

Independent Testing of DoW Essential Medicines

to Protect the Warfighter and Incentivize Quality and American-Made Medicines

David Y. Light^{1,2}

Valisure, New Haven, Connecticut¹

Long Island University College of Pharmacy, Brooklyn, New York²



Session: Biomanufacturing for Supply Chain Resilience

Acknowledgements, Disclosures, and Disclaimer

Supporting Pls

Dr. Tracey Pérez Koehlmoos
USUHS, Bethesda, Maryland

COL (Ret) Vic Suarez
BluZoneBio, Frederick, Maryland

Disclaimer and disclosures

The information, conclusions, and views expressed in this presentation are solely those of the presenter and do not necessarily represent the official views of, nor should any official endorsement be inferred on the part of the Uniformed Services University of the Health Sciences, Department of War, or U.S. Government. David Light declares he is an employee and equity owner in Valisure, an independent testing laboratory.

Valisure Team

- David Light
- Wolfgang Hinz
- Mara Dubnicka
- Amber Hudspeth
- Nicola Zenzola
- Shannon Williams
- Tara Svendsen
- Shakeem Williams
- Diamond Bakare
- Yarida Urbina
- Nicholas Chieppo
- Andrew Lioio
- Maxwell Korman

DoW Team

- Tracey Koehlmoos
- Miranda Janvrin
- Amandari Kanagaratnam
- Jade Parker
- Cathaleen Madsen
- Irwin Lucki
- David Saunders
- Daoqin Bi
- Kristine Townsend
- Jason Hughes
- Aileen Mooney

BluZoneBio Team

- Victor Suarez
- Brad Powell

Our Drug Supply is in Crisis



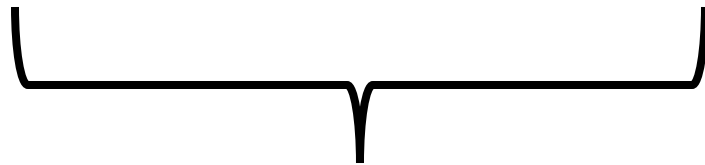
~300 **drug shortages**,
~76% due to quality
problems



~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

Topic of Growing Concern

Broad engagement across bi-partisan lawmakers, academia, and press



FULL COMMITTEE HEARING
Poisoned Pills: The Human Cost of Dangerous Foreign Drugs [Link](#) ➤

THE HILL [Link](#) ➤

Reliance on dangerous foreign generic drugs is killing Americans



Substandard Generic Drugs — Threats to Patient Safety and National Security

Kevin Schulman, M.D.,^{1,2} and Arthur L. Kellermann, M.D., M.P.H.³

[Link](#) ➤



From the Science Lab to the Medicine Cabinet: How China is Cornering the Market on Our Medicines

Meeting Status: Scheduled
Wed, 03/18/2026 - 10:00

DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 2027

USUHS CHSR PHARMACEUTICAL SUPPLY CHAIN

The Committee recognizes the importance of ensuring the quality, resilience, and security of the Military Health Program pharmaceutical supply chain. The Committee directs the Defense Health Agency, in coordination with the Defense Logistics Agency as appropriate, to expand and operationalize the Uniformed Services University of the Health Sciences (USUHS) Center for Health Services Research (CHSR) pharmaceutical supply chain portfolio by: (1) defining a bounded essential medicines list; (2) employing independent laboratory testing to assess product quality; (3) generating a repeatable risk scoring methodology incorporating quality and supply chain security factors, including country-of-origin transparency; and (4) describing how outputs will be integrated into procurement. The Committee further directs the Director of the Defense Health Agency to brief the congressional defense committees not later than 180 days after enactment on implementation status, barriers, and a plan to scale.

DoW 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](#)

Author affiliations include:

6 Universities – Including Yale, Stanford, Columbia

3 Health Systems – Including Cleveland Clinic, NYU Langone
Department of War

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

**Suspected “reds” sent for secondary
testing at academic and industry labs**

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

What is Independent Testing?

Independent testing aims to answer *fundamental question*:

IS THIS A QUALITY PRODUCT?

