



valisure[®]

partner for quality

**INDEPENDENT QUALITY
ASSURANCE**

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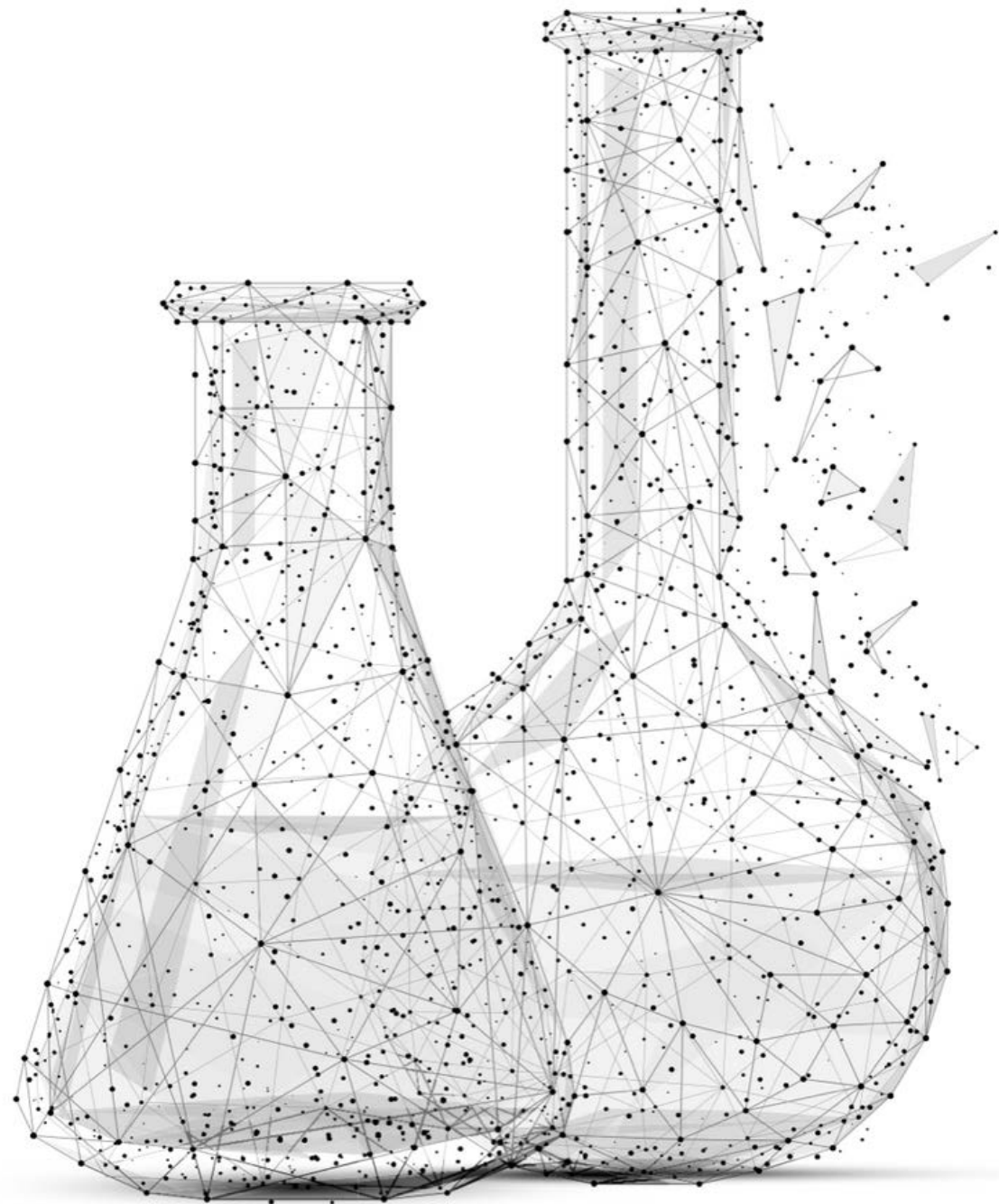


ABOUT VALISURE & INDEPENDENT QUALITY ASSURANCE



Valisure is an independent laboratory and partner for quality that provides increased transparency and quality assurance throughout the healthcare industry. In response to rising concerns and quality issues in the global supply chain, Valisure's team of Harvard- and Yale-trained scientists developed proprietary analytical technologies to independently test products, identify critical issues, and offer services to help distinguish quality stakeholders and products. Valisure's novel approach to independent quality assurance has had a tremendous global impact and built a foundation of thought leadership that increasingly influences academia, government, and private industry to help improve public health.

