



Independent Drug Quality Testing & Benzene in Consumer Products

David Light, President

Drug Quality is a Serious and Growing Concern

Press Highlights

**Bloomberg
Businessweek**



2019

[Link ►](#)

The New York Times

Our Drug Supply Is Sick. How Can We Fix It?

“The system that we have right now is so broken that we need a big shake-up.”

“Who cares if it is a nickel more if it’s a much better drug?”

2021

[Link ►](#)

MILKEN INSTITUTE
review

Fixing Generic Drugs With Voluntary Privatized Regulation
BY LAWRENCE M. FISHER

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 ►](#)

Regulation of Quality is Based on Self-Reported Data

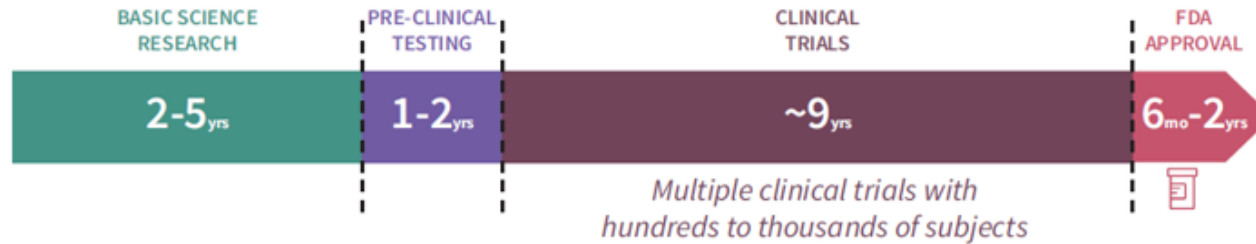
The FDA does **NOT** routinely test drug products

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

[Link](#)



Independent quality data is complementary to regulatory efforts

A Simple Solution: **Independently Test & Certify Drugs**

Just like:

Electronics by industry demand



Food by consumer demand

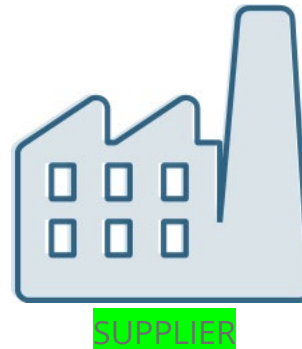
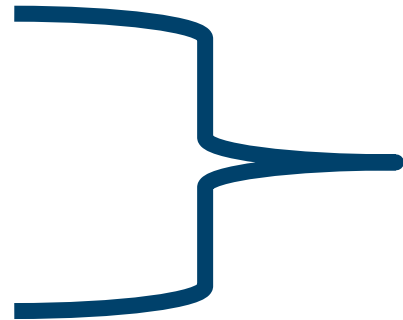
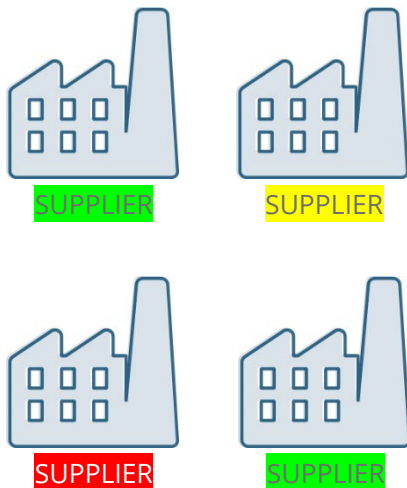


Large Scale Independent Drug Quality Models

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

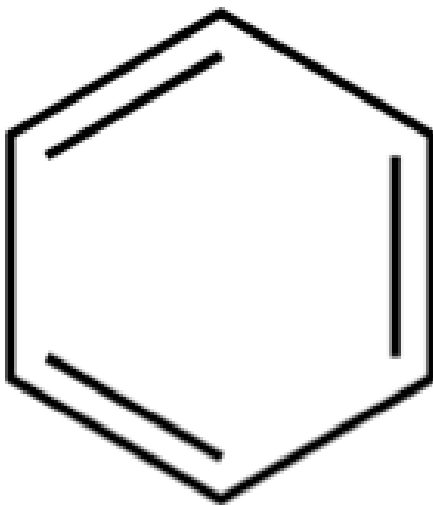


KAISER
PERMANENTE®



Benzene

Benzene: C₆H₆



CAS 71-43-2

Added to Valisure's screening in late 2020

Hazardous Industrial Solvent

- Was used in pharma production
- Broadly banned in many industries
- Known contaminant in petroleum industry