“ISO” Screening vs “GMP” Product Validation

- **GMP/Regulatory:** 1,000s of methods for 1 product
- **ISO/Independent:** 1 method for 1,000s of products



~10X cheaper than GMP and complementary to FDA efforts

*Speaking on Independent Testing
at June 2020 Senate Hearing*

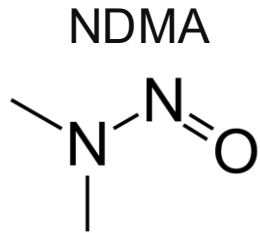
UNITED STATES SENATE
COMMITTEE ON FINANCE



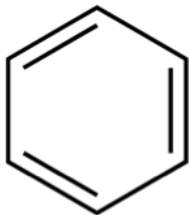
C-SPAN: Valisure Opening Remarks

[Link >](#)

Historical Results from Independent Testing



Benzene



Drug Product	Independent Testing	FDA Actions
VALSARTAN, LOSARTAN, IRBESARTAN	Novartis 2018: Tests on valsartan API detected carcinogen NDMA. Valisure 2019: 34 valsartan tested - Detected carcinogen DMF	- Recalls of over 1,000 drug lots in the US - Valisure filed FDA Citizen Petition on DMF in valsartan, 6/13/19
ZANTAC / RANITIDINE	Valisure 2019: 10 products tested. - Detected carcinogen NDMA and determined drug degrades into NDMA	- Recalls - Market withdrawal - Clinical and in vitro studies conducted by FDA
NIZATIDINE	Valisure 2019: 1 product tested. - Detected carcinogen NDMA and determined drug degrades into NDMA	- Recalls - Drug discontinued by multiple companies.
METFORMIN	Valisure 2020: 38 products tested. - Detected carcinogens NDMA and DMF	- Recalls for NDMA - DMF not yet addressed by FDA
HAND SANITIZERS	Valisure 2021: 260 products tested. - Detected carcinogen benzene, in addition to methanol and other impurities	- First recall due to benzene on 4/28/21 - FDA alert for ArtNaturals products 10/4/21
SUNSCREEN	Valisure 2021: 294 products tested. - Detected carcinogen benzene	- Recalls due to benzene of multiple major brands
ANTIPERSPIRANTS	Valisure 2021: 108 products tested. - Detected carcinogen benzene	- Recalls due to benzene of multiple major brands
DRY SHAMPOO	Valisure 2022: 148 products tested. - Detected carcinogen benzene	- Recalls due to benzene of multiple major brands
BENZOYL PEROXIDE ACNE TREATMENTS	Valisure 2024: 252 products tested. - Detected carcinogen benzene	- Recalls due to benzene of multiple major brands

**8 Valisure FDA
Citizen Petitions**
testing 1,145
products

**FDA responded
with dozens of
national recalls,
withdrawals and
alerts affecting
over 25 million
products in the
United States
worth over
\$9 billion**

First 21 of 42 Drugs: Summary Results

	Market Sweep (Companies)			Primary Reason for "Reds"
	Green	Yellow	Red	
Metformin	20	7	3	Carcinogen: "DMF"
Lisinopril	8	0	2	Toxin: Arsenic
Potassium	15	3	4	Toxins: Lead, Thallium
Metoprolol	11	5	2	Slow Dissolution
Magnesium Sulfate	7	0	0	N/A
Tacrolimus	4	4	4	Fast Dissolution
Ampicillin	13	1	1	Toxin: Lead
Atorvastatin	11	3	5	Toxins: Lead, Arsenic, Lithium
Ca Gluconate	4	0	2	Toxin: Lead
Vancomycin	20	0	1	Toxin: Arsenic
Bupropion	17	4	5	Fast Dissolution
Metronidazole	19	0	2	Toxins: Lead, Arsenic, Lithium
Pantoprazole	17	0	4	Fast Dissolution
Dextrose	4	0	0	N/A
Norepinephrine	10	1	0	N/A
Atropine	8	1	0	N/A
Furosemide	17	7	3	Carcinogen: Nitrosamine, Slow Dissolution, Talc
Amlodipine	10	5	1	Fast Dissolution
Duloxetine	1	2	5	Carcinogen: Nitrosamine, Fast Dissolution, Talc
Sodium Bicarbonate	5	0	2	Toxins: Arsenic, Particulates
Amiodarone	8	1	1	Fast Dissolution
% of 320 Suppliers:	71.6%	13.8%	14.7%	

