

HCMA “Patient Meeting” - 2025

Generic Drug Quality – The Problem and Solutions



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Saturday, October 18, 2025

Agenda

- **Pharma supply chain crisis**
- **DoD engagement**
- **Initial results from DoD Project**
- **Solutions overview**



Growing Concern with Drug Quality

**Bloomberg
Businessweek**



2019

[Link >](#)

MILKEN INSTITUTE
review



2022

[Link >](#)

THE WALL STREET JOURNAL.

Drug Shortages Stem From Quality Problems in Indian Factories

Eye drops, chemotherapy drugs raise concerns about generic products

2023

[Link >](#)



FULL COMMITTEE HEARING

Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans

[Link >](#)

FULL COMMITTEE HEARING

Bad Medicine: Closing Loopholes that Kill American Patients

[Link >](#)

THE HILL

Reliance on dangerous foreign generic drugs is killing Americans

2025

[Link >](#)

Our Drug Supply is in Crisis



>300 **drug shortages**,
~76% due to quality
problems



~3 **drug recalls**
per day, ~100/yr
with risk of death



~80% of US drugs
originate from
India or China



Hurts public health
Costs billions of dollars



Geopolitical risk and
national security threat

Estimated Annual Health & Financial Impact in US

| Disease | Patients using medications in the US | Data of concern | Potential impact of low-quality generic drugs: <u>Cost</u> | Potential impact of low-quality generic drugs: <u>Adverse events</u> |
|------------------------------|--------------------------------------|---|--|--|
| Epilepsy | 2,700,000 | Generics use associated with higher adverse events and costs compared to brand | \$845 Million (3.02% of total economic burden) | 20,780 hospitalizations |
| Atherosclerosis (statins) | 8,938,600 | Generics use associated with higher adverse events and costs compared to brand | \$364 Million (0.18%) | 200,403 outpatient visits |
| Multiple Sclerosis | 690,000 | Patient switched to generic concurrently suffered relapse – testing showing substantially poor quality generic used | \$599 Million (0.70%) | 24,972 relapses |
| Hypertension | 57,536,325 | Variability in blood pressure increases adverse events; reports of generics causing variation | \$344 Million (0.16%) | 1,736 strokes 2,111 heart attacks |
| TOTAL CHRONIC DISEASE | | | \$18.4 Billion (0.40% - weighted average) | |

Publication pending review

Regulation of Quality is Based on Self-Reported Data

The FDA does **NOT** routinely test drug products

FDA APPROVAL RIGOR

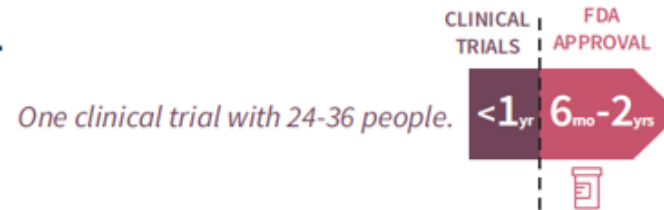


QUALITY & SAFETY MONITORING

NEW DRUG APPROVAL



GENERIC DRUG APPROVAL



MANUFACTURER

~80% in India and China



HONOR SYSTEM
Self-reported data

TESTING DATA

FACILITY INSPECTIONS

CONCERNING BACKLOG
In 2022, 61% of high-risk facilities were not inspected in 5 years