WHAT IS INDEPENDENT ANALYSIS



In most consumer markets, independent measures of quality are available to help differentiate brands and offer independent quality assurance to purchasers. However, in pharmaceutical and consumer healthcare products, this largely doesn't exist, and that's what Valisure is working to change.

Regulators, like the FDA, consistently inspect facilities and require that manufacturers perform routine testing of their products according to Good Manufacturing Practices ("GMP"). However, very rarely are products sampled and tested by regulatory agencies. GMP testing is very brand-specific, often leading to dozens of methods for a single type of product, but independent testing follows scientific principles that apply broadly and can screen many different products with a single method.

Valisure's independent testing, accredited to International Organization for Standardization ("ISO") standards, has been uniquely developed to effectively screen through thousands of products and has already made a global impact.



**David Light,
Chief Executive Officer**

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David Light, Chief Executive Officer of Valisure, is a biotech entrepreneur and scientist with over 15 years of broad experience in the field. A graduate of Yale University, David studied molecular biology and has worked in various scientific and business roles at start-ups like Synthetic Genomics, Ion Torrent, and Valisure.

As Founder and CEO of Valisure, an independent laboratory and Partner For Quality that checks and certifies the chemical composition of medications and healthcare products before they reach consumers, David helped fund and invent the core technology and led its entry and impact into the market. David is named inventor on numerous patents, published in journals including Nature and the cover of Electrophoresis, and has been invited to submit testimony at congressional hearings and speak at the U.S. Capitol Building.

David sits on multiple boards of non-profit organizations, was appointed an Affiliate Professor at Long Island University, has lectured at Yale University for the past decade, and is passionate about entrepreneurship and improving public health. He has been quoted in numerous publications, including Bloomberg, The New York Times, The Wall Street Journal, The Washington Post, CBS News, NPR, and Forbes, to name a few.

HISTORY & TIMELINE



Founders Adam Clark-Joseph and David Light, friends since their Yale days, reconnected after Adam suffered severe complications from his anticonvulsant medication due to batch variability. Shocked by the vulnerability of the existing drug supply chain, they began to grasp the magnitude and pervasiveness of the problem throughout the pharmaceutical industry. Working together to bring a team of like-minded scientists and pharmacy experts to create Valisure, they founded a company dedicated to bringing improvements in quality and consistency to consumers and the overall healthcare industry.

Valisure was founded and funded by a team of Yale entrepreneurs.

Valisure successfully builds and licenses the first online pharmacy that dispenses chemically-validated medications

Valisure's independent testing and subsequent discoveries generate a growing impact recognized by government and industry

Valisure's enterprise business successfully integrates independent quality assurance into major, national health systems and continues to build engagement throughout healthcare.

2015

2017

2018

2019

2020

2021

2022

Valisure achieves laboratory accreditation to ISO 17025

Valisure broadly launches pharmacy and files its first two FDA Citizen Petitions creating global impact

Valisure's business evolves from direct-to-consumer into enterprise services as impact grows both in drug and consumer products

VALISURE SERVICES



Independent Product Certification: Independent product certification is the cornerstone on which Valisure was built and the driving force behind what keeps us tirelessly seeking to improve the products of our clients. This means developing standards that at times go beyond the current, often outdated benchmarks by continuously evolving our quality assurance testing.

Consultation & Diligence: We provide our clients with various consulting services from concept to completion by anticipating challenges and ensuring quality commitment. Our support ranges from guiding you through vendor validation to due diligence, selecting the proper analysis to conduct, and facilitating resolution if testing discrepancies arise, giving you confidence in your products and the tools to demonstrate their quality.

Analytical Studies & Advocacy: The supply chain is complex, and with our broad capabilities for product testing, we are able to survey the market in both pharmaceutical and consumer products to give our clients unique insights into their own and competitive products. This requires the expertise of our ISO 17025 accreditation and the understanding to know when and how to apply the methods accurately. With these insights, hand in hand with Valisure's support, these can lead to publications, reporting, filings, etc. that underscore the public support and recommendations for industry-wide transparency.

Vendor Validation: Ensuring quality begins at a product's origin. Through our rigorous vendor validation process, Valisure can assist industry partners in confirming that a supplier or manufacturer is of the highest quality standards. With transparency upfront, we seamlessly integrate into an organization's selection process by bringing independent quality assurance and value.



