Updating the Operating System for Consumer Health

Why Incremental Reform Failed — and Why It's Time for DSHEA 10.0

Todd A. Harrison
Partner | +1 202.344.4724 | taharrison@Venable.com

VENABLE LLP

Trust Is a System

Trust depends on rules, visibility, and accountability.

Outdated systems fail quietly.

VENABLE LLP

The Question

What happens when markets evolve faster than the rules meant to govern them?

VENABLE LLP

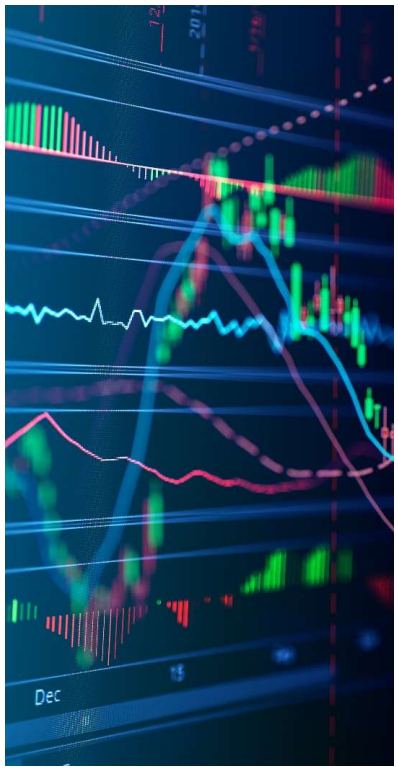
DSHEA Worked

DSHEA was the right framework—for 1994.

Post-market oversight enabled access and innovation.

VENABLE LLP

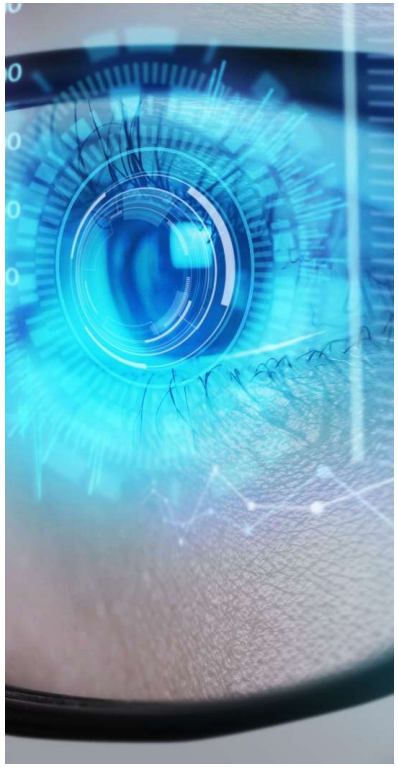
The Market Changed



- E-commerce
- Global supply chains
- Advanced chemistry
- Platform distribution

VENABLE LLP

What FDA Can't See Today



Products without identifiable responsible persons

Products that appear and disappear overnight

Enforcement that starts with detective work, not risk prioritization

VENABLE LLP

Ambiguity Became Policy

Guidance and discretion filled statutory gaps.

Rules became interpretations.

VENABLE LLP

Why Incremental Fixes Failed

Guidance instead of law

Discretion instead of durable rules

Ambiguity instead of accountability

VENABLE LLP

A Shared Institutional Failure

Industry adapted defensively.

FDA stretched interpretation.

Bad actors exploited gaps.

VENABLE LLP

Not DSHEA 2.0

Incremental reform had its moment.

That moment has passed.

VENABLE LLP

DSHEA 10.0

A generational reset

A modern operating system

VENABLE LLP

A Different Premise

Clear rules that bind regulators and industry alike

VENABLE LLP

Visibility Without Permission

Post-market product listing

No premarket approval

No permission gate

VENABLE LLP

Listing: Then vs. Now

Before: Fear of premarket control

Now: Statutory prohibition on delay or conditioning

Result: Visibility without licensing

VENABLE LLP

Unlisted = Illegal

A simple, enforceable rule

Anonymity ends here

VENABLE LLP

Funding Oversight

Funded through congressional appropriations

Supports the FDA and industry without user fees

Accountability, oversight, not permission

VENABLE LLP

Modern Ingredient Science

Chemical identity and exposure drive safety.

Origin alone does not.

VENABLE LLP

Bioidentical ≠ Assumed Safe

Bioidentical ingredients are included—but notified.

Safety equivalency is required.

Evidence replaces assumptions.