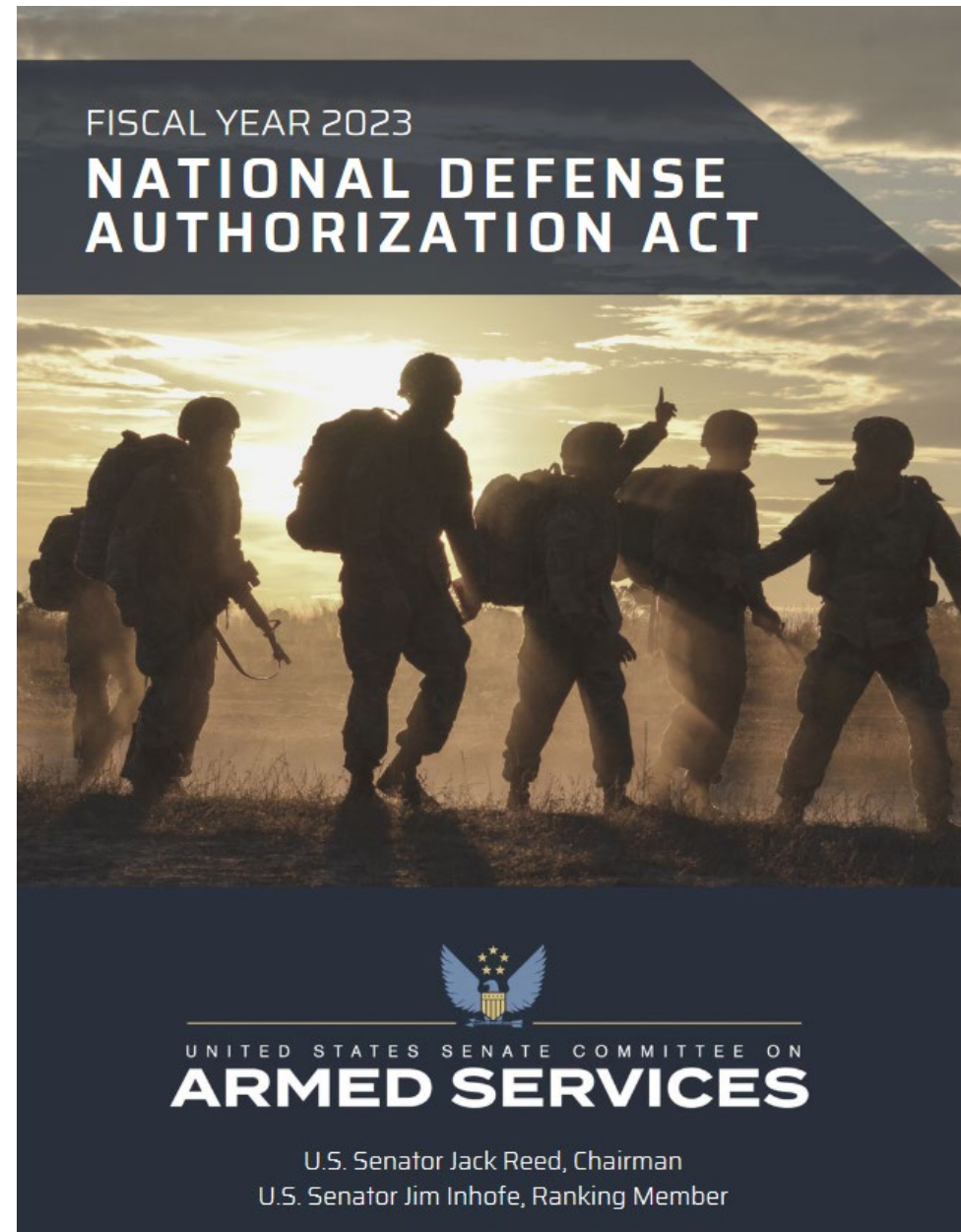
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Independent quality data is complementary to regulatory efforts

Congress Mandates Pharmaceutical Supply Chain Risk Assessment in the NDAA

- FY23 NDAA Section 860, paragraph (b):
Director, DHA shall-
 - **“Establish a working group” to “assess risks to the Department’s pharmaceutical supply chain”**
- Working group divided into two investigations:
 - **Logistical Risk:** >50% of DoD drugs from China
 - **Quality Risk**
 - **Focus on independent testing and quality scoring of DoD essential medicines**



DoD Quality Scoring Based on Consortium Paper Using Independent Testing



Journal of the
American Pharmacists
Association

“Evidence-Based Quality Scores for Rating Drug Products and Their Utility in Health Systems”

[Link](#) ➤

| SCORE | DESCRIPTION |
|--------|--|
| RED | High risk of containing chemical quality issues |
| YELLOW | Medium risk |
| GREEN | Low risk |

Author affiliations include:

6 Universities – Including Yale, Stanford, Columbia
3 Health Systems – Including Cleveland Clinic, NYU Langone
Defense Department

