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# Informa Medicaid Drug Rebate Program Conference

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INFORMA MEDICAID DRUG REBATE PROGRAM CONFERENCE 2021

# 340B: Living with the Adolescent Colossus

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# Agenda

1. Preface
2. The colossus among us
3. The program is set up for abuse
4. Case study: the contract pharmacy disputes
5. What the future may hold

# Preface

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# These thoughts are my own

The following personal observations are my own and are not the opinions of my clients, my firm, or my friends

Any errors, omissions, generalizations, mischaracterizations and/or misconstructions are mine and mine alone

# Covered entities do very important work

Most CEs deserve praise and appreciation for the very important safety net services they provide

Particularly during the pandemic

They are often under-funded and under-resourced, yet provide remarkable benefits to communities in need

# A sane system would provide for them directly

Because covered entities often serve the neediest among us, they deserve a funding system that is direct, reliable, and calibrated to compensate them for the charitable care they provide

# A sane system would provide for them directly (cont'd)

Not one that is:

- based on exploiting the spread on one commercial input of their operations (pharmaceuticals)
- funded exclusively by one private industry
- susceptible to shock when government payors want to pay fair reimbursement
- fundamentally reliant on massive markups to patients
- prone to compromise care through overutilization of high-spread drugs

# Instead, we have an adolescent colossus

Conceived by Congress in a fit of passion without thought to its long-term maturity and needs

