

# Webinar Agenda for May 18<sup>th</sup> Discussion of 340B ESP 1:30-3:00 PM Eastern

- Housekeeping-5 minutes
- Status of Contract Pharmacy Lawsuits and Speaker Introductions-10 minutes
- Opening Remarks from Speakers and Dialogue-20 minutes
- Questions Raised by Attendees in Advance -30 minutes
- More Q & A From Attendees-20 minutes
- Wrap up and how to contact speakers-5 minutes



### Housekeeping

- To use Q&A during the webinar:
  - Tap "Ask a Question"
  - Enter your question into the Q&A box
  - Tap the send button to send your question to the host
  - If the host replies via Q&A, you will see a reply in the Q&A window
  - The host can also answer your question live
- Zoom technical questions can also be entered into the Q&A box so that you will receive assistance
- Recording of this webinar will be available behind the paywall



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- Questions? Contact Lee-Anne Gabrielli at <u>lee-anne.gabrielli@340breport.com</u>



# Types of Contract Pharmacy Restrictions

### Restrictions on 340B Discounts by CE Type

- Hospitals AbbVie, Amgen, BMS for non-IMiDs, Boehringer Ingelheim, GSK, J&J, Novartis, Novo Nordisk, Pfizer, UCB,
- Hospitals and FQHCs Merck (all hospitals and FQHCs) and Sanofi (DSH and FQHCs)
- All CEs AstraZeneca, BMS for IMiDs, Gilead, Lilly, United Therapeutics

Conditioning Access to 340B Discounts on Submitting Contract Pharmacy Claims to 340B ESP™

• AbbVie, Amgen, Gilead, GSK, J&J, Lilly, Merck, Pfizer, Sanofi, United Therapeutics

### No ESP Exception

• AstraZeneca, Boehringer Ingelheim, Novo Nordisk and UCB

Source: Powers Law



### Types of Contract Pharmacy Restrictions (cont'd)

### Geographic Restrictions on Contract Pharmacies

Novartis

Conditioning Access to 340B Discounts on Submitting Claims Directly to Manufacturer

BMS for IMiDs

Most Manufacturers Allow CE to Designate One Third Party Contract Pharmacy, Use In-House Pharmacies or Wholly-Owned/Affiliated Contract Pharmacies

- Exceptions:
  - United Therapeutics does not allow any contract pharmacy
  - J&J allows wholly-owned contract pharmacy only if owned by CE, nonprofit and located in CE
  - AstraZeneca does not have exception for wholly owned pharmacies

Source: Powers Law

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# Contract Pharmacies: Manufacturer Lawsuits – District Court Actions and Appeals (2021-2022)

	Complaint Filed	District Court Decision	Appeal Filed
<b>Eli Lilly</b> S. District of Indiana	Jan. 12 – Complaint filed	March 16 – Courts issues order prohibiting enforcement of ADR against Lilly	<b>Nov. 10</b> –Lilly filed appeal in Seventh Circuit
	May 27 – Amended complaint filed	Oct. 29 – Decision on merits issued	Dec. 28 – HHS cross-appealed
<b>AstraZeneca</b> Delaware	Jan. 12 – Complaint filed  July 9 – Amended complaint filed	<b>Feb. 16</b> – Decision on merits issued	April 12 – HHS filed appeal in Third Circuit
<b>Sanofi</b> New Jersey	Jan. 12 – Complaint filed	<b>Nov. 5</b> – Decision on merits issued	<b>Nov. 19</b> – Sanofi filed appeal in Third Circuit
	May 25 – Amended complaint filed	(consolidated with Novo Nordisk)	<b>Dec. 28</b> – HHS cross-appealed
<b>Novo Nordisk</b> New Jersey	Jan. 12 – Complaint filed	Nov. 5– Decision on merits issued	Nov. 19 – NNI filed appeal in Third Circuit
	May 25 – Amended complaint filed	(consolidated with Sanofi)	Dec. 28 – HHS cross-appealed
<b>PhRMA</b> Maryland	Jan. 22 – Complaint filed	N/A	N/A
<b>Novartis</b> District of Columbia	May 31 – Complaint filed	<b>Nov. 5</b> – Decision on merits issued (consolidated with United Therapeutics)	Dec. 28 – HHS filed appeal in DC Circuit
<b>United Therapeutics</b> District of Columbia	June 23 – Complaint filed	<b>Nov. 5</b> – Decision on merits issued (consolidated with Novartis)	Dec. 28 – HHS filed appeal in DC Circuit
Boehringer Ingelheim  District of Columbia	Oct. 25 – Complaint filed  Nov. 9 – Court granted request for administrative stay	N/A	N/A

