Disease Control and Prevention (CDC)
 - U.S. Patent and Trademark Office (USPTO)
 - Direct-to-Consumer (DTC) Advertising
- U.S. Case Law Development
 - *Novartis v. Novadoz Pharmaceuticals, MSN Pharmaceuticals, and MSN Laboratories*

U.S. Regulatory and Political Developments



Prescription Drug Pricing



Tariffs & Domestic Manufacturing



U.S. Food
Center



U.S. Patent and Trademark Office (USPTO)



Direct-to-Consumer (DTC) Advertising

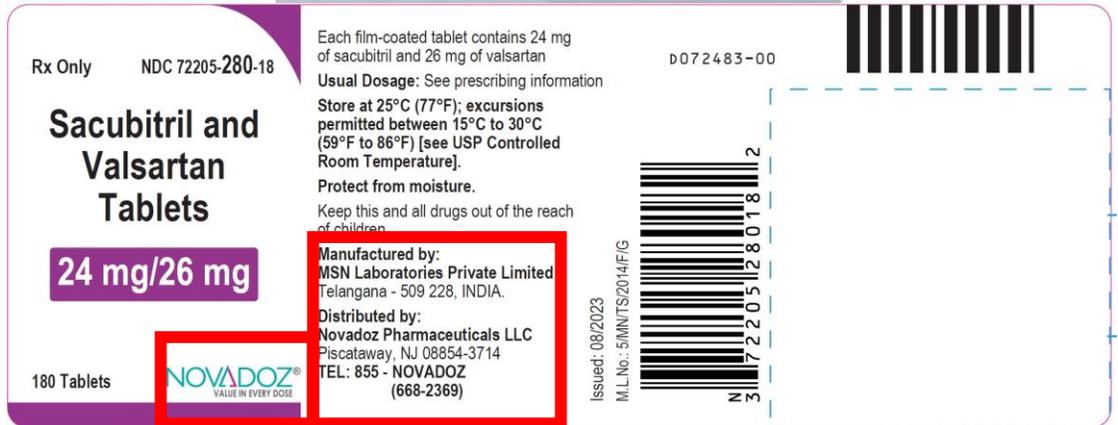


U.S. Case Law Development



Novartis v. Novadoz Pharmaceuticals, MSN Pharmaceuticals, and MSN Laboratories

Entresto® – sacubitril + valsartan



*Novartis v. Novadoz Pharmaceuticals, MSN Pharmaceuticals,
and MSN Laboratories*

		
24 mg/ 26 mg		
49 mg/ 51 mg		
97 mg/ 103 mg		

Initial Decision Granting PI: No. 25CV849 (EP) (JRA), 2025 WL 830368 (D.N.J. Mar. 17, 2025)
Interim Decision Staying PI: No. 25CV849 (EP) (JRA), 2025 WL 1482417 (D.N.J. May 22, 2025)
Final Decision on Reconsideration Denying PI: No. 25CV849 (EP) (JRA), 2025 WL 1937082 (D.N.J. July 15, 2025)

*Novartis v. Novadoz Pharmaceuticals, MSN Pharmaceuticals,
and MSN Laboratories*

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