



DRUG SHORTAGES

Supply Chain Conference
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Disclaimer



The content of these presentations are for educational purposes and intended to provide clarity to the public regarding existing requirements under the law and DEA regulations. These materials should not be construed to have the force and effect of law and are not meant to bind DEA's registrant population in any way.



Mission of the Diversion Control Division

To prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources **while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.**





Drug Shortages Controlled Substances

- As of March 23, 2024, there were **1,894** product presentations actively on the drug shortage list
41% increase from last year
- **396** (21%) - controlled substances
68% increase from last year
- Quota Drugs dominate shortage list (73%)

Molecule	Schedule	Form	Presentations
Lisdexamfetamine	II	Oral	87
Amphetamine	II	Oral	73
Methylphenidate	II	Oral	39
Morphine	II	IV	29
Hydromorphone	II	IV	22
Fentanyl	II	IV	20
Remifentanyl	II	IV	9
Sufentanyl	II	IV	4
Oxycodone	II	Oral	3
Methamphetamine	II	Oral	2

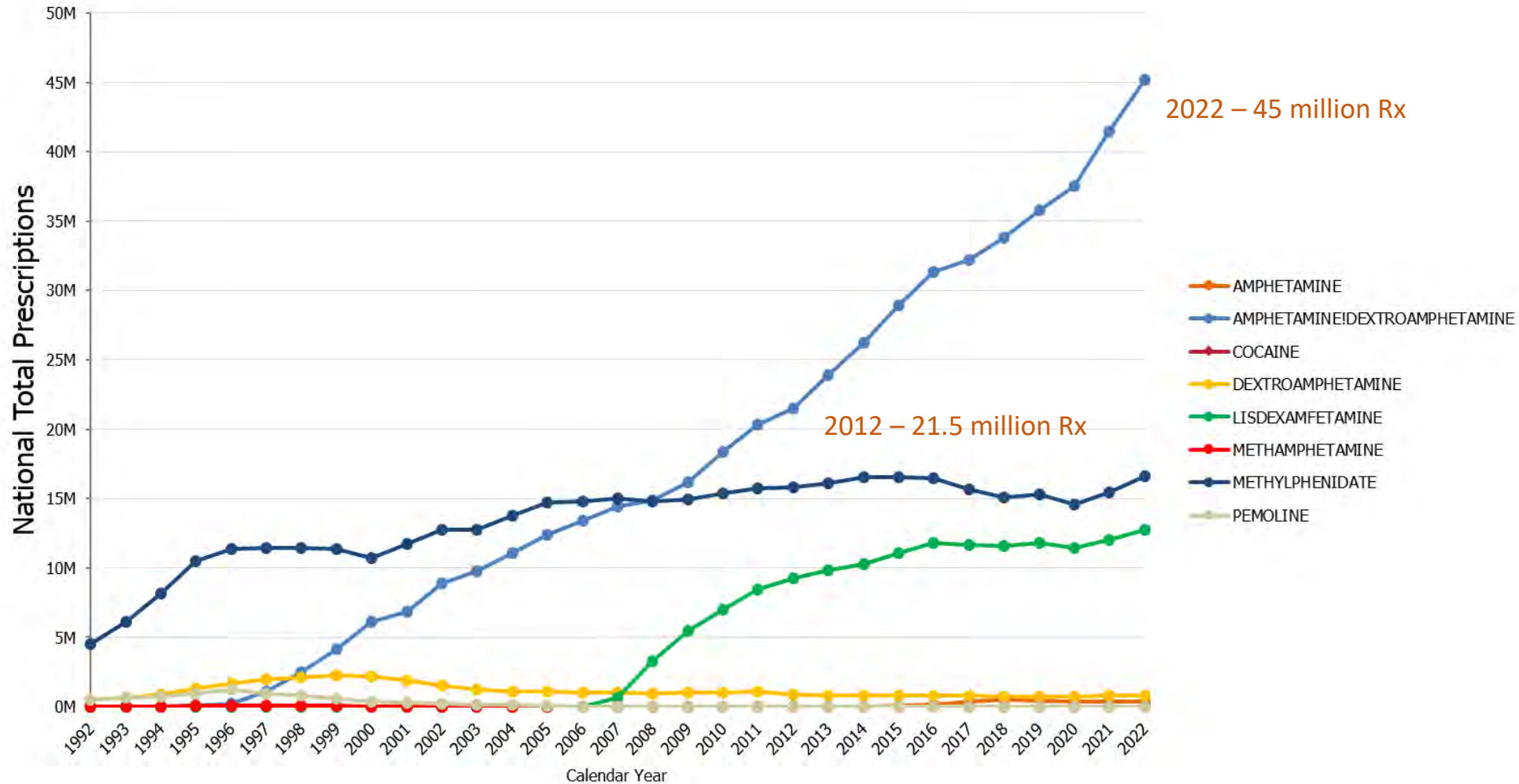


REASONS FOR DRUG SHORTAGES



- Inflation and Energy prices
- Decreasing Profit Margins – cost of doing business does not match profitability
- Logistical Challenges: equipment, material, labor
- Regulatory requirements at the federal level: FDA and DEA.
- Unanticipated Changes in Demand
- An increase in infection rates (e.g., COVID-19) contributed to strains on injectable medications used for analgesia and respiratory distress
- Unanticipated demand resulting from DTC advertising

Total Stimulant Prescriptions by Combined Molecule



ADDITIONAL CONSTRAINTS in this MOMENT



Highly genericized markets – shifts in market share from year-to-year

- Lisdexamfetamine

*“Schedule II market is radioactive”**

- Impact of Multi-District Litigation
- Manufacturers electing to discontinue marketing
- Access to Capital
- Congress (and OIG) critical of DEA

Role of Quota

BY THE NUMBERS – AMPHETAMINE (CY 2023)



2023

Aggregate
Prod. Quota
42.4 MT

3.8 MT unallocated

Manufacturing
Quota (API)
38.4 MT
allocated
(91%)