	DoW Formulary (NDCs)			
	Green	Yellow	Red	Gray*
Metformin	38	7	7	4
Lisinopril	34	0	8	1
Potassium	17	0	0	2
Metoprolol	11	11	2	1
Magnesium Sulfate	9	0	0	4
Tacrolimus	3	9	3	1
Ampicillin	32	3	0	3
Atorvastatin	37	4	19	10
Ca Gluconate	5	0	2	0
Vancomycin	16	0	0	1
Bupropion	33	9	18	12
Metronidazole	20	0	3	0
Pantoprazole	11	0	6	3
Dextrose	7	0	0	1
Norepinephrine	7	0	0	2
Atropine	6	1	0	2
Furosemide	9	21	10	2
Amlodipine	11	8	1	0
Duloxetine	1	1	7	0
Sodium Bicarbonate	3	0	3	0
Amiodarone	9	3	0	8
% of 542 NDCs:	58.9%	14.2%	16.4%	10.5%

71.6%

13.8%

14.7%

Key Findings:

- Many "Reds" exist but most of market contains "Greens"
- DoW formulary quite similar to private market

Analysis Summary:

- 320 suppliers of 21 drugs
- 542 DoW NDCs scored
- 851 unique drug lots tested
- 3,114 unique tests performed

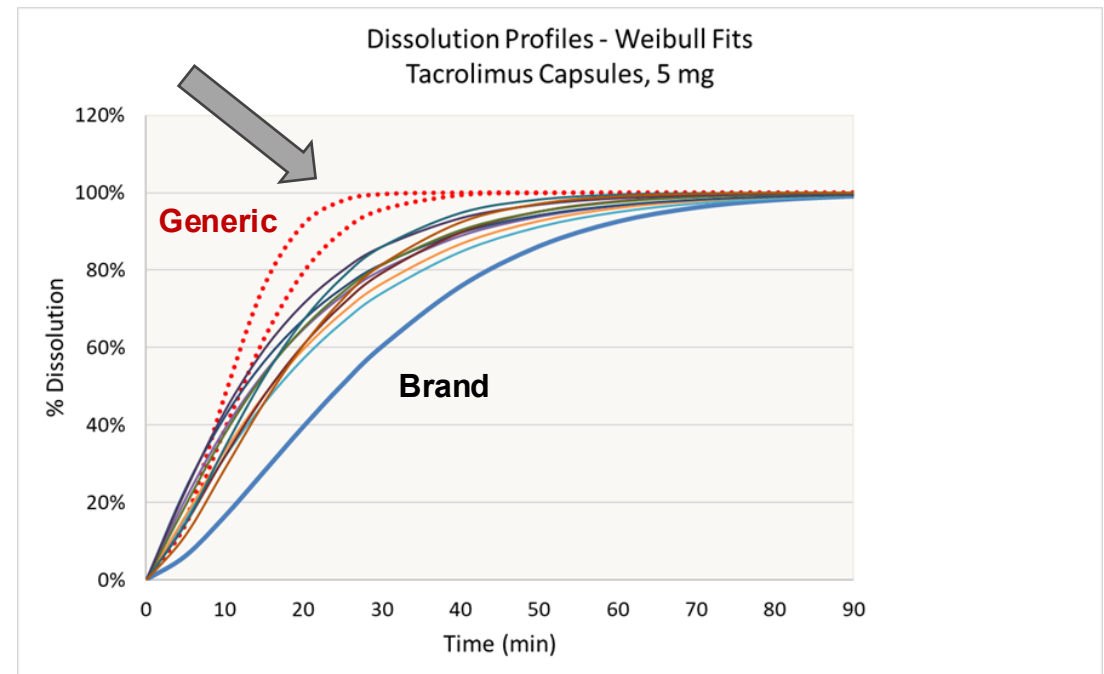
More detailed datasets with latest results available upon request