**“DoD Expert Review Panel”
comprised of co-authors which
create Red / Yellow / Green scores**

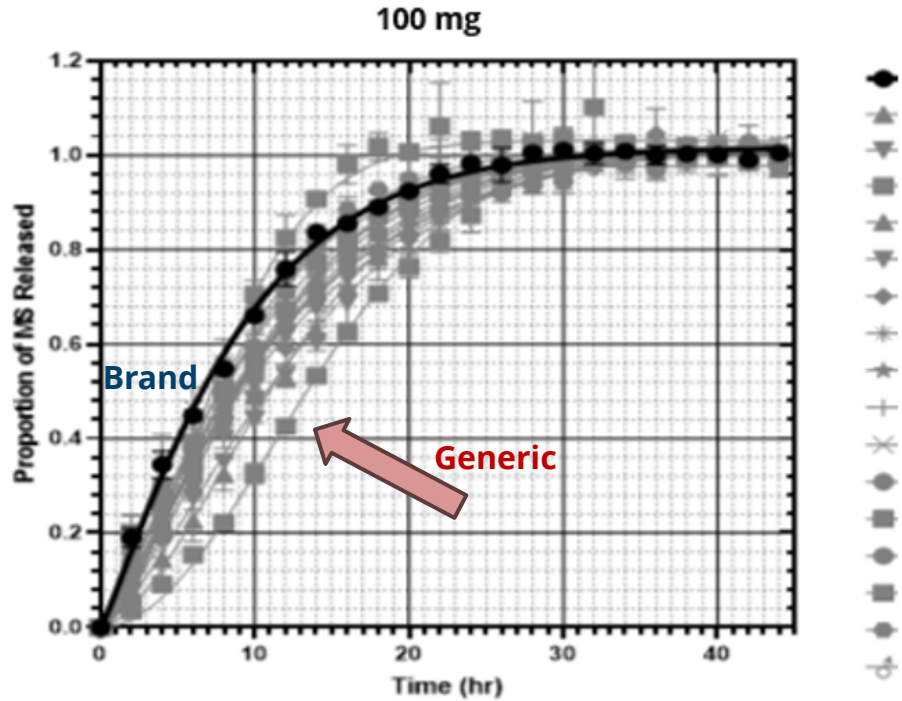
First 10 Drugs: Summary Results

Many “Reds” exist but most of market contains “Greens”

| | Market Sweep | | | | | | | | | | | |
|---------------------------|-------------------|----------------|------------------------|------------------|------------|------------------|-------------|--------------------------------|--------------|----------------|-------|-------|
| | Metformin | Lisinopril | Potassium | Metoprolol | Mg Sulfate | Tacrolimus | Ampicillin | Atorvastatin | Ca Gluconate | Vancomycin | Total | % |
| Green | 20 | 8 | 15 | 11 | 7 | 4 | 13 | 11 | 4 | 20 | 113 | 70.6% |
| Yellow | 7 | 0 | 5 | 5 | 0 | 4 | 1 | 2 | 0 | 0 | 24 | 15.0% |
| Red | 3 | 2 | 2 | 2 | 0 | 4 | 1 | 6 | 2 | 1 | 23 | 14.4% |
| Total: | 30 | 10 | 22 | 18 | 7 | 12 | 15 | 19 | 6 | 21 | 160 | |
| Primary Reason for “Reds” | Carcinogen: “DMF” | Toxin: Arsenic | Toxins: Lead, Thallium | Slow Dissolution | N/A | Fast Dissolution | Toxin: Lead | Toxins: Lead, Arsenic, Lithium | Toxin: Lead | Toxin: Arsenic | | |

