Connecticut Office of the Attorney General

340B Litigation Update

Report to DSS 340B Working Group

December 19, 2023

Takeaways from the OAG's 340B Actions

- 340B has received broad, bipartisan support since its creation by Congress in 1992. It is a lifeline for low-income patients and community-based providers. Preserving access to affordable medication, including through use of "contract" pharmacies, is critical.

- Program has evolved and expanded significantly since its inception. Regulations, enforcement, and audit authority at the federal Health Resources and Services Administration (HRSA) must keep pace.

- Drug manufacturers should not unilaterally impose their own conditions on covered entities because they are unhappy with the pace of reform.

- Can states step in? Drug manufacturers actively challenging state efforts to regulate in this space on preemption grounds.

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340B Actions to Date

- **October 6, 2020:** Attorney General Tong sends letters to drug makers Eli Lilly, Astra Zeneca, Merck, Sanofi, and Novartis calling on companies to honor contract pharmacy orders. Letter takes issue with the companies imposing unilateral changes to participation in the program, instituting new data sharing requirements that may violate federal health privacy laws, and abruptly refusing to ship drugs to contract pharmacies.

- **December 14, 2020**: Attorney General Tong leads bipartisan multistate coalition urging U.S. Department of Health and Human Services (HHS) to hold accountable drug manufacturers who are unlawfully and unilaterally refusing to provide discounts and/or ship to contract pharmacies.

- **December 31, 2020**: Attorney General Tong praises HHS advisory opinion concluding that drug manufacturers are required to deliver 340B discounts to contract pharmacies.

- **May 16, 2022:** Attorney General Tong leads bipartisan multistate coalition filing two amicus briefs defending actions in the D.C. Circuit and 3rd Circuit Court of Appeals against drug manufacturers refusing to comply with contract pharmacy orders.

- **July 28, 2023**: Attorney General Tong leads bipartisan multistate letter in response to Senate request for information seeking to improve integrity and sustainability of 340B program.

340B Litigation Streams

- Contract pharmacy litigation
- Federal preemption litigation
- Patient definition litigation

Contract Pharmacy Litigation

- Series of cases brought by drug manufacturers across multiple federal district courts against HRSA/HHS for issuance of violation letters
- Ultimate legal question in all cases:
  - **Does 42 U.S.C.S. § 256b require drug makers to deliver drugs to an unlimited number of contract pharmacies?**
- Three circuit court cases:
  - *Sanofi Aventis LLC v. United States HHS*, 58 F 4th 696 (3rd Circuit 2023) – held that drug makers are not required to deliver drugs to an unlimited number of contract pharmacies.
  - *Eli Lilly and Company et al. v. Becerra/U.S. Department of Health and Human Services et al.* (7th Circuit) (Awaiting Decision)
  - *United Therapeutics Corporation v. Carole Johnson, et al.*; *United Therapeutics Corporation v. Espinosa et. al.* (D.C. Circuit) (Awaiting Decision)

Federal Preemption Litigation

- *PhRMA v. McClain et al. (Arkansas)* – 8th Circuit
  - Arkansas Act 1103 provides that manufacturers (1) may not prohibit pharmacies from contracting with 340B covered entities by denying access to the drugs they make and (2) may not deny 340B pricing "for an Arkansas-based community pharmacy" that receives 340B-purchased drugs under a 340B contract pharmacy arrangement.
  - The Arkansas Insurance Department further published implementing regulations in September 2022.
  - Arkansas federal district judge ruled in December 2022 that Arkansas Act 1103 is not preempted by the 340B statute nor the Food, Drug, and Cosmetic Act (FDCA).
- PhRMA appealed to the 8th Circuit – Oral arguments held; awaiting final decision

Federal Preemption Litigation

- *PhRMA v. Landry (Louisiana)* – W.D. Louisiana
  - In July 2023, PhRMA preemptively filed suit in the U.S. District Court for the Western District of Louisiana challenging provisions in Louisiana Act 358 that seek to require manufacturers to provide 340B-priced medicines to pharmacies under contract with a 340B covered entity.
  - AstraZeneca and AbbVie filed a similar suits in the U.S. District Court for the Western District of Louisiana alleging that Louisiana Act 358 is unconstitutional and an "erroneous interpretation of federal law." The manufacturers allege that Act 358 violates both the Supremacy Clause and the Contracts Clause of the U.S. Constitution.
  - All three cases (*PhRMA, AstraZeneca,* and *AbbVie*) are currently briefing motions to dismiss and oppositions

Patient Definition Litigation

- *Genesis Health Care, Inc. v. Becerra* – U.S. District Court for District of South Carolina
- Litigation dealing with definition of "patient" for purposes of the 340B program
- Litigation arises from a HRSA audit of Genesis Healthcare, a South Carolina-based FQHC
  - HRSA alleged that Genesis dispensed 340B drugs to ineligible patients and moved to remove Genesis from 340B program
  - HRSA eventually allowed Genesis back into 340B program, Genesis moved the court to block HRSA from enforcing a stricter definition of "patient" than what is included in the 340B statute
- Court ruled that the HRSA's restrictive interpretation of the term "patient: was contrary to the plain language of the 340B Statute, and the statute instead supported a "broad reading" of the term

State Transparency Requirements

- Minnesota and Maine both recently passed transparency laws requiring 340B covered entities to report:
  - Minnesota (all covered entities)
    - Aggregated acquisition cost of 340B drugs
    - Aggregated payment received for 340B drugs
    - Aggregated payments made to contract pharmacies for dispensing
  - Maine (hospitals only)
    - Uses of 340B program savings
    - Data comparing 340B acquisition price to group purchasing organization acquisition price
- Both laws have not yet been challenged by PhRMA and/or covered entities