**Gray denotes no data available to determine a score*

Results Highlight: Tacrolimus

Critical immunosuppressant administered after transplant

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	--	--	--

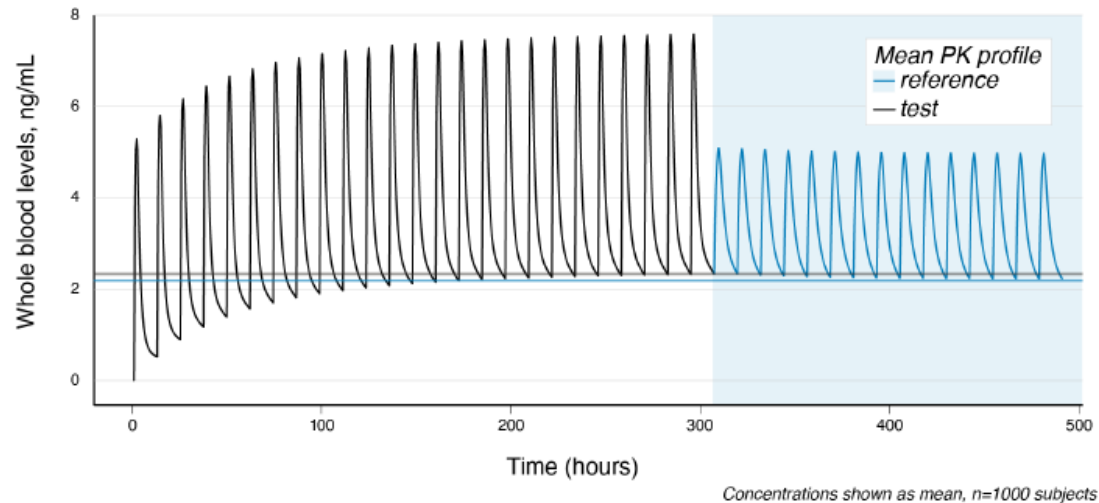


FDA Gives “Red” Rating After 11 Years

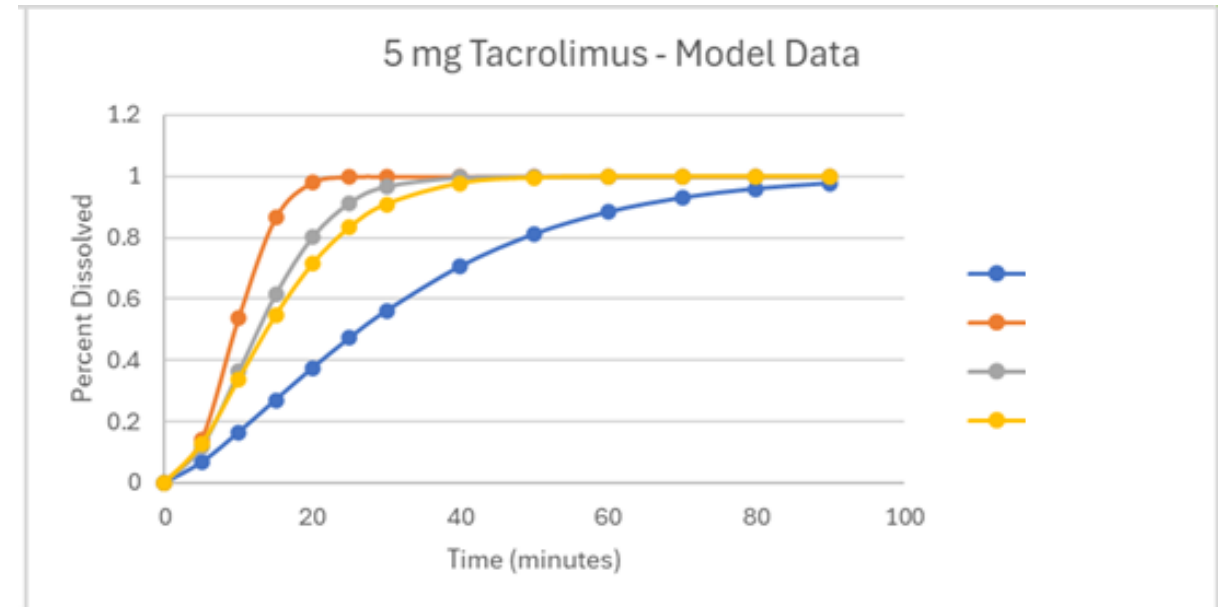
Received concerns in 2012 and ran clinical trials showing “red”-rated manufacturer not bioequivalent in 2023

