Drug Shortages

Reporting and Communication with the Agency

APOTEX 50 YEARS
Canadian-Based
Global Health Company

Adam Steinberg, PharmD
Associate Director, US Regulatory Affairs
Apotex Corp.

Disclaimer

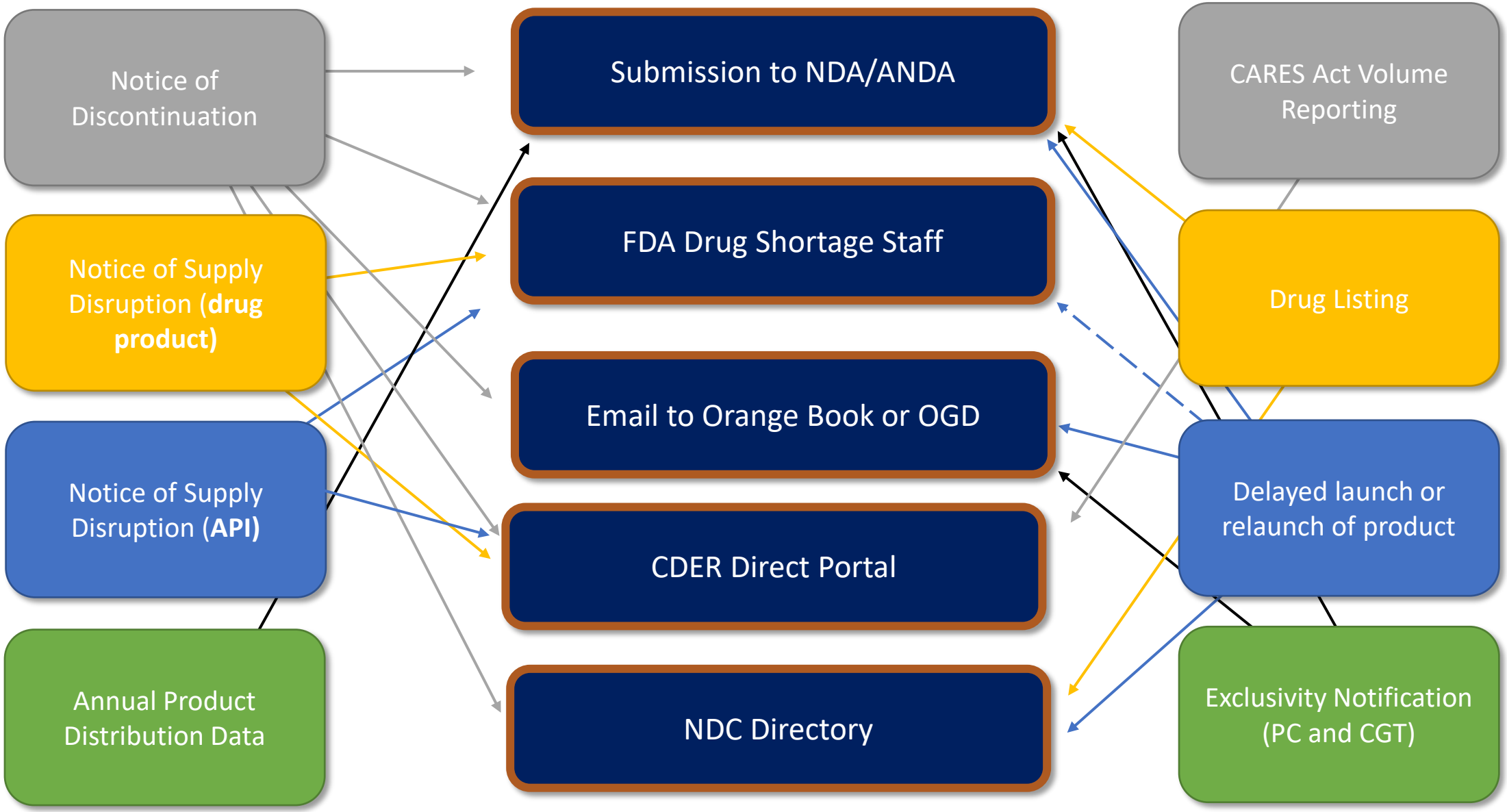
The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of Apotex. Apotex does not condone the presenter's views nor guarantee the accuracy or reliability of the information provided herein

