340B Litigation Update

Lucas W. Morgan, Esq., Shareholder
Tina Hu-Rodgers, Esq., Shareholder
Buchanan, Ingersoll & Rooney, PC

OHIO PHARMACISTS ASSOCIATION

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- Lucas Morgan and Tina Hu-Rodgers have no relevant financial relationship(s) with ineligible companies to disclose.

and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

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About Our Presenters

Lucas W. Morgan, Esq.

Shareholder

lucas.morgan@bipc.com

Lucas's practice is focused on advocating for the rights of pharmacies and other healthcare providers. In this focus, Lucas handles various types of legal matters including disputes with Pharmacy Benefit Managers (PBMs) and other third-party payors including Medicare and Medicaid. Lucas also regularly navigates administrative and regulatory matters, including frequently handling state Board of Pharmacy (BOP) matters. Lucas's practice related to PBMs, and other third-party payors, includes audit disputes, reimbursement disputes, and network access issues. Lucas's in-depth understanding of the highly consolidated PBM marketplace, which is dominated by a small number of large, powerful corporations, allows him to counsel independent providers and operators on developing successful strategies for navigating this unique and challenging environment.

About Our Presenters

Tina Hu-Rodgers, Esq.

Shareholder

tina.hu@bipc.com

Tina is Co-Leader of the firm's Life Sciences Industry Team and a shareholder in the FDA/Biotechnology group, focusing her practice on issues related to the approval, regulation, promotion, sale, and reimbursement of drugs, medical devices, biologics, dietary supplements, foods, and cannabis-related products. She assists clients in interactions with federal agencies such as the FDA, CMS, DEA, and FTC, including obtaining product approvals, reviewing and revising labeling to ensure compliance with FDA laws and regulations, petitioning the FDA for safety and effectiveness, and handling various compliance and enforcement matters. Tina also advises on user fee issues, federal and state Sunshine Act reporting obligations, state price transparency disclosure rules, and licensing requirements. A thought leader on artificial intelligence and machine learning in the life sciences industry, she has spoken and published extensively on AI/ML in drug discovery, development, and FDA regulation of AI/ML-powered medical devices.

LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Discuss the current legal and regulatory landscape impacting the 340B program in 2026.
- Analyze recent court decisions and ongoing litigation trends affecting stakeholders' strategies and compliance.
- Evaluate the implications of legal disputes and enforcement actions for the future management and integrity of the 340B program.

What's Happening in the 340B Space

- Manufacturer Data Collection Policies
- Defining a 340B Patient
- State Contract Pharmacy Laws

Manufacturer Data Collection Policies

- Key cases:
  - ***Florida Health Sciences Center, Inc. v. Eli Lilly and Company et al. (M.D. Fla. Jul 02, 2026)***
  - ***Mary Hitchcock Memorial Hospital v. Eli Lilly and Company (D.N.H. Jul 27, 2026)***
- Eli Lilly's new claims data collection policy has been the center of litigation from entities that have been cut-off from 340B pricing for noncompliance.
- The cases question whether manufacturers can impose such requirements on 340B entities, with significant implications for Covered Entities.

Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital

"For hospitals who have caved to Lilly's new demands, Lilly's requirements effectively increase the cost of covered outpatient drugs above the 340B ceiling price, due to the substantial administrative costs of providing claims level data for all 340B claims, in violation of Section 340B's pricing mandate."

Mary Hitchcock Memorial Hospital

"No law, rule or regulation authorizes Lilly to unilaterally impose these reporting mandates or data-sharing requirements as a prerequisite to purchasing covered outpatient drugs."

Defining a 340B Patient

- Key case: ***AbbVie Inc. v. Kennedy et al.***
- AbbVie seeks to use its own stricter patient definition to audit 340B covered entities, challenging HRSA's guidance.
- The case questions whether HRSA's definition aligns with Congress's intent when enacting the 340B statute.
- The outcome could impact patient eligibility and the integrity of the 340B program.

AbbVie – Government Motion to Dismiss

"This case presents an attempt by a highly profitable pharmaceutical company to upend the long-settled operation of the statutory 340B Program that provides discounted medication to healthcare providers and their patients."

State Contract Pharmacy Law Challenges

- Several states have enacted laws protecting 340B contract pharmacy arrangements by requiring drug manufacturers to honor discounted pricing at those locations to preserve patient access
- Manufacturers have challenged these laws in courts nationwide
- Most courts are ruling against manufacturers, upholding state laws
- No circuit split (yet)

AbbVie, Inc. v. Murrill (5th Cir. July 6, 2026)

- Louisiana's law challenged by AbbVie, Inc., Astrazeneca, and PhRMA in separate lawsuits
- In a single opinion, the district court denied the manufacturers' motions for summary judgment and granted summary judgment in favor of Louisiana on every claim
- 5th Circuit affirmed

Section 40:2884. Prohibition of certain discriminatory actions by a manufacturer or distributor related to 340B entities

A.
A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

B.
A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

Novartis Pharms. Corp. v. Hanaway (8th Cir. July 1, 2026)

- Novartis alleged that Missouri's law violates the dormant Commerce Clause and is preempted by federal law
- The district court denied Novartis's motion for a preliminary injunction
- 8th Circuit affirmed

2.
A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services. A wholesale drug distributor, as defined in section **338.330**, shall not be considered an agent or affiliate for purposes of this subsection.

Pharm. Rsch. & Mfrs. of Am. v. McCuskey (4th Cir. March 31, 2026)

- PhRMA, Novartis, and AbbVie each moved for a preliminary injunction to block West Virginia's law
- The district court granted a preliminary injunction after holding that federal law likely preempts the West Virginia statute and that the manufacturers are entitled to equitable relief
- 4th Circuit affirmed, but the ruling is now set for further review

(b)
Distribution of drugs to safety net providers and contract pharmacies.

(1)
A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug, unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services.

(2)
A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

References

Florida Health Sciences Center, Inc. v. Eli Lilly and Company et al., Docket No. 8:26-cv-01918 (M.D. Fla. Jul 02, 2026), Court Docket

Mary Hitchcock Memorial Hospital v. Eli Lilly and Company, Docket No. 1:26-cv-00616 (D.N.H. Jul 27, 2026), Court Docket

AbbVie Inc. v. Kennedy et al., Docket No. 1:26-cv-01190 (D.D.C. Apr 08, 2026), Court Docket

AbbVie, Inc. v. Murrill, 2026 BL 252898 (5th Cir. July 6, 2026)

Novartis Pharms. Corp. v. Hanaway, No. 25-1619, 2026 BL 246858 (8th Cir. July 1, 2026)

Pharm. Rsch. & Mfrs. of Am. v. McCuskey, 171 F.4th 675 (4th Cir. 2026)

NEED MORE INFORMATION?

- Lucas W. Morgan, Esq.
  - lucas.morgan@bipc.com
- Tina Hu-Rodgers, Esq.
  - tina.hu@bipc.com

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