Benzene is a good GC-MS analyte

- Benzene is highly volatile, boiling point 80.0 °C
- Amenable to electron and chemical ionization

FDA June 6, 2022 Update on Benzene

FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs

Finding	Contact Method	Notes
Drug product batches already in distribution with benzene impurities above 2 ppm	Contact appropriate ORA Division Recall Coordinators	Field Alert Reports are required for ANDAs and NDAs with such findings for distributed drug products (21 CFR 314.81(b)(1)). Application holders notified of benzene results from the manufacturer of an API used in their product are required to submit FARs
Active pharmaceutical ingredient lot with benzene above 2 ppm	Contact appropriate ORA Division Recall Coordinators	FDA will advise on appropriate next steps such as notifying any entity that received contaminated API.
Any drug product or active pharmaceutical ingredient with benzene above the limit of detection but below 2 ppm	Contact FDA at CDER-benzene@fda.hhs.gov	The manufacturer should also be prepared to share with FDA the methods used and any available information on the potential source of the benzene to assist with FDA's analysis

<https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs>

Valisure Analysis of Benzene

Hand Sanitizer

March 24, 2021



Valisure Detects Benzene in Hand Sanitizer

260 products analyzed

- Drug products

Benzene detection in
batches of products:

> 2 ppm: **8%**

> 0.1 ppm: **17%**

Sunscreen & Suncare

May 25, 2021



Valisure Detects Benzene in Sunscreen

294 products analyzed

- Drug & cosmetic products

Benzene detection in
batches of products:

> 2 ppm: **5%**

> 0.1 ppm: **14%**

Body Sprays

November 4, 2021



Valisure Detects Benzene in Body Spray Products

108 products analyzed

- Drug & cosmetic products

Benzene detection in
batches of products:

> 2 ppm: **22%**

> 0.1 ppm: **35%**

Valisure Analysis of Benzene

Body Sprays

November 4, 2021



Valisure Detects Benzene in Body Spray Products

108 products analyzed

- Drug & cosmetic products

Benzene detection in batches of products:

> 2 ppm: **22%**

> 0.1 ppm: **35%**

Dry Shampoos

October 31, 2022



Valisure Detects Benzene in Dry Shampoo Products

148 products analyzed

- Cosmetic products

Benzene detection in batches of products:

> 2 ppm: **22%**

> 0.1 ppm: **70%**

Acne Products (BPO)

March 5, 2024



Valisure Detects Benzene in Dry Shampoo Products

241 products analyzed

- Drug & cosmetic products

Stability testing shows benzene formation in **ALL batches** of BPO products..

On-shelf analysis:

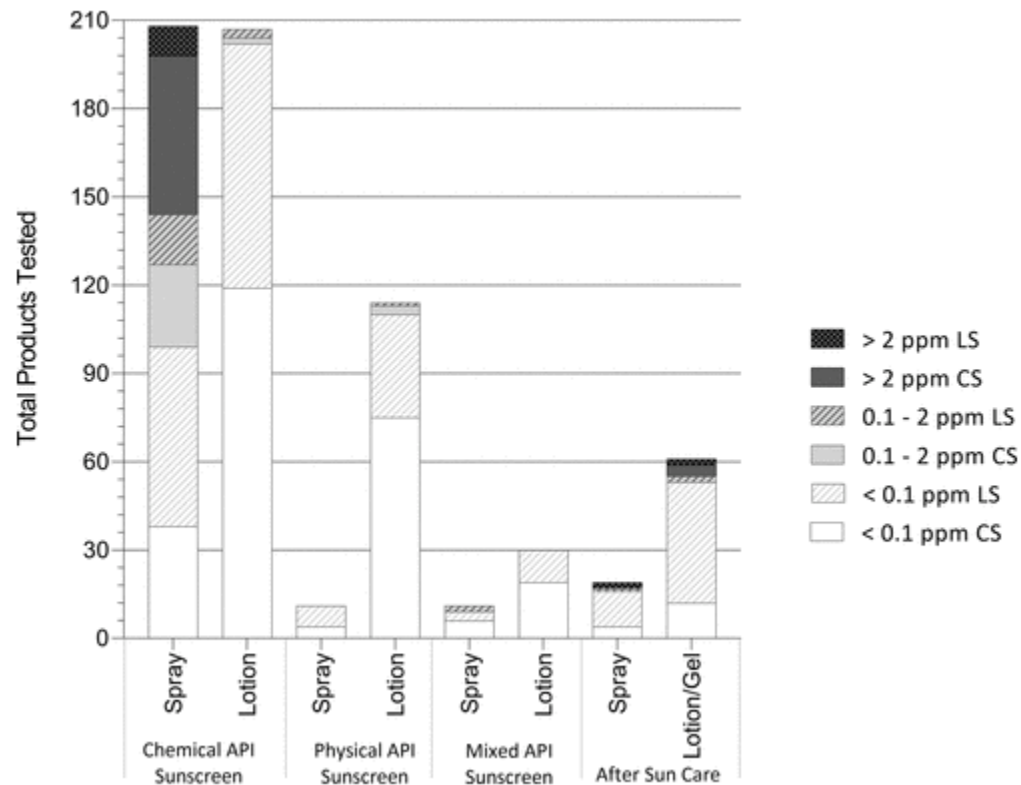
> 2 ppm: **34%**

> 0.1 ppm: **100%**

Raw Materials Major Source of Benzene

Independent Sun Care Product Screening for Benzene Contamination

Amber Hudspeth, Nicola Zenzola, Kaury Kucera ✉, Qian Wu, and David Light

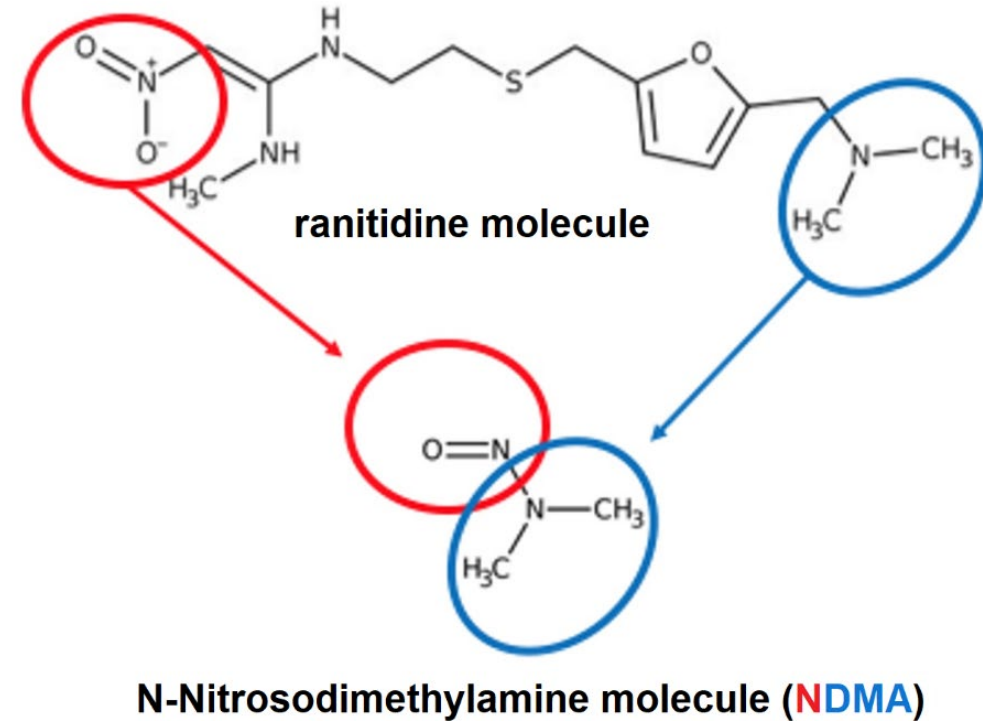
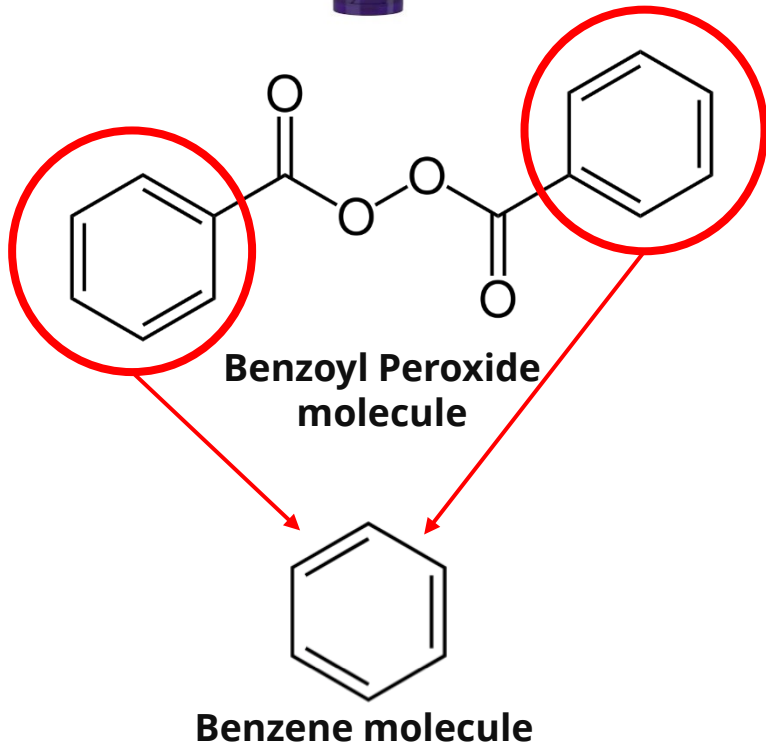