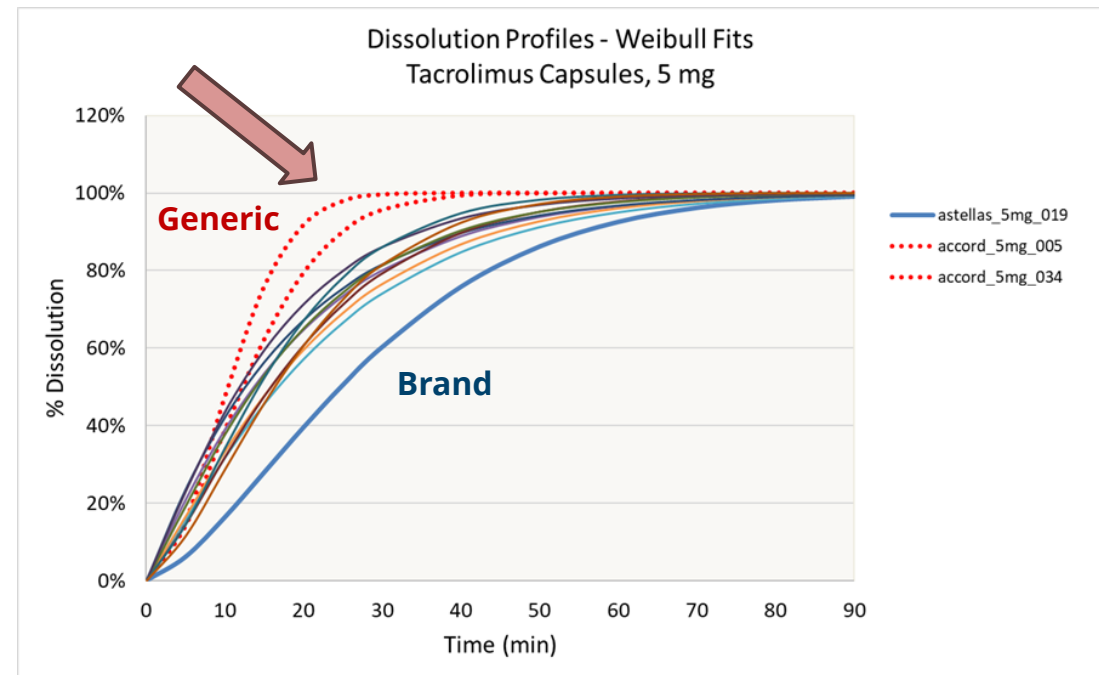
Results Highlight: Metoprolol Succinate

| Company | Score | Dosage | Dissolution | Carcinogens: Nitrosamines | Carcinogens: DMF | Toxic Elements |
|-----------|-------|--------|-------------|------------------------------|---------------------|-------------------|
| Labeler A | 90 | -- | -10 | -- | -- | -- |
| Labeler B | 9 | -- | -61 | -- | -- | -30 |
| Labeler C | 80 | -- | -10 | -- | -- | -10 |
| Labeler D | 70 | -- | -30 | -- | -- | -- |
| Labeler E | 100 | -- | -- | -- | -- | -- |
| Labeler F | 90 | -- | -10 | -- | -- | -- |
| Labeler G | 70 | -- | -30 | -- | -- | -- |
| Labeler H | 40 | -- | -30 | -- | -- | -30 |
| Labeler I | 100 | -- | -- | -- | -- | -- |
| Labeler J | 100 | -- | -- | -- | -- | -- |
| Labeler K | 70 | -- | -30 | -- | -- | -- |
| Labeler L | 100 | -- | -- | -- | -- | -- |
| Labeler M | 90 | -- | -10 | -- | -- | -- |
| Labeler N | 100 | -- | -- | -- | -- | -- |
| Labeler O | 60 | -- | -30 | -- | -- | -10 |
| Labeler P | -22 | -- | -61 | -- | -- | -61 |
| Labeler Q | 100 | -- | -- | -- | -- | -- |
| Labeler R | 90 | -- | -10 | -- | -- | -- |



Results Highlight: Tacrolimus

| Company | Score | Dissolution | Carcinogens: Nitrosamines | Carcinogens: DMF | Toxic Elements |
|-----------|-------|-------------|------------------------------|---------------------|----------------|
| Labeler A | 39 | -61 | -- | -- | -- |
| Labeler B | 39 | -61 | -- | -- | -- |
| Labeler C | 90 | -10 | -- | -- | -- |
| Labeler D | 100 | -- | -- | -- | -- |
| Labeler E | 70 | -30 | -- | -- | -- |
| Labeler F | 70 | -30 | -- | -- | -- |
| Labeler G | 100 | -- | -- | -- | -- |
| Labeler H | 70 | -30 | -- | -- | -- |
| Labeler I | 70 | -30 | -- | -- | -- |
| Labeler J | 100 | -- | -- | -- | -- |
| Labeler K | 39 | -61 | -- | -- | -- |
| Labeler L | 39 | -61 | -- | -- | -- |