Source: Powers Law

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## Today's Panelists



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# 340B ESP Overview

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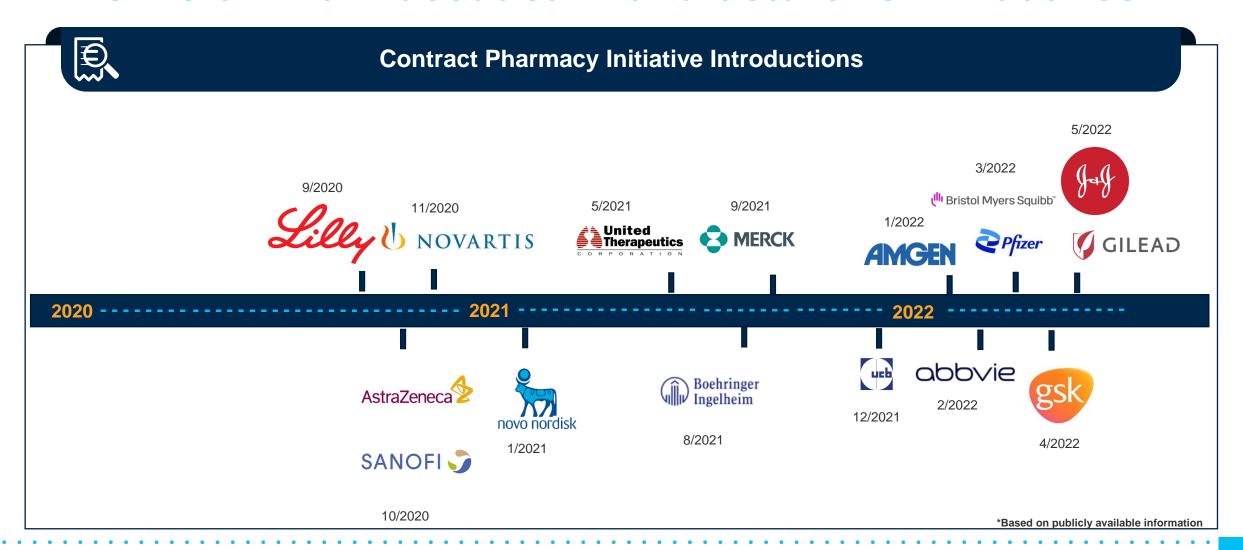


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### Timeline of Pharmaceutical Manufacturer CP Initiatives





### 340B ESP: Utilization Metrics

		COVERED ENTITIES	Over <b>1,400 340B covered entities</b> are registered on and utilizing the 340B ESP platform to qualify for 340B pricing on their contract pharmacy utilization
		CONTRACT PHARMACIES	Over <b>25,000 distinct pharmacy locations</b> have retained pricing eligibility through the use of 340B ESP
		SUBMITTING ENTITIES	500+ 340B covered entities are actively submitting 340B claims through the platform on a regular basis
		WHOLESALERS	Over <b>30 national and regional wholesalers</b> are administering 340B contracts on behalf of the pharmaceutical manufacturer suppliers and 340B customers
		NDCs	Claim submissions via 340B ESP encompass over 600 distinct NDCs
		CLAIM SUBMISSIONS	340B ESP users are submitting ~100,000 340B claims per submission cycle (i.e. bi-monthly)
	<b>/43</b>	SUPPORT INQUIRIES	Our support team handles ~250 support inquiries per week via email, chat and call center