“Spray” or aerosol products often detected with the highest levels of benzene.

“Gel” products, likely containing carbomers, also have high prevalence of benzene.

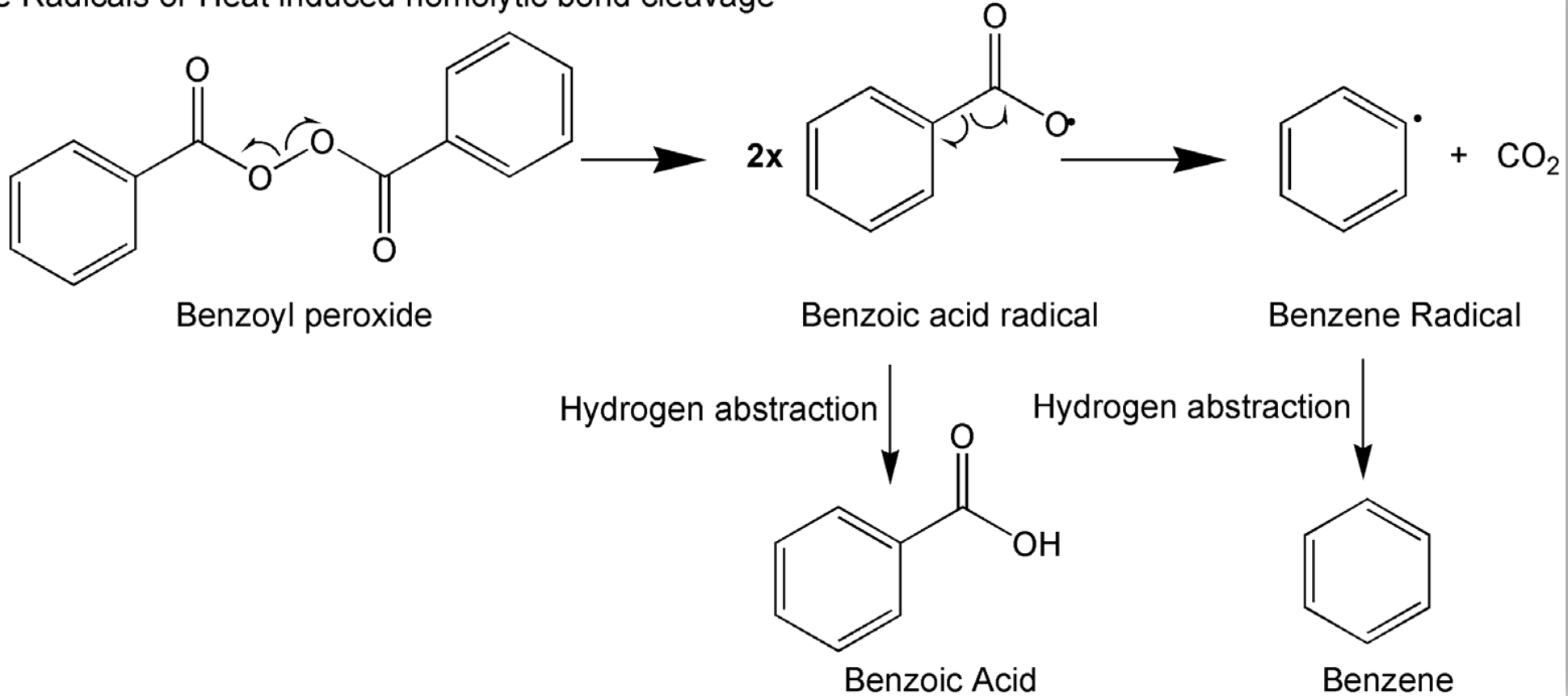
BPO is a special case...

Unstable Drug that Degrades into Carcinogen



Unstable Drug that Degrades into Carcinogen

Free Radicals or Heat induced homolytic bond cleavage





DAVID LIGHT, President

david.light@valisure.com