APOTEX 50 YEARS

Canadian-Based
Global Health Company

Drug Shortage Reporting

Product Status Reporting to FDA



Drug Shortage Notifications

Background

- Because drug shortages can pose a significant public health threat that can delay, and in some cases even deny, critically needed care for patients, drug shortages remain a top priority for FDA.
- Drug companies must notify FDA about manufacturing interruptions or product discontinuances

Purpose

- Early notification of any issue is critical to preventing or lessening the impact of drug shortages
- Requirements related to early notification of interruptions and discontinuances in manufacturing and FDA's own actions are helping to reduce the threat and impact of drug shortages*

Regulations/ Guidance

- *Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry*
- Section 506C of the FD&C Act as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA, 2012), Title X–Drug Shortages
- 21 CFR 310.306, 314.81, and 600.82

*Report to Congress: Drug Shortages CY 2023 https://www.fda.gov/media/179156/download

Reporting Requirements

New Drug Shortage Notification

- **Who** – Applicants with an approved NDA, ANDA, BLA (and BLA for blood or blood components with significant market share*) for a covered drug or biological product and manufacturers of a covered drug product marketed without an approved NDA or ANDA.
- **What** – **Meaningful disruption** of prescription drugs and biological products that are **life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition**
- **When** – At least 6 months in advance of discontinuance/interruption
  - If 6 months is not possible then notification must be submitted as soon as practicable thereafter, but in no case later than 5 business days after the discontinuance or disruption occurs.

Biweekly Drug Shortage Update

- Biweekly reports sent to industry from DrugShortagesWebsiteUpdates-Industry@fda.hhs.gov
- Industry to confirm shortage information on the reports and return completed report to DSS
- The purpose of this report is to update the information on products that are currently listed on the FDA Drug Shortages Database

* Per FDA guidance, significant percentage is supplying 10% or more of the US market for blood or blood components

Industry Perspective: Drug Shortages

APOTEX 50 YEARS
Canadian-Based Global Health Company

Benefits

- Early notification provides opportunity to plan and potentially prevent
  - DSS outreach to other manufacturers
  - Regulatory discretions
  - Prioritization of reviews
- Most effective tool to ensure patient access and continuity of care

Challenges

- Notifications at least 6 months
- Ambiguity on what should be reported
  - Is the product life saving
  - Is there a meaningful disruption
- Reacting to a potential disruption

Recommendations

- List of life supporting, life sustaining, or drugs intended for use in the prevention or treatment of a debilitating disease or condition
- Continued provision of potential market shortfall and duration
- Requirement only for drugs with significant market share

APOTEX 50 YEARS

Canadian-Based
Global Health Company

Communication with DSS

Communication: Working with DSS proactively

Drug shortage reporting requirements only applicable when a disruption has occurred or will occur

What can industry do to mitigate the risk of the disruption occurring in the first place?

Case Study 1

Scenario

- Filing a supplement for additional API source for a drug product with significant market share
- New API source was required due to abrupt discontinuation of API source
- No active drug shortage for this product

Action

- Informed DSS of the upcoming supplement submission and request consideration to prioritize reviews
- Supplement filed with priority request to mitigate a potential shortage

Outcome

- DSS requested expedited review of the supplement
- The PAS was granted priority review with a 4-month goal date
- Supplement was approved 3 months ahead of the goal date
- Potential supply disruption averted

Case Study 2

Scenario

- CBE supplement for new intermediate DS site elevated to PAS
  - New site required cGMP inspection
- Potential supply disruption based on availability of pre-change API
- Apotex has significant market
- No active drug shortage for this product