ProPublica Investigates Patient's Tacrolimus

Health Care

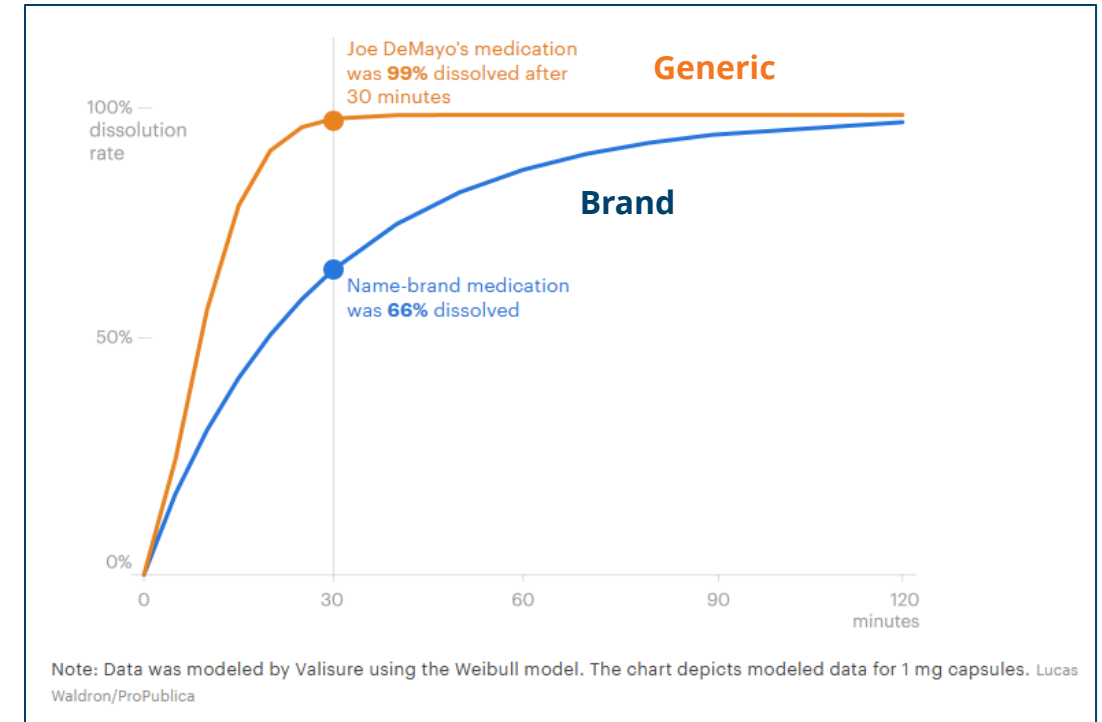
His Kidney Failed. He'll Never Know if a Transplant Drug From a Banned Factory Was to Blame.

When Joe DeMayo's donated kidney started to fail earlier than expected, he didn't know that the drug he was taking could've left him vulnerable — and that one of the most formidable drug regulators in the world may have failed to protect him.