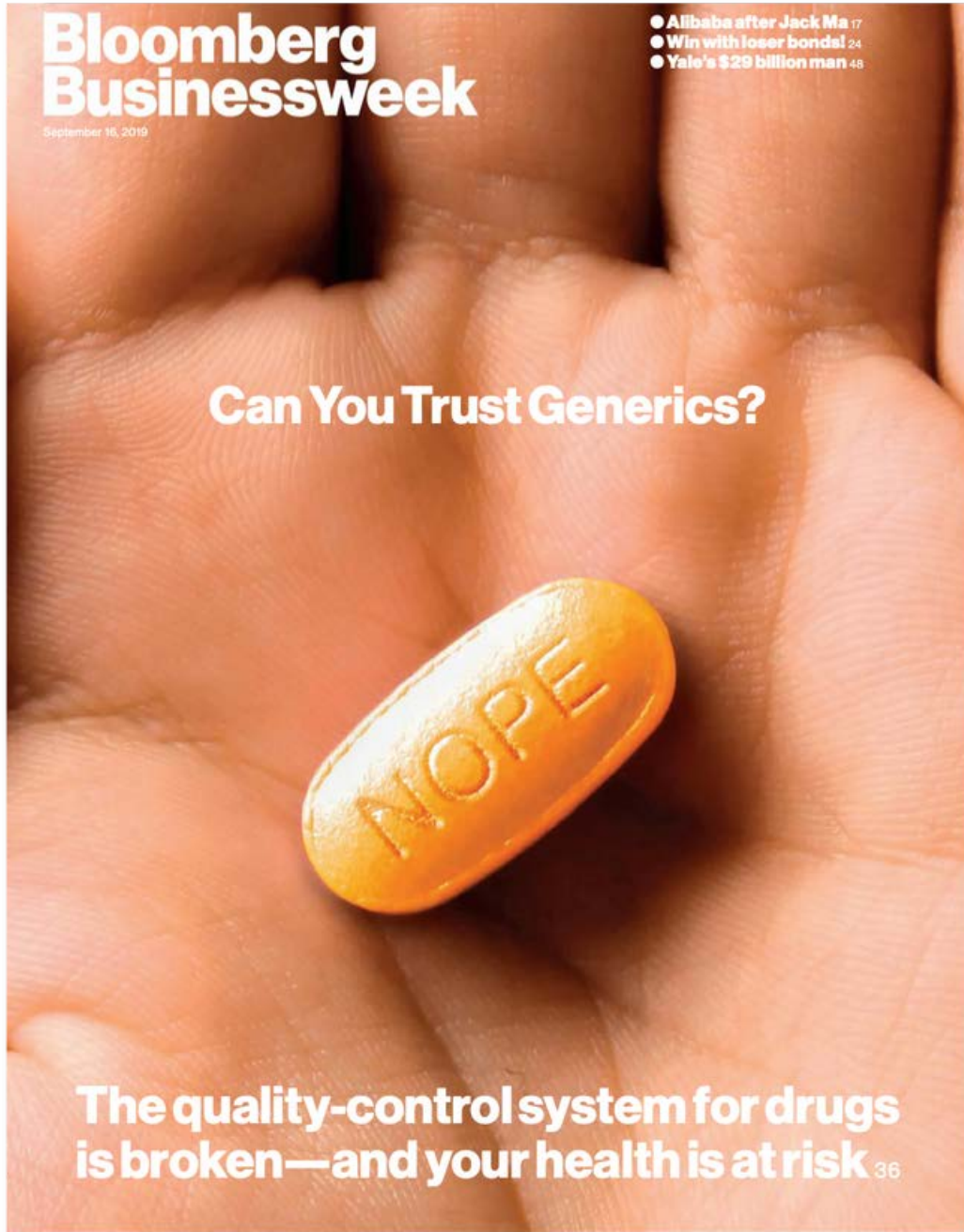
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A Tiny Lab Finds Danger on Drugstore Shelves While the FDA Lags Behind

Valisure has found tainted heart burn pills, sunscreens and dry shampoos, shaking up products that generate more than \$9 billion in sales. Why are they outrunning regulators?





REUTERS

"Online pharmacy Valisure says tests show carcinogen in diabetes drug metformin"



The Washington Post

"A tiny pharmacy is identifying big problems with common drugs, including Zantac"





"Valisure links 'unstable' Zantac and its ilk to carcinogen buildup, cancer risk"



"Lab finds benzene in 78 sunscreens and sun-care lotions."

"NDMA, a contaminant found in multiple drugs, has industry seeking sources and solutions."

"Finding benzene everywhere we look."

