

When the Supply Runs Dry: Mapping the Belladonna-Opium Suppository Shortage to Policy Solutions in Urologic Care

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Background

- Belladonna and opium (B&O) suppositories are a longstanding, effective therapy for postoperative bladder spasm and ureteral stent discomfort.
- From 2018–2024, urologists faced prolonged unavailability due to recurrent manufacturing and regulatory disruptions.
- Despite their essential role in urologic practice, little attention has been given to understanding the associated structural factors and the policy levers that can be used to mitigate the shortage.

Objective

To characterize the chronology and root causes of the B&O shortage using publicly available data and to identify policy mechanisms to prevent recurrence of essential urologic drug shortages.

Causes and Systemic Vulnerabilities

Root Causes Identified:

- Raw ingredient scarcity
- Manufacturer consolidation (Perrigo → Padagis)
- Regulatory lag
- DEA quotas
- Low commercial incentive

Five Points of Fragility in the B&O Supply Chain

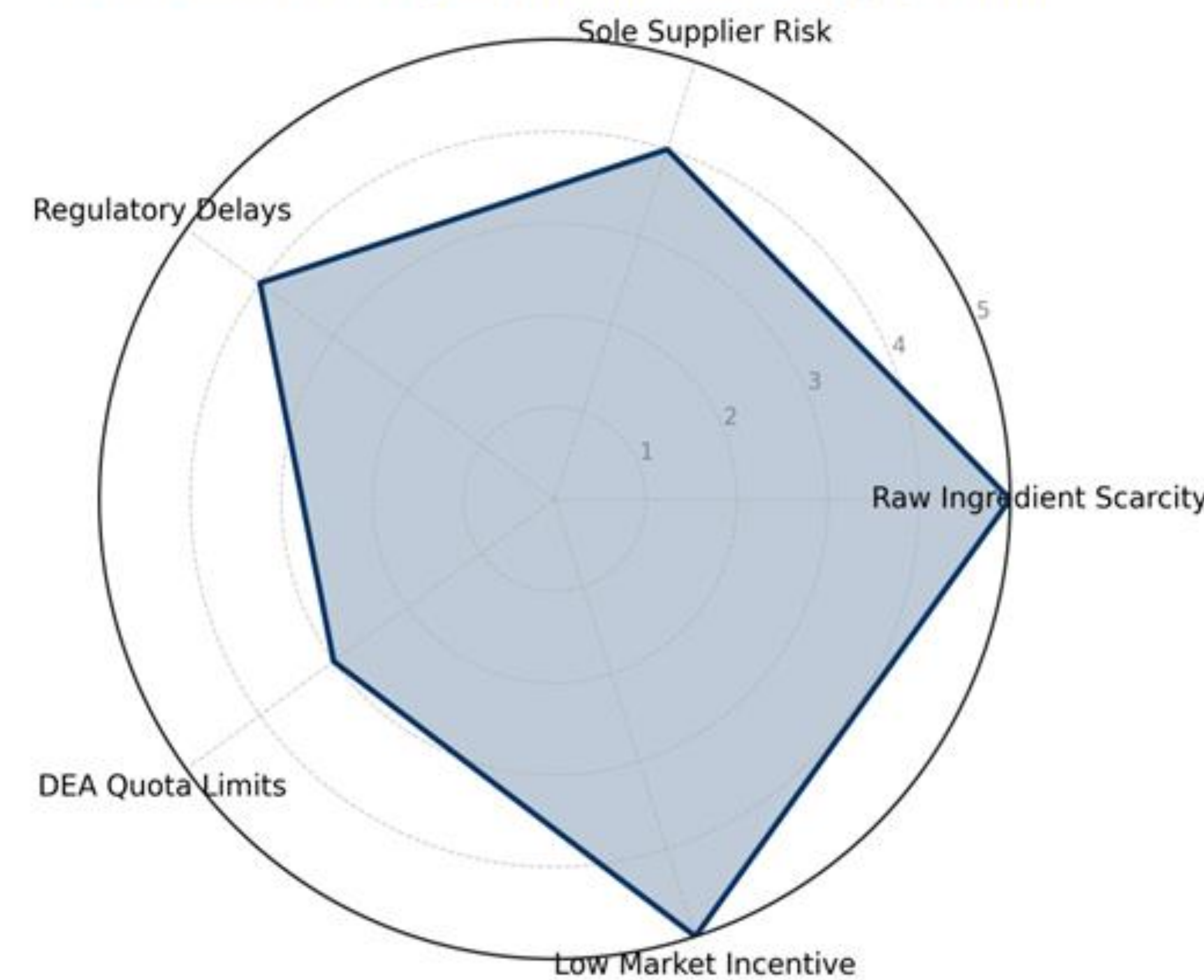
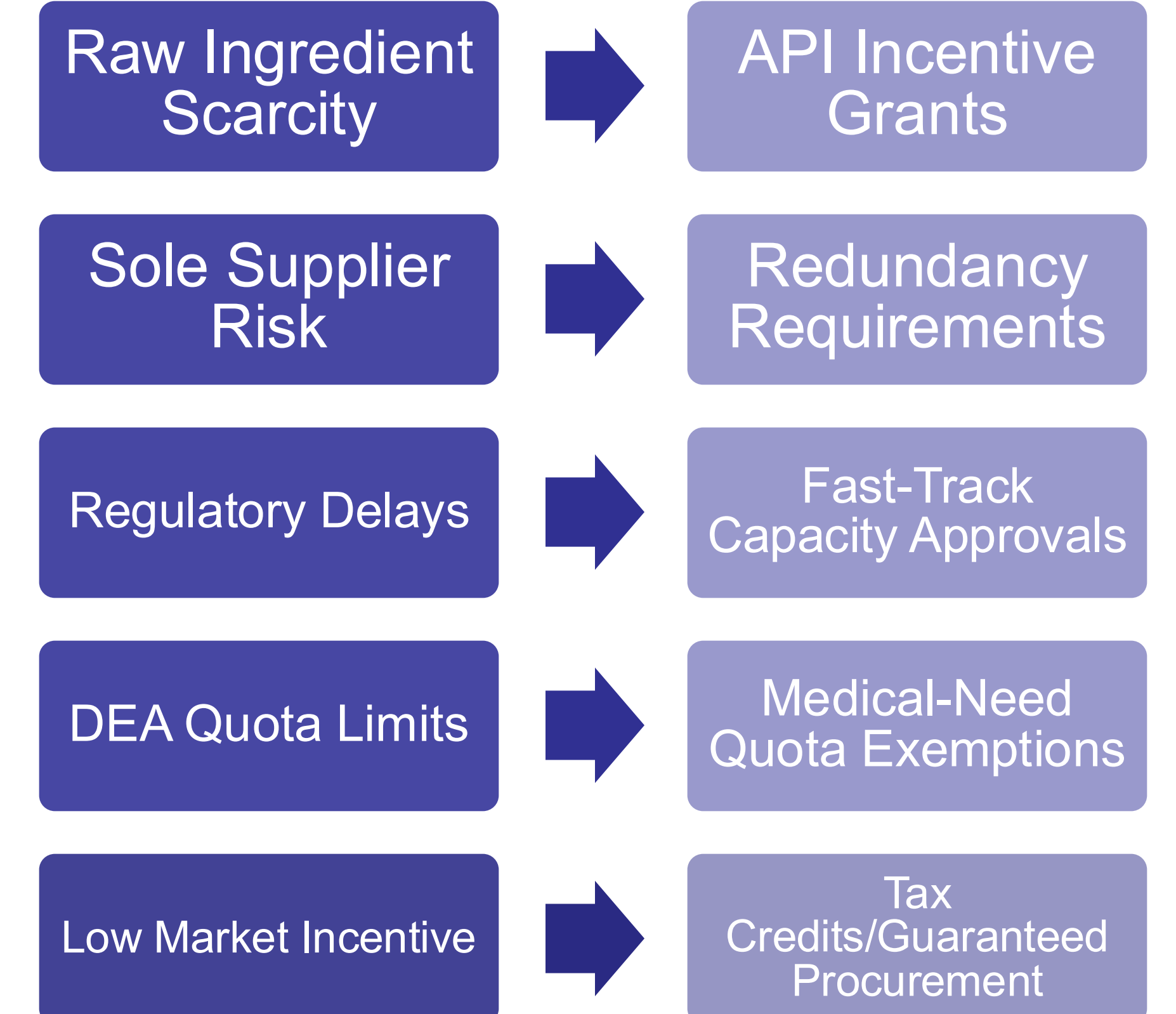