by Debbie Cenziper and Megan Rose

June 23, 2025, 5 a.m. EDT

[Link](#) ▶

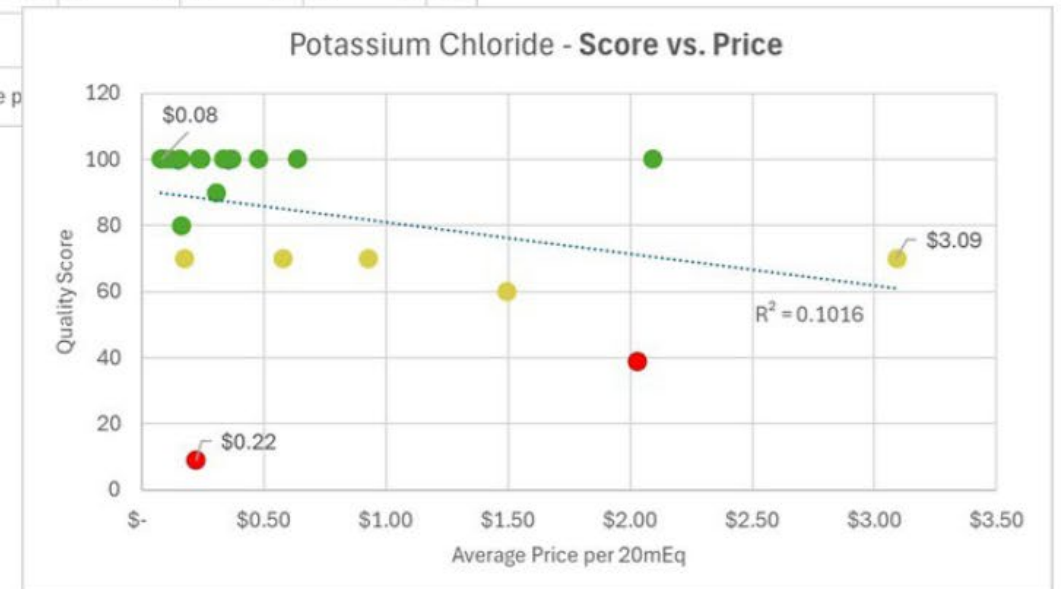
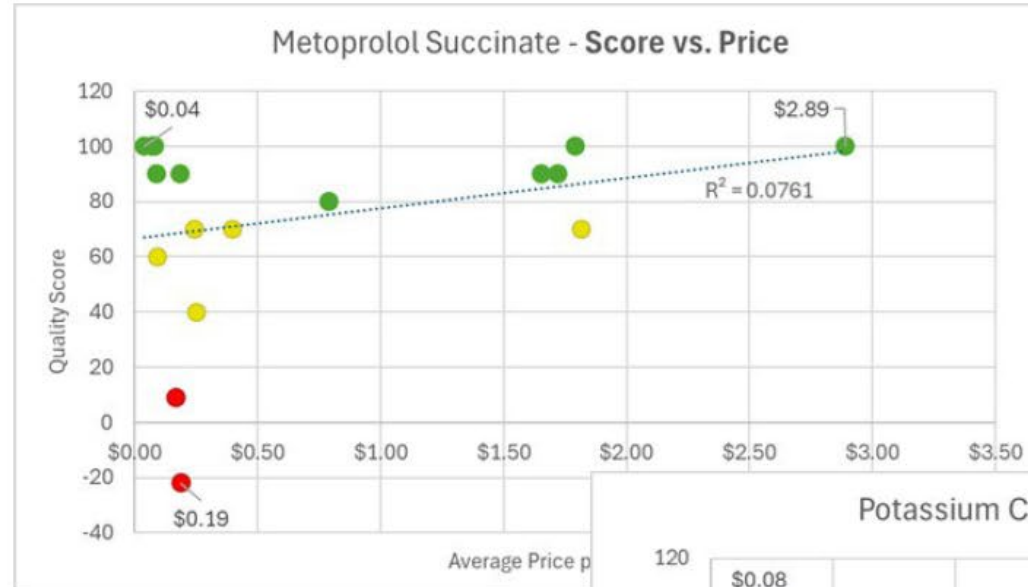


Quality Scores vs Price

Conclusions:

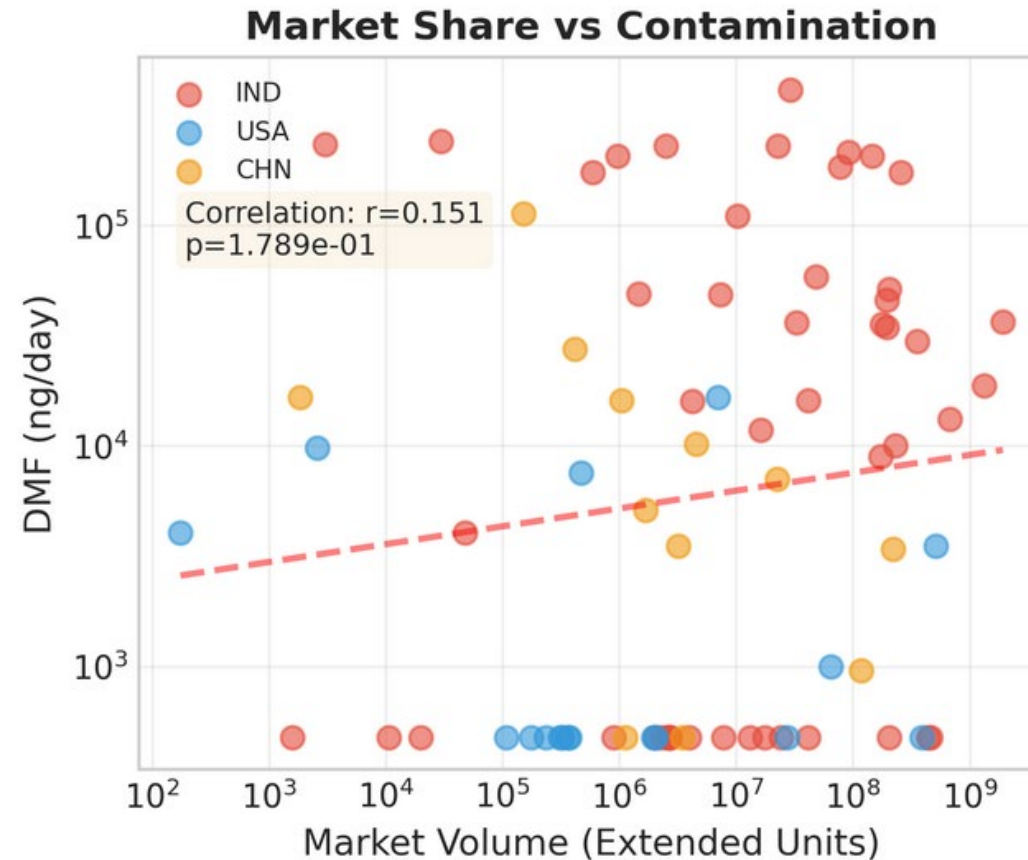
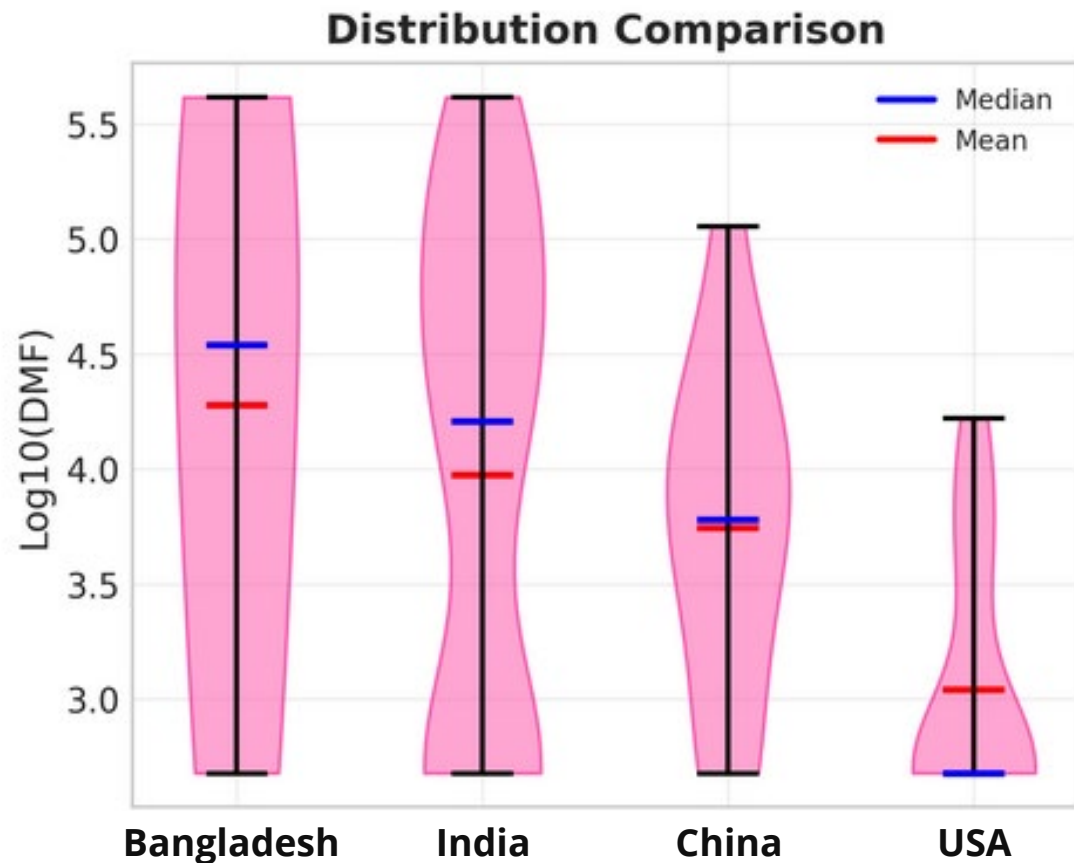
No correlation
between price
and quality