A rapidly growing program that does not appreciate its own size

Strong feelings of entitlement

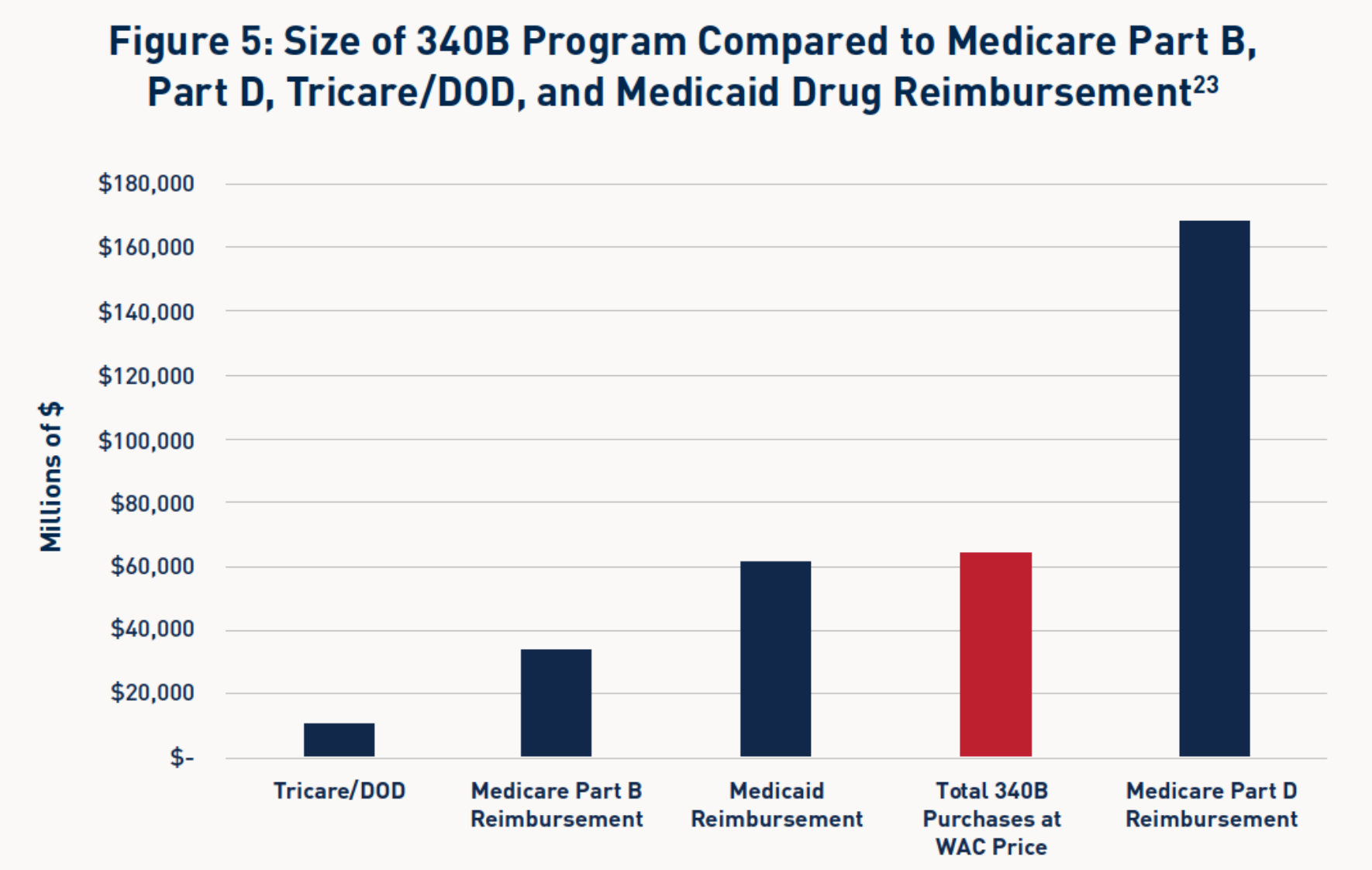
Ungoverned and abetted

Quick to bite the hand that feeds it

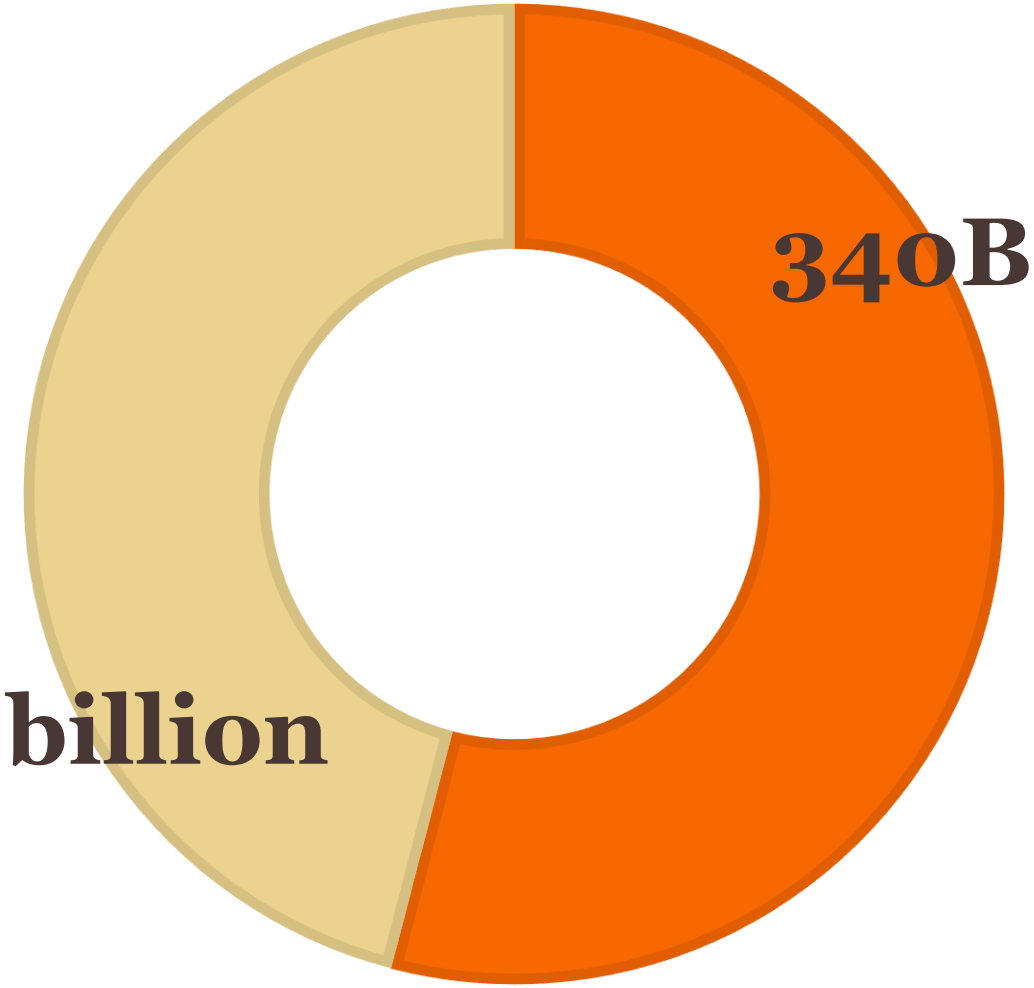
# The colossus among us

# Drug Channels Data

# BRG Data



# 2020 Drug Expenditures



# Other indicia of size and growth

$80.1 billion is **16%** of total 2020 gross U.S. sales of brand drugs at list prices

CAGR of 340B purchases 2014-2020 was **27.1%,** compared to 5% growth in annual brand drug sales

Manufacturers gave **$42.1 billion** in 340B discounts in 2020, 19% of all discounts

Source: Drug Channels June 16, 2021

# Despite this size, little standard measurement

Whether by accident or design, there is very little publicly available data on 340B

No standard approach to report total purchases through the program

340B hospitals (90% of the purchases) have **no reporting requirements** on 340B income or expenditures