QMS

Purchasing Power



42.6 MT
or
3.6 billion d/u
1 g = 88.42 d/u

QMS

Actual Purchases



38 MT

ARCOS Code P

Actual Sales



34.1 MT
or
3.02 billion d/u

ARCOS Code S

Dispensed RX
& Exports



0.2 billion d/u
2.0 billion d/u

IQVIA

IMEX

Inventory
12/32/2023



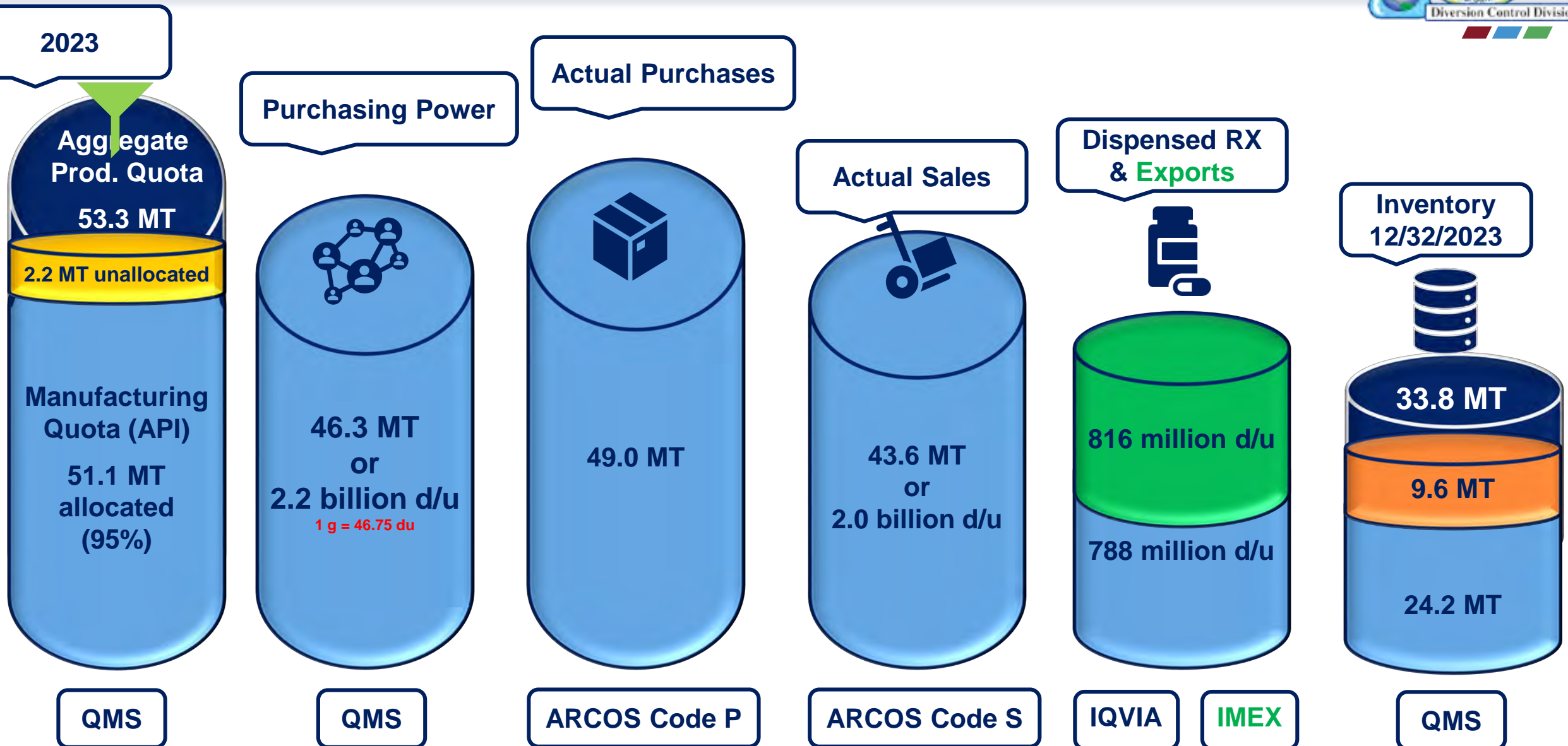
35 MT

4 MT