Figure 2. Five Points of Fragility in the Belladonna–Opium Supply Chain. Radial chart illustrating the main drivers of recurrent shortages—raw ingredient scarcity, sole-supplier dependency, regulatory delays, DEA quota limits, and low market incentive—with severity scaled from 1 (low) to 5 (high).

Recurrent shortages of B&O suppositories illustrate how fragile the supply of low-volume essential urologic drugs can be. **Strengthening reporting requirements, incentivizing small-batch manufacturing, and expanding quota flexibility represent actionable steps** toward securing patient comfort and procedural safety in urology.

Policy Implications

Root Cause → Policy Lever



Policy Recommendations:

- DEA flexibility for essential drugs
- FDA redundancy mandates (≥ 2 suppliers)
- Tax incentives for small-batch manufacturing
- Enhanced shortage transparency (FDASIA update)
- Creation of a Urology-Essential Medications List

Belladonna-Opium Suppository Availability Timeline (2018–2024)



Figure 1. Belladonna–Opium Suppository Availability Timeline (2018–2024). Each colored segment represents the supply status reported in FDA and ASHP drug-shortage bulletins. **Blue** indicates confirmed shortage periods, **gold** denotes manufacturer transition and regulatory instability, and **green** marks recovery and restored supply.

References

FDA Drug Shortages Database (2018–2024)
ASHP Drug Shortage Bulletins (2018–2024)
DEA Production Quota Reports

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