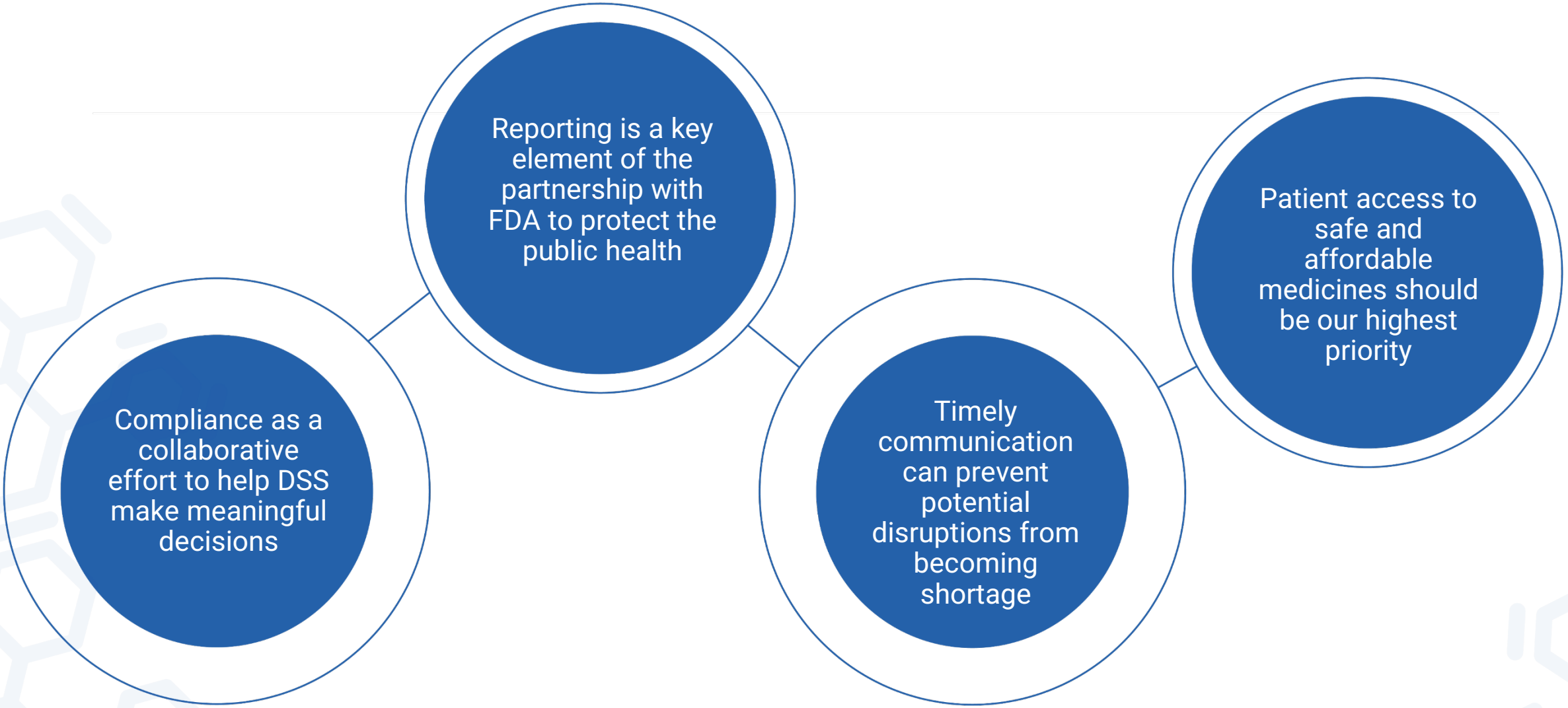
Action

- Informed DSS that CBE elevated to PAS and potential supply impact of a delay in approval
- Coordination with the OPQ review teams on the urgency of the supplement

Outcome

- FDA prioritized site inspection
- Successful outcome leading to PAS approval within 3 months
- Continuity of supply maintained

Conclusion and Key Takeaway



APOTEX 50 YEARS

Canadian-Based
Global Health Company