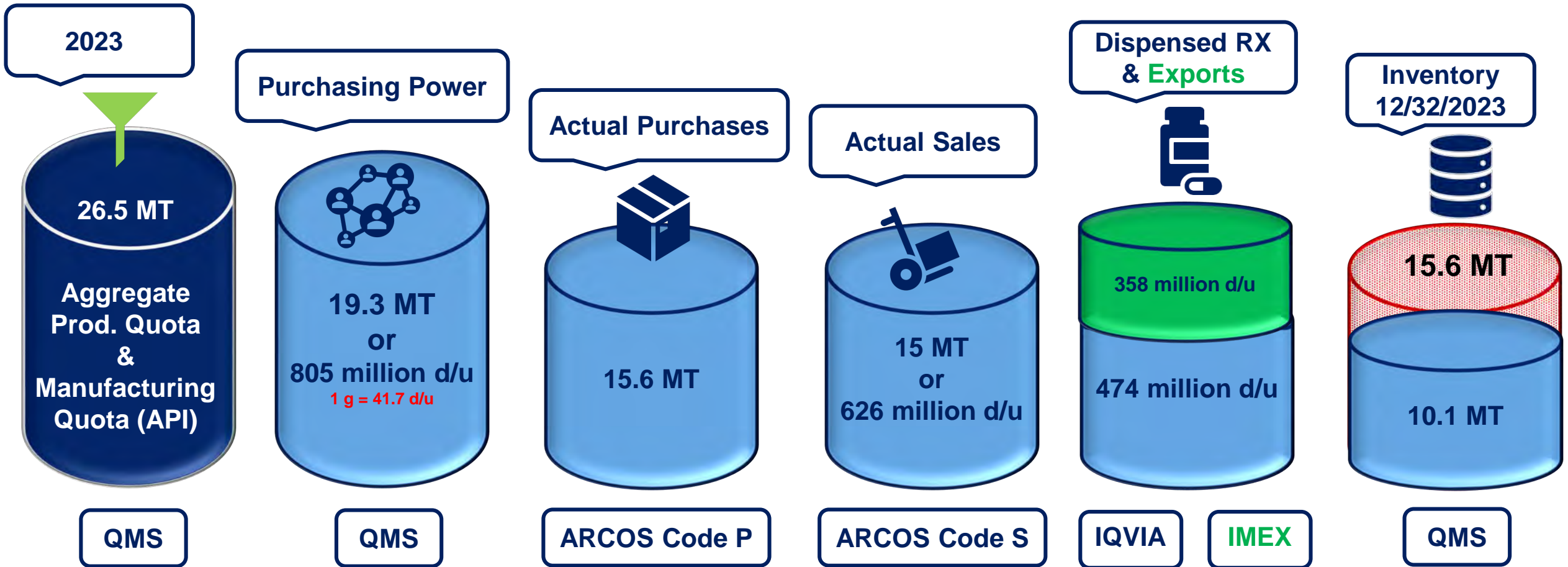
31 MT

QMS

BY THE NUMBERS – Methylphenidate (CY 2023)



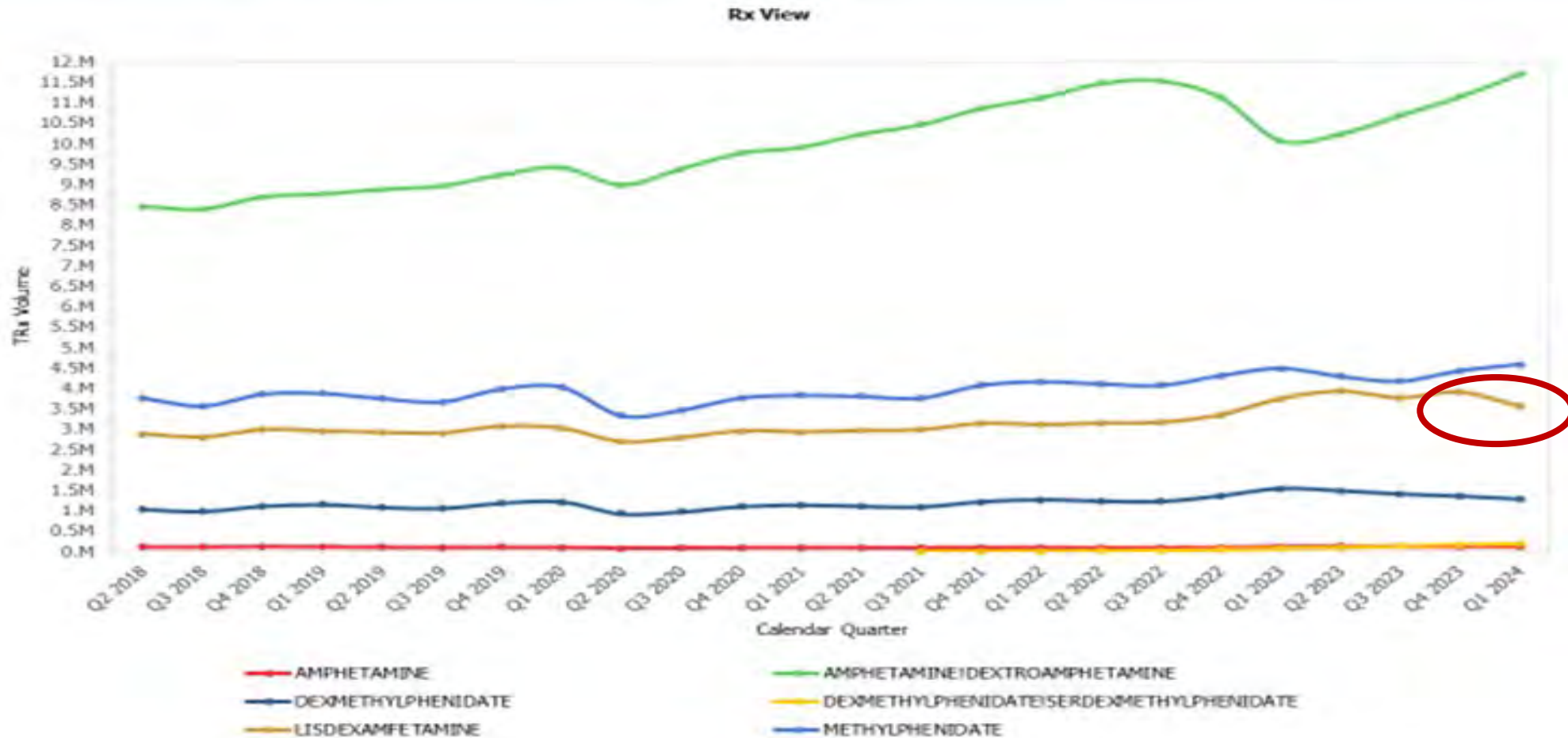
BY THE NUMBERS – Lisdexamfetamine (CY 2023)