### 340B ESP: Contract Pharmacy Purchasing Process

### **Summary**

- In general, there are 3
   phases of maintaining
   340B eligibility for products
   incorporated in 340B ESP:
   Eligibility Determination,
   Wholesaler/Contract
   Administration and 340B
   CP Purchasing
- Eligibility determination encompasses those steps necessary to establish and communicate pharmacy eligibility
- Contract Administration includes those steps taken by wholesalers to administer PHS contracts
- 340B CP Purchasing encompass those steps taken by covered entities and their third-party vendors to identify and place orders for 340B eligible prescriptions

### **Eligibility Determination**

#### **Submit Claims Data**



 Covered entity submits 340B claims for one or multiple contract pharmacies



### **Request Exemption**

- 1 contract pharmacy exemption
- Wholly owned contract pharmacy exemption



#### **Validate Pharmacy Eligibility**

- Review exemption requests
- Apply manufacturer specific aspects of contract pharmacy initiatives

### **Create and Send Eligibility File**



- Convert eligible contract pharmacies to wholesaler files
- Apply wholesaler specific criteria to file formats

### Wholesaler/Contract Administration

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#### **Create and Send 832 Files**

 Generate 832 files and send to various 340B contract pharmacy administrators and other parties

### Load Eligibility Files



 Load eligibility files into contracting system and associate with relevant 340B contracts on a manufacturer-bymanufacturer basis



### Validate Eligibility Files

 Evaluate eligibility files for valid provider identifiers and eligibility dates

### 340B CP Purchasing



### **Incorporate 832 Files**

- Ingest 832 files from relevant wholesalers
- Update pricing and pharmacy eligibility in 340B claims identification processes

### **Identify Eligible 340B Claims**



- Process prescription claims to identify 340B eligible prescriptions
- Account for pharmaceutical manufacturer requirements related to lookback periods



#### **Place Replenishment Orders**

- Based on identified 340B eligible claims, place replenishment orders with wholesalers
- Manage downstream processes as per current set up

# Wholesaler, Customer and Vendor challenges

### Where problems arise

 In general, there are two common themes for delays in 340B pricing restoration: Eligibility defects and Delays/Inaccuracies

### **Eligibility Defects**

#### **Inaccuracies**



- CP or CE mismatch when attempting to match in wholesaler platform
- · Chain pharmacies- not all listed

### **OPAIS** changes



 Shipping address or contract pharmacy designation

#### HINs



- · What and Why?
- Incorrect HINs
- New accounts or changes to accounts
- · Reports available from wholesaler

#### 340B ID Number



- 340B ID changes (DSH to RRC)
- Some suppliers will provide 340B ID as only identifiers (DEA)

### **Delays/Inaccuracies**

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#### 832 Files

TPAs frequency of receipt and ingestion of price files



### Eligibility future date

- 3-15 (longer) day from receipt of file to eligibility date as determined by manufacturer
- · Sometimes less frequent



#### Where is the file?

- · Not received, file size issue, secure mail
- · Multiple files



#### **Manufacturer**

- Delayed or incomplete quarterly price file updates from suppliers also create pricing challenges
- Chargeback denials, incorrect contract alignment

### **Resolution pathway**



#### **Covered Entity**

- False starts high %
- 340B ESP
- TPA
- Wholesaler

### **Contract Pharmacy**



 Pricing correct in ordering platforms but not in TPA platform

#### **TPA/Management company**



- Adding and removing blocks from qualification, capture, ordering
- Price restoration typically drives claim capture
- Policy implementation- when to block ordering - upcoming



### How to Contact Today's Speakers

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