High quality drugs
available at low prices



Location Correlates with Quality

Stanford Univ, Valisure, DoD analysis of carcinogens in metformin merged with Ohio State Univ. supply map



Study links India-made generic drugs with 54 pc more severe adverse outcomes than US-made ones

PTI • Last Updated: Feb 20, 2025, 04:19:00 PM IST

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EXPRESS: Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events

[In Joon Noh](#), [John Gray](#) , [George Ball](#), [Zachery Wright](#), and [Hyunwoo Parks](#)  [View all authors and affiliations](#)

[Accepted Manuscripts](#) | <https://doi.org/10.1177/10591478251319691>

[Link](#) 

Incentivizing **Quality** Fixes Broken Marketplace

- **Policy proposal:** Government essential medicines purchasing by "best value" instead of "lowest cost technically acceptable" status quo

| | Status Quo | | "Best Value" Contracting | | | | |
|-----------|--------------|--------------------|--------------------------|--------------------------------------|--|-------------|--------------------|
| Supplier | FDA-Approved | Price ^c | Quality Score → | Manufacturer Location ^a → | Independent Certification ^b → | Final Score | Price ^c |
| Labeler 1 | Yes | \$6.57 | 100 | USA | Yes (+10) | 110 | \$6.57 |
| Labeler 2 | Yes | \$6.24 | 100 | USA | No | 100 | \$6.24 |
| Labeler 3 | Yes | \$6.90 | 100 | India (-30) | No | 70 | \$6.90 |
| Labeler 4 | Yes | \$6.37 | 100 | India (-30) | No | 70 | \$6.37 |
| Labeler 5 | Yes | \$6.77 | 90 | China (-61) | No | 29 | \$6.77 |
| Labeler 6 | Yes | \$19.71 | 39 | Taiwan | No | 39 | \$19.71 |
| Labeler 7 | Yes | \$6.04 | 39 | China (-61) | No | -22 | \$6.04 |
| Labeler 8 | Yes | \$7.10 | 39 | China (-61) | No | -22 | \$7.10 |

Example Based on Current Data and DoD formulary for 30mg lisinopril

← **Best value:** save money, improve quality, buy American

← Potentially most purchased currently

← Cheapest

^a Currently based on manufacturer headquarters location and public records

^b Labeler generally engages in independent certification

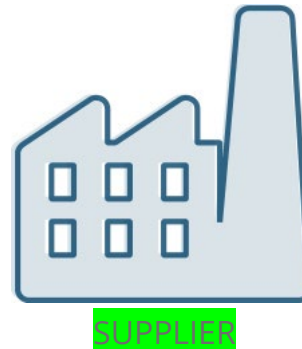
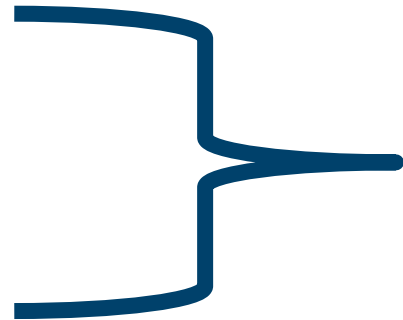
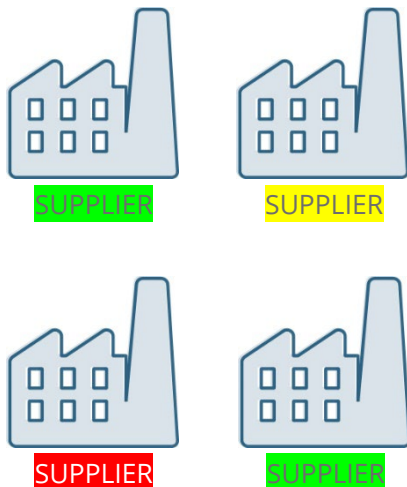
^c Pricing model centered on private market average for 100-count bottle

Quality Scores + Contracting Programs

Data for selecting “green” supplier and ongoing certification requirement to ensure product remains green



KAISER
PERMANENTE®



Growing Engagement to Improve Quality for Patients



Internal Testing Program



External Testing Program

Most Scalable Solutions



Contract Requirements
for Certification by
Independent Lab



Drug Quality Scores
Generated by
Independent Testing

Improve confidence in generics & fix broken marketplace



Drug Quality Research

Thank you

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