Lisdexamfetamine



IQVIA Monthly Module Views-Rx (NPA) - Rx View



ROLE OF QUOTA



When a PQ is granted, DEA cannot compel a company to:

Make a
specific
product
presentation
or strength

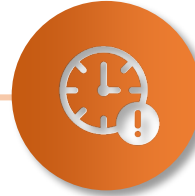
Prioritize
sales to a
specific
customer

Charge API to
manufacturing

ROLE OF QUOTA – EXISTING CHALLENGES



**Limited Visibility
Into Projected
Manufacturing Cycle**



**Delayed Visibility
Into Real-Time
Inventory,
Manufacturing and Use**



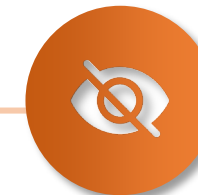
**Limited Transparency
with Registrants**



**Manufacturers May Not
Use Available Quota to
Make Medications**



**Lengthy Process
To Reallocate Quota**



**Growing Export
Demand Competing for
Limited Capacity**

PRESCRIPTION FOR SUCCESS



Changes Made and Those Planned

- ❑ Moving Toward Real-Time Reporting of Sales and Purchase Data – **ARCOS monthly reporting**
- ❑ Acquiring Data from Manufacturers relating to production cycles – **DEA-189 and DEA-250**
- ❑ Identifying New Data to Complement Manufacturers' Sales Data – **IQVIA MIDAS**
- ❑ Assuring that Quotas Support Domestic Patients – **Domestic PQ vs. Export PQ**
- ❑ Improving Transparency – **Control Tower**

Control Tower BETA



DIVERSION CONTROL

Diversion Regulatory UN Reporting & Quotas Section

Registrant Name Drug Name NDC Number
All METHYLPHENIDAT... All

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MANAGEMENT: DRUG CODE

HOME

APPLICATIONS

REGISTRANTS

DRUG CODE

APQ

REPORTED DRUG SHORTAGE

Select or drag fields to

No Data for Drug shortage flag from exported QMS Data



YTD TOTAL AMOUNT FOR SELECTED DRUG

Select or drag field

Quota Types (QMS) data and Sales/Purchases (ARCOS) data not yet available in a central table