FDA *in vivo* clinical trial

Simulation of Generic Switch in Healthy Subjects: Test to Reference Switch



In vitro dissolution testing in DoW project shows concordant results in weeks instead of years



ProPublica Investigates Patient's Tacrolimus

Health Care

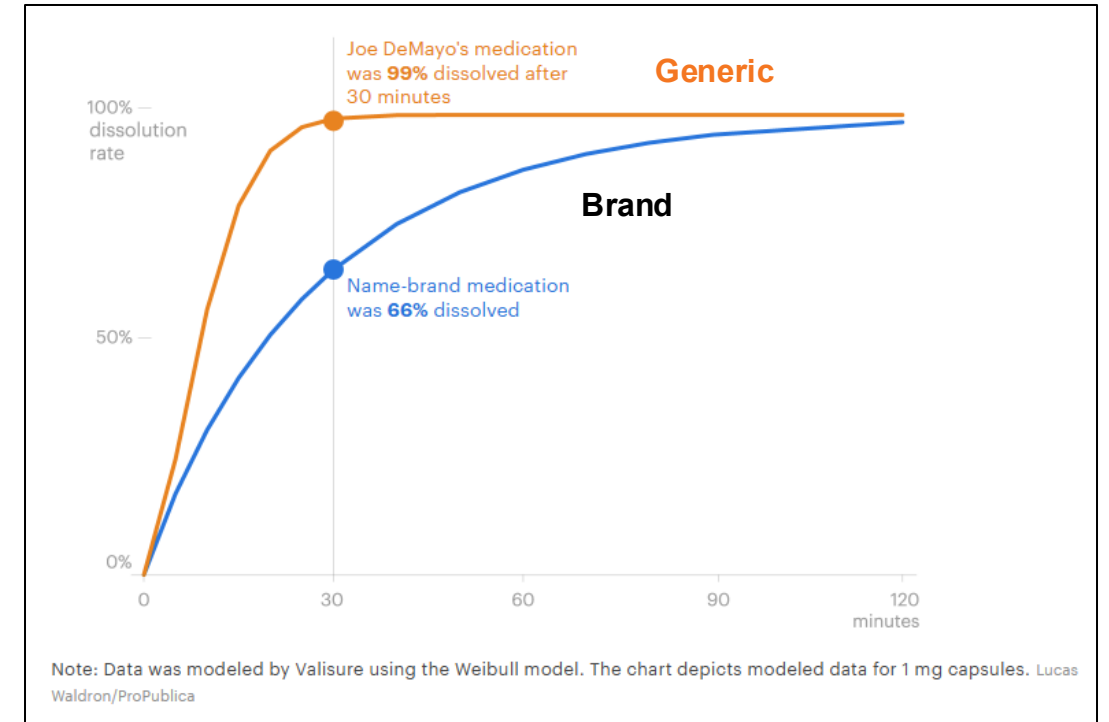
His Kidney Failed. He'll Never Know if a Transplant Drug From a Banned Factory Was to Blame.