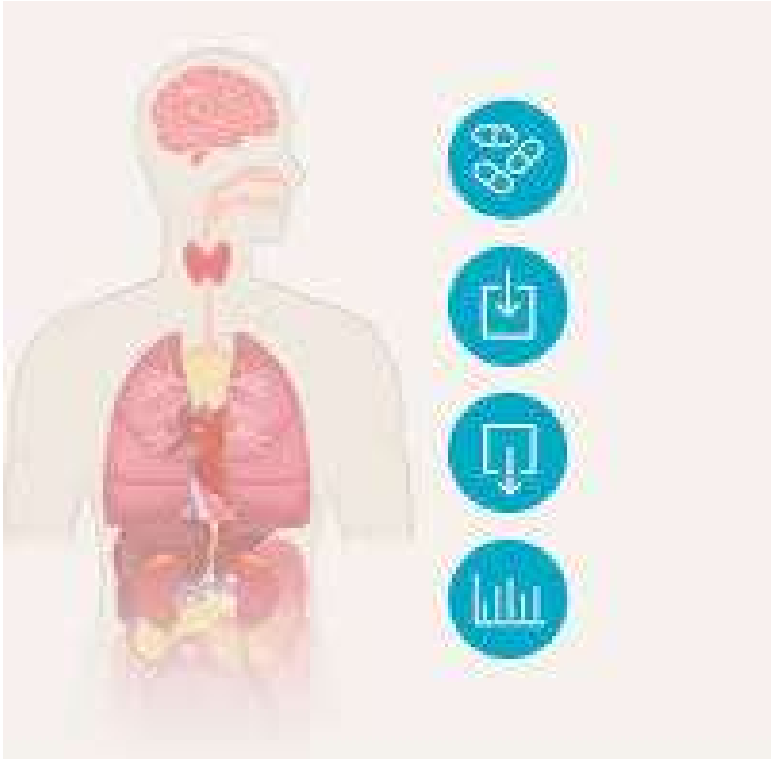
VENABLE LLP

Safety Equivalency in Practice

Toxicology and exposure data

Bioavailability and pharmacokinetics where appropriate

Consideration of manufacturing impurities and non-target substances



VENABLE LLP

What This Stops

Endless re-notifications

Process-change NDIs

Defensive paralysis by responsible companies

VENABLE LLP

Fixing Drug Preclusion

Same molecule

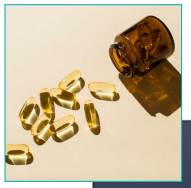
Different dose or route

Different regulatory outcome

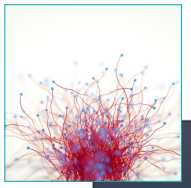
VENABLE LLP

A Line That Makes Sense

Local effects → cosmetic



Systemic delivery → drug



A scientific boundary

VENABLE LLP

Ingestion Is a Continuum

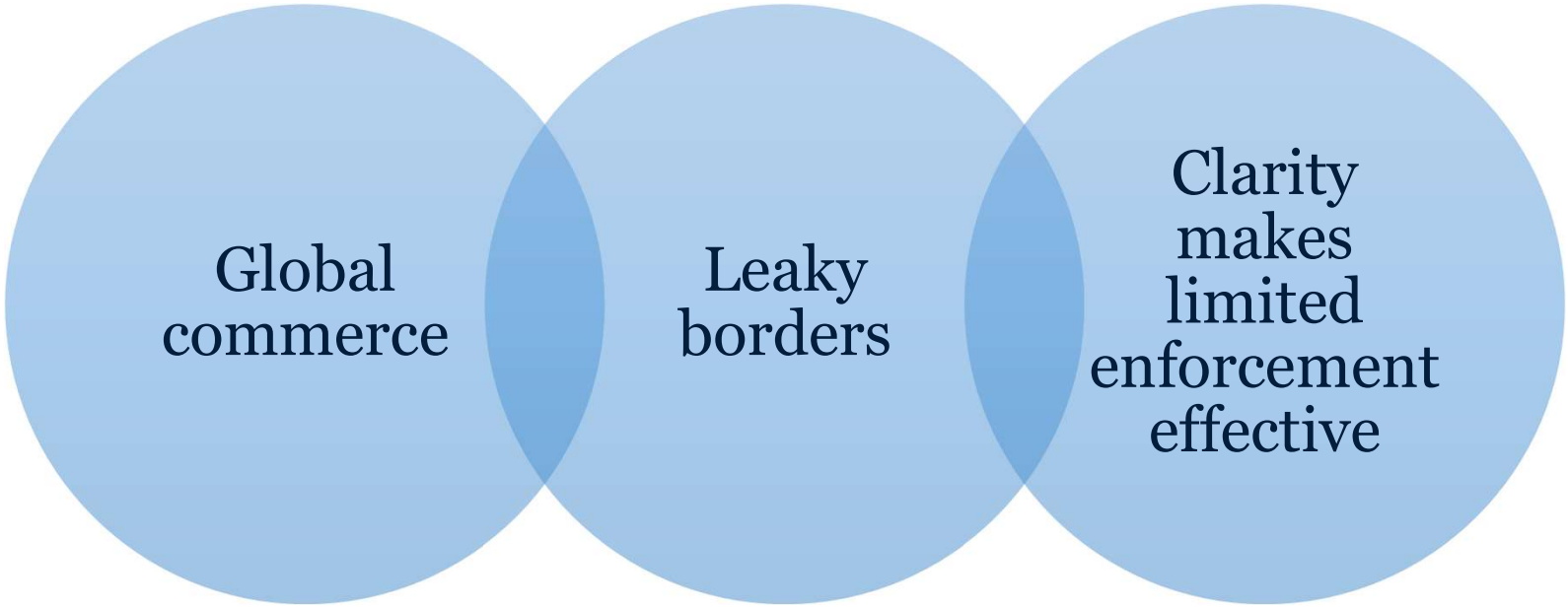
Mouth → stomach → intestine

Different absorption pathways

Same act: ingestion

VENABLE LLP

Enforcement Reality



VENABLE LLP

Rules That Can’t Be Gamed

- Clear triggers
- Bounded discretion
- Shared accountability

VENABLE LLP

The Choice

PRESERVE AMBIGUITY

OR REBUILD TRUST

VENABLE LLP

Call to Action

Join me on March 5, 2026
Hilton Anaheim – Montery Room 5th Floor

Introducing DSHEA 10.0

An audacious plan for real, lasting change

VENABLE LLP

VENABLE LLP