APPLICATION OVERVIEW

Request ID	Registrant Name	QMS_DEA Num	Drug Name	Drug Code	Quota Type	Quota Request	Quota Allotment
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	47,750.00	25,377.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	56,130.00	12,520.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	146,200.00	0.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	172,930.00	57,643.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	182,800.00	0.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	182,809.00	18,025.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	215,320.00	0.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	238,470.00	35,462.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	244,043.00	0.00
			METHYLPHENIDATE (FOR SALE)	1724-B	PROCUREMENT	319,725.00	0.00

Control Tower BETA



Division Control Division

DIVERSION CONTROL

Diversion Regulatory UN Reporting & Quotas Section

Drug Schedule
All

Drug Name
All

Data for Drug Class
Not Yet Available

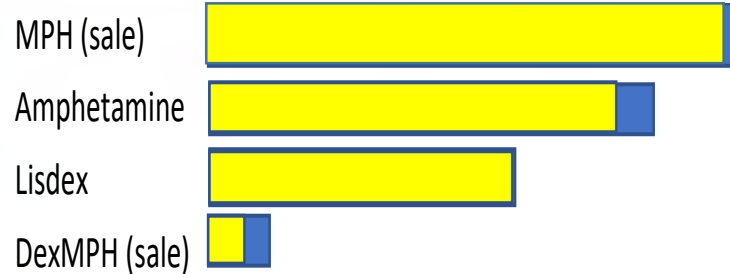
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MANAGEMENT: APQ

- HOME
- APPLICATIONS
- REGISTRANTS
- DRUG CODE
- APQ**

STIMULANTS OVERVIEW

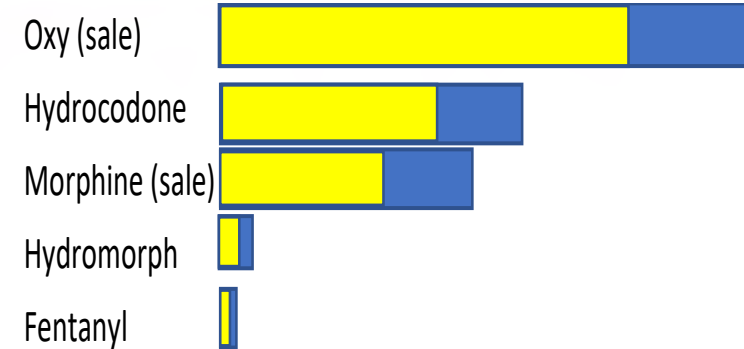
DATA NOT YET AVAILABLE FOR APQ VIEWS



	APQ (kg)	MQ (kg)
Methylphenidate (sale)	53,283	51,088
Amphetamine	42,400	38,366
Lisdexamfetamine	26,500	26,500
Dexmethylphenidate (sa	6,200	3,956

OPIOIDS OVERVIEW

DATA NOT YET AVAILABLE FOR APQ VIEWS



	APQ (kg)	MQ (kg)
oxycodone (for sale)	53,840	40,480
hydrocodone	27,239	20,192
morphine (for sale)	21,747	14,412
hydromorphone	1,994	1,132
fentanyl	731	668

Control Tower BETA



Diversion - Schedule II Control Tower BETA

Source: TBD QMS - Static Spreadsheet

Molecule: Amphetamine



Quota Awards



Date Awarded
Wednesday, November 30, 2022
Amount Awarded (G)
394170



Date Awarded
Wednesday, November 30, 2022
Amount Awarded (G)
1375663



Date Awarded
Friday, February 10, 2023
Amount Awarded (G)
518647



Date Awarded
Wednesday, February 22, 2023
Amount Awarded (G)
601135

Awarded Amount (G)	Avg Days to Receive API	Avg Days to Produce	Avg Days to Distributor	Avg Days to Pharmacy
394K	84.00	56.00	7.00	14.00

Estimated Dosages to Pharmacy