Source: BRG June 2020

# The program is set up for abuse

# Mandated transfer between two private parties

Fundamental question about whether or not a loosely regulated mandatory transfer program is fair or constitutional

340B is not voluntary for the vast majority of manufacturers

# Incentives and ability to push limits

Profound incentive for covered entities to generate as much 340B utilization as possible, on the highest spread drugs possible

Abetted by the commercial contract pharmacy industry, which reaps billions annually

Other than toothless audits, little threat of enforcement against covered entities

# Incentives and ability to push limits

Manufacturers have no practical ability to restrict utilization, to overcharge, or to audit

# Unwillingness to police abuses/protect program integrity

No taxpayer dollars at stake

Political alignment with continued private subsidy of public good

Unwillingness to promulgate binding regulations that would strengthen the system

*However*: OPAIS and number of CE audits

# Examples of specific government failures to enforce

Inadequate measures to combat duplicate discounting

Outdated and ignored patient definition (see *Genesis*)

Refusal to demand transparency in use of 340B revenues

Unwillingness to see extreme growth in contract pharmacy utilization as an abuse

Absurd alignment with CE positions (see “lunar surface”)

# The government's obligation is to be impartial

In these circumstances, it is the government's responsibility to **fairly interpret and enforce the statute** (and any binding regulations)

The government should **push for clarity** and fairness when those authorities do not provide it, recognizing that the **drugs belong to the manufacturers** and that any gaps in the statute must be construed in their favor

# Case study: the contract pharmacy disputes

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# The contract pharmacy disputes

A quick summary:

- Eight manufacturers, exhausted by the government's unwillingness to protect the integrity of 340B, adopted policies limiting CPs
- HRSA reanimated the long-dead 340B ADR rule in an effort to satisfy covered entity demands
- HHS OGC issued a colorful advisory opinion condemning manufacturer self-help

# The contract pharmacy disputes (cont'd)

- Six manufacturers sued the administration arguing that they were under no enforceable obligation to facilitate contract pharmacy distribution
- In May, HRSA issued enforcement letters against the six
- In September, HRSA referred all six to OIG seeking CMPs
- Court rulings are expected imminently

# Good faith questions put to federal court

The manufacturers' positions in litigation are good-faith, reasonable questions of statutory interpretation and program administration

One court (D. Ind.) preliminarily enjoined application of the ADR process against Lilly

Another court (D. Del.) declared that the 340B statute is silent as to contract pharmacies, and vacated the advisory opinion

# Allow the litigation to proceed

If the government were acting responsibly, it would litigate vigorously but fairly, and allow the courts to perform their function: deciding matters impartially

# Allow the litigation to proceed (cont'd)

Instead, the government is:

- Using inflammatory language in briefing
- Threatening administrative enforcement on the very question before the courts
- Promoting parallel ADR proceedings despite the preliminary injunction
- Referring manufacturers for parallel consideration of CMPs at OIG
- Threatening to ignore district courts judgments with which it disagrees

# The ADR process is biased against manufacturers

Manufacturers must audit before bringing claims

The tribunal that hears ADR cases are HHS employees

Covered entities are entitled to discovery, manufacturers are not

Manufacturers cannot consolidate claims, but 340B industry associations can

# ‘Full regulatory authority’

HRSA claims the only way it can effectively oversee the 340B program is for Congress to give it full regulatory authority

Not only is this wrong as a matter of law (e.g., patient definition)

But the government’s tactics in the contract pharmacy disputes suggest that it cannot be an impartial, objective partner to all stakeholders

# What the future may hold

# Action in response to the contract pharmacy cases

Courts may force HRSA to confront the inadequacy of their non-binding guidance

OIG may or may not take district court results into account in considering CMPs

The ADR rules may have to be rewritten

Manufacturer victories may encourage Congressional reform of 340B (narrow or broad)

# Lifting of URA cap in 2024

The 100% of AMP cap on URA is scheduled to be eliminated in January 2024

Will covered entities seek “negative pricing,” like Medicaid?

Unlike Medicaid, 340B CEs are providers, not insurers, raising potential for abuse

# State action

Arkansas has passed a law that would require manufacturers to ship to contract pharmacies

Pre-empted by federal law or otherwise legally invalid?

Will other states follow in efforts to promote 340B?

# Covered entity action

Covered entities are generally barred from suing manufacturers directly to enforce the PPA

A covered entity has brought suit alleging that several manufacturers' contract pharmacy policies were adopted concurrently in violation of the antitrust laws

# Continued 340B growth?

Will 340B maintain its blistering pace of growth?

Will growth and abuses be moderated by the courts, the administration, or Congress, or will manufacturer self-help be the only impediment to this adolescent colossus?

# Any Questions

# Thank You

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