GOVERNMENT ENGAGEMENT



Congresswoman Rosa DeLauro and Valisure held a joint press conference in the Capitol Building to call for the withdrawal of Zantac (ranitidine) products and reintroduce DeLauro's Recall Unsafe Drugs Act.

Valisure CEO David Light was invited to testify before the US Senate Finance Committee on June 2, 2020 regarding Oversight of the FDA's Foreign Drug Manufacturing Inspection Process and present Valisure's findings and solutions for improving drug quality.



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PROTECTIONS

November 14, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We are writing to express our deep concerns over recent reports of high levels of benzene, a cancer-causing chemical that was discovered in several cosmetic, personal care, and over-the-counter drug products including, sunscreen, hand-sanitizer, deodorant, and dry-shampoo.

Benzene is known to cause certain blood cancers in humans, according to the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), the World Health Organization, and other regulatory agencies. According to the FDA, exposure to benzene can occur by inhalation, orally, and through the skin and it can result in cancers including leukemia and blood cancer of the bone marrow and blood disorders which can be life threatening. The EPA also lists drowsiness, dizziness, headache, and unconsciousness as symptoms of benzene inhalation.

As you know, Valisure, a New Haven, Connecticut-based analytical laboratory recently tested 148 batches from 34 brands of spray-on dry shampoo and discovered that 70 percent contained benzene with samples testing as high as 170 times the 2 parts per million (ppm) FDA drug application limit. On October 21, 2022, the FDA issued the latest benzene contamination warning on dry aerosolized shampoo by Unilever brands Dove, Nexxus, Suave, TIGI, and TRESemmé. Over the past two years, benzene has been found in tests of sunscreen, hand-sanitizer, deodorant, and dry-shampoo.

As such, we have the following questions:

1. What is the FDA's immediate next steps in addressing the high levels of benzene in cosmetic, personal care, and over-the-counter drug products?
2. What is the FDA's long-term plan to ensure that benzene levels in cosmetic, personal care, and over-the-counter drug products are safe for American consumers?
3. What additional authorities or resources would be helpful to the agency in controlling contaminants like benzene in commonly used consumer products?

We thank you for considering this important request.

Sincerely,

Haley Stevens
Member of Congress

Debbie Dingell
Member of Congress



U.S. Senator Richard Blumenthal and Valisure held a joint conference at Hartford Hospital to present Valisure's discovery of carcinogenic contamination in suncare products and to urge the FDA to expeditiously utilize Blumenthal's recently passed Sunscreen Innovation Act.

Congresswoman Dingell and Congresswoman Stevens wrote a joint letter to FDA highlighting Valisure's citizen petitions on benzene contamination and requesting action. Both government officials added that Americans shouldn't have to worry about whether or not their everyday products cause cancer.

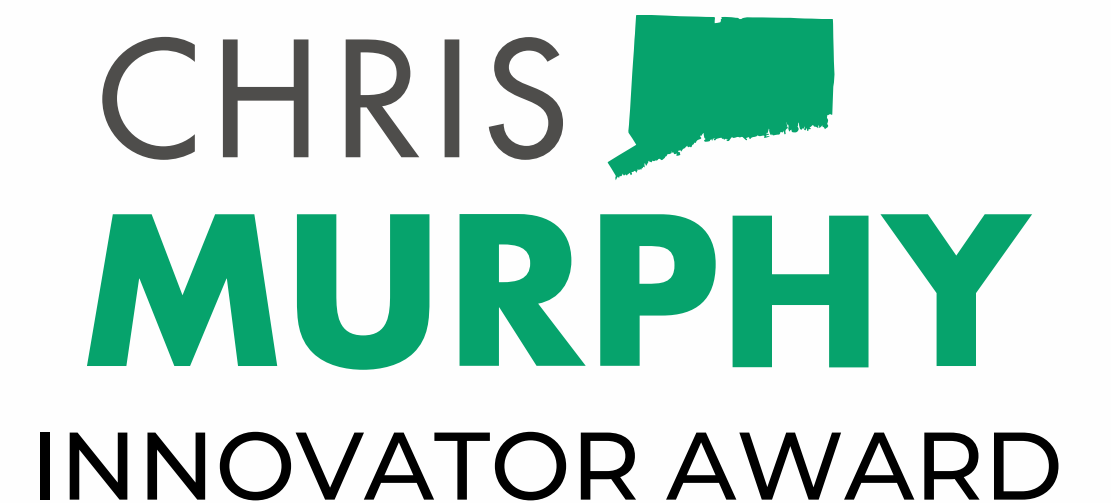
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Entrepreneur Of The Year



Healthcare Disruptor



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