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](#) ►

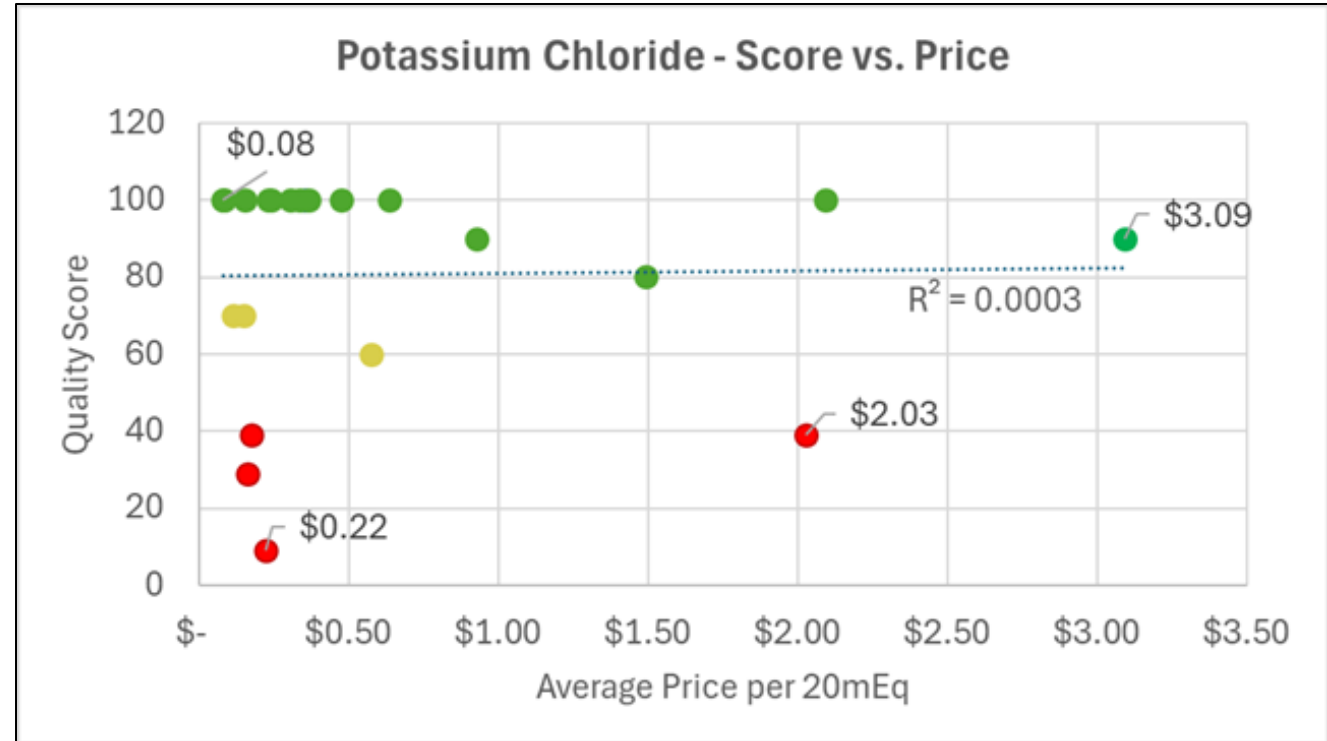


Quality Scores vs Price

Conclusions:

No correlation
between price
and quality

*High quality drugs
available at low prices*

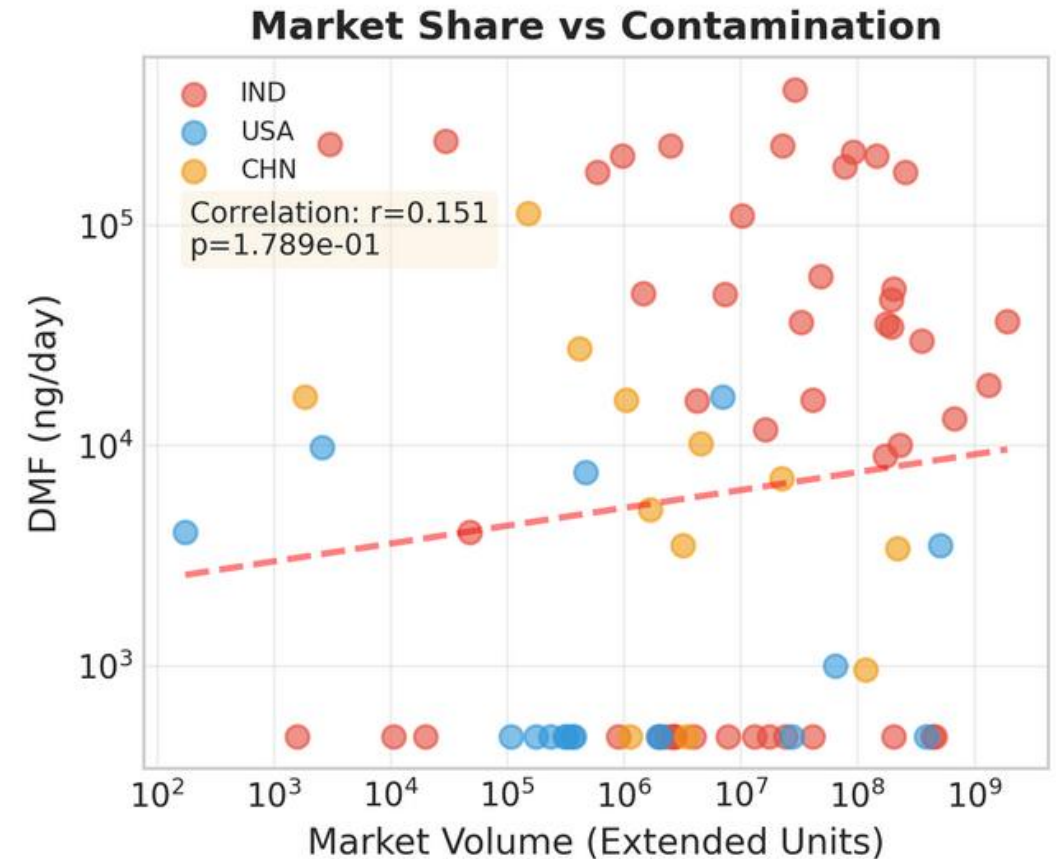
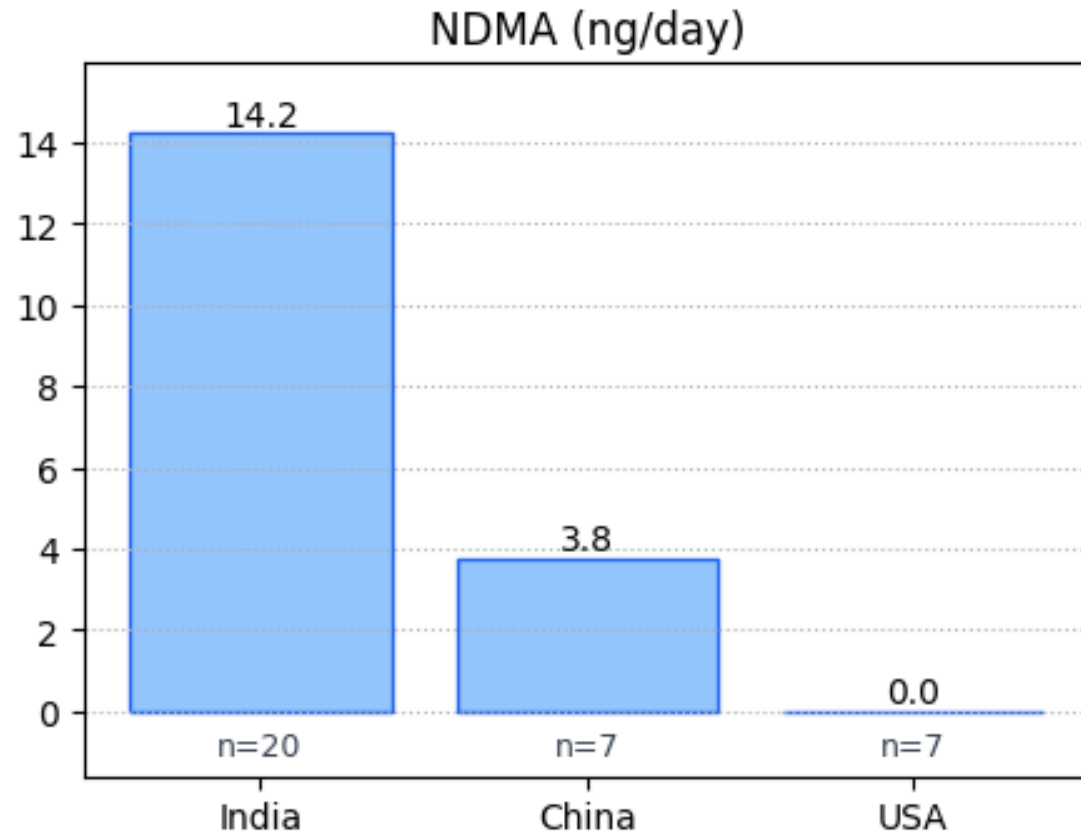


The Price and Quality of Methylphenidate Products

Aditya Narayan^a, BS , Ben Teasdale^b, MD, MPhil , A.J. Hudspeth^c, MS , David Y. Light^{c,d}, BS ,
Jill K. Nailor^c, RPh , Kevin Schulman^{a,e,f,*}, MD 

Manuf. Location Correlates with Quality

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



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 DoW 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

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

www.fda.gov

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Thank you

Contact: David Light
david.light@valisure.com